General requirements for the competence of testing and calibration laboratories

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General requirements for the competence of testing and calibration laboratories

1. Scope

1.1 This document prescribes management system and technical requirements that laboratories wishing to receive accreditation of Voluntary EMC Laboratory Accreditation Center (hereafter referred to as “this Center”) shall implement and fulfill.

1.2 This document is applied to laboratories specified in Article 1 of VLAC VR100 which includes laboratories being a constituent of manufacturers, product accepting traders and products certifying machineries as well as third-party laboratories not affiliated to product manufacturers. Organization size of laboratories is not a factor of applicability as well as whether the organization is for-profit or not for-profit.

1.3 This document provides applicant laboratories with interpretation of referenced standards with guidelines and examples for achieving conformity to those standard required by this document.

1.4 This document is designed to be used for development and implementation of management system on managerial and technical aspects of the laboratory seeking accreditation of this Center. It should be noted that meeting requirements of this document does not mean that quality of products is vouched whose conformity was assessed by the applicant laboratory.

1.5 Conformity to statutory and safety requirements on the operation of laboratories is out of scope of this document.

1.6 Laboratory which conforms to requirements of this document can be said to operate its management system meeting the principles of ISO 9001 and JIS Q 9001. However, accreditation by this Center does not vouch the conformity to ISO 9001 or JIS Q 9001. Also the fact that a laboratory is certified as conform to ISO 9001 or JIS Q 9001 does not justify avoidance of whole or part of accreditation by this Center.

2. Normative references

Requirements in this document are harmonized with those of the following standards which normatively referenced by this document.

(1) ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories

(2) JIS Q 17025:2005 The above standard translated in Japanese as a Japanese Industrial Standard

Exception: Requirements applied to “calibration laboratories” do not apply to laboratories to be accredited by this Center because calibration laboratories are not addressed by this Center as stipulated in Article 1 of VLAC VR100. However, self calibration done by laboratories themselves will be assessed with requirements applied to calibration laboratories.

Requirements item numbers after 4 inclusive are consistent with those of the referenced standards.

3. Terms and definitions

(Omitted as applied only to the original Japanese version of this document)

4. Management requirements

4.1 Organization

Management system shall be built with individual requirements considered together, not in piece by piece

4.1.1 If the laboratory is a part of an organization, it shall be able to operate independently of other departments of the organization. Top management of the laboratory, if he/she is not necessarily CEO or even one of officers of the organization, shall be given power to secure management resources. This Center will ask the laboratory for a copy of registry to confirm legal responsibility of the laboratory.

4.1.2 (No additional qualification or customization). Requirements in this item shall be met in accordance with 4.2.2e.

4.1.3 Management system is defined to be a system built on quality, control and technology to keep the laboratory running. It is required to have an integrated organization controlled by a single management system. There shall be a clear demarcation between operations and facilities belonging to the laboratory and those belonging to other organizations. Necessary facilities for the operation of laboratory shall independently be owned by the laboratory in principle because sharing of facilities with other business (departments) should be avoided as much as possible. Scope of operations shall be clarified in documents (including Website) together with specialized technical fields, applicable standards and executable testing items (see 5.3.1 for facilities and relate matters). In

case it is unavoidable to share staff and facilities with other department there shall be a clear description of responsibility and right of sharing parties as required in 4.1.5e. As far as facilities are concerned they shall be under the control of the laboratory. Therefore, if the facilities are used by other persons (departments) the laboratory shall make sure by inspection and verification afterwards that they are in good working order for the laboratory to continually use them (see 5.5.9).

4.1.4 Freedom of judgment by key personnel of the laboratory shall be secured (not to be confused with organizational independence). Where, for example, the laboratory is a part of a manufacturer's organization the laboratory shall be free from undue pressure from production department on testing plan and test report of the laboratory. In case the laboratory acts as a third party machinery, management system shall be built in such a way that the laboratory can prove it is free from any undue commercial, financial and other pressures which might compromise their judgment on test results. Responsibility of key personnel may be defined in job descriptions but writing on details shall follow 4.2.6.

4.1.5 Refer to 4.2.2e and 4.2.3 for implementation, maintenance and improvement of the management system.

a) Have managerial and technical personnel who have power to make managerial decisions (on organization, funds and facilities) at their own discretion. With that power they are held responsible for activities based on quality policy. How to manage departure form management system is described in 4.9.1.

b) Managing subject is defined as a person or group of persons (such as committee) who manage both system and procedure. Build a system designed to prevent undue influence from occurring on personnel. If the laboratory is a part of organization performing design, manufacturing, certification and related activities, demarcate responsibilities in writing. Introduce a rule to prevent testers from being engaged in the work that may compromise independence of decisions on test results. Also a caution shall be exercised in introducing a system of compensation that is indexed to volume of incoming business.

c) Documented policies and procedures shall be in place to ensure the protection of its customers' confidential information and proprietary rights. Security procedure includes document control with passwords and electronic signature, area control, access restriction and special caution exercised at witnessed testing. (Follow 5.3.4 for entry to areas including test rooms that may impact quality)

d) Have policies and procedures to avoid involvement in any activities that would diminish confidence in the integrity of testing. Always maintain integrity as individual and organization. In EMC testing it is necessary to modify EUT to improve its EMC characteristics from time to time. If this modification is done by the tester(s) that action may be regarded as violation to this requirements. Therefore, it is recommendable to ban testers engaged in final conformity assessment testing to do countermeasure modifications or clearly separate personnel to do countermeasure modifications from testers engaged in conformity assessment testing depending on the situation.

e) Clarify and document the responsibility and right in shared use of personnel and facilities. Also document the implementation of supporting services (refer also to 4.7.1). Retention of those records shall follow 5.3.1.

f) Design management system to cover all personnel engaged in work affecting the quality of the tests. Clarify criteria for nominating and qualifying personnel. Appoint a responsible person for each of quality, technical management and signed test report issuer. See 5.2.1 for granting qualification on specific work within the scope of accreditation.

g) Assign personnel knowledgeable about verification of each process and familiar with methods and procedures of work

h) Nominate a responsible party (individual, committee or group of people) for technical management (based on 4.1.5a) who can cope appropriately with technical problems of testing. If a committee or group of people are nominated, single out a person who makes the final decision.

i) Nominate quality manager based on 4.1.5a who shall have direct access to the highest level of management (top management). Quality manager can serve concurrently as technical manager (or managing subject) provided that both responsibilities are performed without inclination.

j) Assign deputy managers for quality manager and technical manager

k) It is desirable to develop a plan on allocation of personnel per target or targets per personnel. One example is, a quality objective broken down to each department which is further allocated to individuals.

4.1.6 Top management is defined to be an individual or group of people who is given power to direct organization from the highest point of the organization. Top management in a divisional organization is the head of operation division. Method of notification, communication and reporting shall match the management modality.

4.2 Management system

4.2.1 The laboratory shall document individual requirement (per policy and procedure) as necessary. If documentation is dispensed with, prepare evidence of quality retention handed down. Those documents shall be reviewed periodically. The scope of documentation may be confined to “areas needed for quality assurance of test results.” If standards and testing methods can be used as procedure manual they can be referenced to instead of newly creating procedure manual. In this case those standards and testing methods shall be accessible whenever needed, if not in the place where one can reach them handily.

4.2.2 The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual. Quality policy shall contain the requirement for continuous improvement. The overall objectives shall be established, and shall be reviewed during management review (see 4.15.1). In case the laboratory is a part of larger organization a quality manual addressing only the laboratory may be established.

a) “commitment” here means “getting positively involved” (see 4.1.2)

b) quality policy may refer to an element that says test is performed in accordance with defined methods and requirements of requesters

c) (no additional qualification or customization)

d) have a procedure to set goals which meet quality policy and communicate them to personnel. Also leave a record of implementation

e) it is for laboratory itself to declare “retention of conformity.” “Commitment” means “getting positively involved (declaration of resolution)” (4.2.3 calls for indication of a proof). It should be noted that the meaning of “being effective” includes “producing satisfactory results”

4.2.3 The laboratory shall keep a record on matters including -
- thorough internal communication on the necessity of strict observation of statutory and regulatory requirements, impartiality (as a third party laboratory) and fulfillment of customers' requirements,

- implemented goal setting and management review of quality policy and quality targets, and
- use of resources.

4.2.4 Calls for documentation as part of 4.2.3. It is specially recommendable to describe the necessity of thorough communication on customers' requirements (proven conformity in testing in general) in quality manual. Include the importance of impartiality as a laboratory in the declaration of top management.

4.2.5 (no additional qualification or customization)

4.2.6 (no additional qualification or customization)

4.2.7 Changes to management system means changes to operational system including organization and personnel and changes to quality documents (revisions).

4.3 Document control

As to record management it is described in 4.13 and as to data management on test/calibration it is described in 5.4.7. "Document" means documented rules and information used in management system. "Record" means a proof (documents or data) produced as a result of operation of system.

4.3.1 General

Here the subject is documents being object of management. As such they shall not be confused with general documents. Prescribe policy and procedure for identification, creation, alteration, approval, issuance and distribution of documents. Externally sourced documents (such as law and standards) are also object of management if they are defined as managed documents. However, computer software built in test facilities shall be handled in accordance with 5.5.5. If documents uploaded in homepage or network servers are defined as managed documents, then prescribe the way to handle them.

4.3.2 Document approval and issue

4.3.2.1 All documents making up management system shall be attached issuance responsibility and approved (see 4.3.2.3). A document list shall be made available for those documents so that status of all documents is readily known. If externally sourced documents such as standards are included in managed documents, information on publication status and editions shall be made available. Maintain procedure for obtainment of standards and other external documents.

4.3.2.2

a) make sure that documents are made available to all locations if test sites are distributed in multiple locations

b) record the result of periodical review of documents

c) (no additional qualification or customization)

d) make them accessible for reference as necessary

4.3.2.3 (no additional qualification or customization)

4.3.3 Document changes

4.3.3.1 “Function” here means a person or organization given the same role.

4.3.3.2 (no additional qualification or customization)

4.3.3.3 In terms of amendment of quality documents by hand, procedure and responsibility shall be established for that. Amendment by hand shall not be made in such a way that amended portion is completely erased.

4.3.3.4 Procedures shall be established to change and approve (electronic) quality documents in computers.

4.4 Review of requests, tenders and contracts

4.4.1 Procedure shall be established to verify skills of laboratory personnel to satisfy requirements of customers and to grasp the limit of laboratory competence in moving into new fields.

a) (no additional qualification or customization)

b) (no additional qualification or customization)

c) Requirements for entries in test report shall be included. Entries are, for example, the name and street address of the customer, name of test types, condition of test items and date of reception

4.4.2 “Record” stands for “a thing with which results of actions are noted.” Handwritten memos are acceptable as long as vital information is recorded such as the date and name of memo writer.

4.4.3 See 4.7 for details

4.4.5 (no additional qualification or customization)

4.5 Subcontracting of tests and calibrations
Subcontracting means to commission the order including responsibility for the work accepted by the laboratory to another laboratory.

4.5.1 “The work” here means testing job entrusted by the customer. Therefore, calibration service asked to external calibration laboratories does not constitute subcontracting. It is the use of external services. Use of external services including calibration, repairs and maintenance is dealt with in 4.6 Purchasing services and supplies. Establish policy for subcontracting. Also establish criteria for proving competency of subcontracted laboratory.

4.5.2 (no additional qualification or customization)

4.5.3 If the subcontracted laboratory has no intention to take responsibility for the work entrusted, this fact shall be noted in test report. Establish procedure to demarcate the result of tests done by the laboratory and the result of tests done by subcontractors.

4.5.4 (no additional qualification or customization)

4.6 Purchasing services and supplies
4.6.1 Examples of purchased services are packing of test items, transportation, printing of certificates, maintenance of equipment and calibration.

4.6.2 In case of use of rental equipment too, inspect and verify before making them available for use. Either that or confirm if appropriate verification has been done.

4.6.3 Purchasing document stands for order sheet and its appendixes

4.6.4 Administer periodical update.

4.7 Service to the customer

Refer to 4.1.5 c) for confidentiality agreement with the customer and to 4.1.5e for clarification of support services.

4.7.1 Unpacking, preparation and packing of test items by the customer are included. Allow the customer or their representatives to enter related places for the purpose of witnessing of tests. Inform the customer of any identified departure from policies and procedures on testing.

4.7.2 “Feedback” means “information returned from customers.” Examples of feedback include responses to customer satisfaction surveys and review of test reports with customers. Feedback shall be reported to management review to solicit their comments.

4.8 Complaints

Define what constitutes complaint. It should be noted that complaints include those from customers and other interested parties (parties given a report by the customer). Establish procedure for handling complaints covering process at contact point, internal communication and responsible personnel for investigation and resolutions. Record complaints at the time of their incoming. Complaints can be in writing and verbally made. Record shall be made in such a way that the current status and resolution are known. In case complaints imply nonconformity in management system, take action to kick additional audit as prescribed in 4.11.5.

4.9 Control of nonconforming testing and/or calibration work

The laboratory shall have a policy and procedures to be followed when any aspect of its testing services do not conform to this document and normative references.

4.9.1 Nonconforming testing can be identified in customer complaints, quality control, instrument calibration, supervision of staff, test report and internal audit and others. Nonconforming testing here does not mean that testing items failed the test but that there was departure in testing work from requirements of this document, normative references or procedure and conditions specified in testing method/standard. The laboratory shall have policy and procedure for toleration of departure from the norm (nonconforming work), method of its verification and manner to make a report on it among others (see 4.1.5 a and 5.4.1)

a) designate a person with the responsibilities and authorities for the management of nonconforming work as a whole (including custody). Establish procedure to implement corrective actions (see 4.11.3) including recurrence prevention if nonconformity is obvious. Corrective

actions for nonconformity resulted from trouble of testing instruments relate to 5.5.5h and 5.5.7 as well. Removing nonconformity is the purpose of actions in essence.

b) establish criteria for “significance”

c) (no additional qualification or customization)

d) if the notification is omitted it may be regarded as a fault of the laboratory, so make sure procedure addresses this point

e) (no additional qualification or customization)

4.9.2 (no additional qualification or customization)

4.10 Improvement

Take actions on improvement by analyzing problems in discussions of regular conferences, committee meetings and management review. Establish policy and procedure in the quality manual to confirm continuous improvement and recommended corrective and preventive actions from management review are implemented

4.11 Corrective actions

4.11.1 General

Nonconforming work can be identified in internal and external audits, management review and others. Responsible person for corrective actions may not be the same person responsible for the work.

4.11.2 Cause analysis

Prescribe the necessity of pursuance and analysis of potential causes of the problem

4.11.3 Selection and implementation of corrective actions

Corrective actions shall be combined with preventive actions if nonconformity is obvious. “Implementation” here means “to remove causes of problems.” Set criteria to distinguish “serious” from “otherwise.”

4.11.4 Monitoring of corrective actions

Prescribe the method to confirm effectiveness of corrective actions

4.11.5 Additional audits

Have additional audits in accordance with 4.14 internal audit. Additional audits shall be implemented when serious problems or risks are identified for the operation.

4.12 Preventive action

Not necessary to follow in ordinary times. Prepare procedure for preventive actions for the time which necessitates their implementation.

4.12.1 Review of procedures, risk analysis on causes and analysis of results of proficiency testing are conceivable ways among others to assure the confirmation of the effectiveness of actions. Corrective actions (4.11.3) shall be implemented together with preventive actions if nonconformity is obvious.

4.12.2 Prepare procedure to be implemented when necessary. Either that or develop it when necessary.

4.13 Control of records

4.13.1 General

(no additional qualification or customization)

4.13.1.1 Shall be kept in a way to enable search at all times

4.13.1.2 Specify duration of retention. Records may be in any media, such as hard copy or electronic media. Follow 4.13.1.3 for treatment of stored records.

4.13.1.3 Have policy and procedure to ban disclosure of information on the customer to other parties without consent of the customer (this is applicable to accreditation bodies and purchasers as well in principle). The policy and procedure shall be designed to be applicable to persons whose responsibility in relation with the customer was dissolved (based on 4.1.5c on protection of customers' confidential information and proprietary rights)

4.13.1.4 Have policy and procedure to prevent unauthorized access to, amendment of and intentional or unintentional deletion of these records stored in computers. Refer to 4.1.5c on protection of customers' confidential information and proprietary rights. Note that application documents transacted in computer network are also subject to control under this requirement.

4.13.2 Technical records

4.13.2.1 Technical records include, for example, raw data, processed data (by correction etc.), correction factors used, operational condition of test items, test identifiers, testing methods, testing instruments used and testers. Caution should be exercised for the protection of data directly fed to computer with no raw data left. When the original test report was sent to the customer, keep a copy of it. Note that “defined period” may be based on statutory requirement. The procedure for retention of data shall be designed in such a way to establish an audit trail from the initial state of test items up to issuance of test report.

4.13.2.2 (no additional qualification or customization)

4.13.2.3 Correction of mistake in record shall be made by way of crossing out, not erasure so the state before correction is visible. All such alterations to records shall be sealed, signed or initialled by the person making the correction.

4.14 Internal audits

The laboratory applying for assessment for accreditation by this Center shall satisfy all four items of VLAC-VR102 Specific requirements for the competence of EMC testing laboratories.

4.14.1 Internal audits are carried out to verify that laboratory's operations continue to comply with the requirements of the management system. Its original intention is, however, to check if operations based on self-made standards are yielding results. “Program” translating into “the gist of implementation plan” shall contain “degree of objectives achievement,” “degree of mission accomplishment,” “degree of procedure adherence,” “quality improvement” and “data quality.” Establish a rule to enforce periodic internal audits and implement it at least once a year. Internal audits are conducted based on internal audits check list. This list shall include requirement for confirmation of implemented corrective actions enforced in the previous audits. Internal audits shall not be acted for by assessment carried out by external machineries including this Center. However, internal audit outsourced in the following way is valid. That is, auditors of subcontracted external machinery carry out internal audit under the supervision of quality manager.

4.14.2 The laboratory shall notify customers in writing if investigations show that the test results may have been affected.

4.14.3 (no additional qualification or customization)

4.14.4 (no additional qualification or customization)

4.15 Management review

This Center requires that all four items of VLAC-VR102 Specific requirements for the competence of EMC testing laboratories be satisfied by the laboratory.

4.15.1 Management review (reevaluation and confirmation by top management) is an activity to ensure continuing suitability and effectiveness of quality system, appropriateness, validity and effectiveness of programs set to attain objectives. Simply put, management review is to verify appropriateness of programs against objectives. Planning and execution of management review shall be carried out by top management himself. It is not regarded as management review if personnel in charge of operations summarizes implementation status on quality system. Setup of review meeting may be a whole meeting attended by director of laboratory, technical manager, quality manager and department managers as necessary plus top management. "Appropriateness" means "being appropriate for the whole." Objectives of "Improvement" shall include system, test process, result reporting and attainability of education and training programs (see 5.2.2).

4.15.2 Minutes of the whole meeting can be a proxy of the record of management review provided that comment by top management is included. The comment shall refer to things including validity of management system, test process and reporting and response to customer requirements. "Being valid" here means "meeting the purposes" from a standpoint of concreteness.

5. Technical requirements

5.1 General

5.1.1 Sampling is out of scope of accreditation assessment by this Center

5.1.2 This item addresses requirements for identifying causes of uncertainty. Estimation of uncertainty shall be done in accordance with 5.4.6.2

5.2 Personnel

Refer also to VLAC-VR102 Specific requirements for the competence of EMC testing laboratories

be satisfied by the laboratory.
5.2.1 Qualification of laboratory personnel is the subject here. Responsibility and rights of personnel are prescribed in 4.1.5.f). There are cases with regard to special technical fields that the retention of certified qualification of personnel may be required. Also certification may be required by the law and customers. The personnel responsible for the opinions and interpretation included in test reports shall have certified technical knowledge (to tell defect from departure from standards) obtained through due education and training (see 5.2.5). "Personnel performing specific tasks" are those who "perform tasks required by this document and normative references."

5.2.2 Set goals for education, training and technical skills development subject to management review. Education and training includes entry level technical education, new fields technical education and routine education on existing technology. Evaluate somehow the degree of achievement of the goals set.

5.2.3 All personnel including contracted workers are required to adhere to management system. Therefore, they shall all be educated on the field they are to be engaged. When facilities are temporarily out of control of the laboratory for use by contractors, requirements in 5.5.9 shall be satisfied.

5.2.4 Job descriptions shall be covered by office regulations or included in some other document. Items to be included are position name and responsibilities and others. See 4.1.5 f) for responsibility and rights of personnel.

5.2.5 Signers and sealers shall be identifiable as personnel approved by the laboratory (see 4.1.5f for their registration). This Center requires registration of signers and sealers by using form VF109. Their authority shall be given by personnel with appropriate qualifications. Keep records of education and training of personnel including contracted workers. Records are desirably made person by person. The personal record should cover detailed history of education, qualification, career and appraisal among others. Have a list of test types which each of personnel including those under education and contracted workers has qualification to perform.

5.3 Accommodation and environmental conditions
Refer also to VLAC-VR102 Specific requirements for the competence of EMC testing laboratories.
Laboratory shall maintain conformity in the following areas to obtain accurate and reproducible

results.
(1) Ambient radio frequency electromagnetic environment or site attenuation for open test site and/or all weather test site

(2) Electric field uniformity of immunity testing facility

(3) Semi-anechoic chamber and reverberation test room for air-borne nose testing

5.3.1 Have policy and procedure for appropriate operation of facilities. Have documentation on facilities and environmental conditions. If premises other than those under control of the laboratory are to be shared with other organizations, control responsibility shall be documented. See 4.1.5e for documentation on responsibility and rights, 4.1.3 for scope of operations and 5.5.9 for facilities and equipment.

5.3.2 Addressed here are environmental conditions. See 5.5.3 for testing facilities conditions. Meet standards by monitoring and controlling factors of adverse effects. Ambient radio frequency electromagnetic environment at open test site described in VLAC-VR102 Specific requirements for the competence of EMC testing laboratories is also subject to monitoring and controlling. Refer to this item if environmental conditions are required in other accreditation fields. Conformity to statutory and safety requirements with regard to operations is out of scope of this standard (see 1.5).

5.3.3 Does not necessarily mean permanent separation.

5.3.4 Have procedure on access to the laboratory and keep its records. Cordoning off by ropes and notice boards may be accepted.

5.3.5 Good housekeeping is to prevent results and precision of testing form getting adversely influenced.

5.4 Test and calibration methods and method validation
5.4.1 General
It is desirable to retain instruction manuals for testing methods and procedures. If related standards are written in a way that they can be used as published by the operating staff, just referencing to the publication is sufficient. Documentation can be dispensed with if operations

are correctly doable only with training and verbal instructions. Otherwise prepare procedure and instruction manuals. In this case documentation can be limited in the areas necessary to maintain quality. This is the same with handling of test items. Prevent departure from the norms. Keep record if departure happened. Rules and criteria shall be set for accepting departure from testing method (see 4.9.1). Requirements for the way to write the departure in the test report are described in 5.10.3.1. This Center requires the laboratory to conduct testing based on testing standards and rules (such as international standards, Japanese Industrial Standards, academic community standards, legal standards and industry standards).

5.4.2 Selection of methods

Select appropriate testing methods meeting customer needs. Testing methods to select shall be those defined in the most recent edition of relevant standards. Make sure the most recent editions are handily accessible to testers. When using existing standards as they are, first make sure they are implementable by the laboratory itself (record the fact that this verification was conducted). If the test method was not agreed upon with the customer at the time of closing the contract, it is acceptable to notify it later to the customer. Procedure manuals and instruction manuals shall include unmistakable instructions, identification of applicable documents, the number of effective digits in reports and an extent of parameters. If methods defined in standards are changed, notify the customer of the fact for agreement. Testing carried out based on methods deviating from standards and methods developed by the laboratory are out of scope of accreditation by this Center.

5.4.3 Laboratory-developed methods

Use of laboratory-developed methods is out of scope of accreditation by this Center

5.4.4 Non-standard methods

Use of non-standard methods is out of scope of accreditation by this Center. The same with combined standards and standard used out of defined limits (laboratory internal standards are also categorized here).

5.4.5 Validation of methods

5.4.5.1 There are two types of method validation. One is to validate currently used method in on-going operations from a quality retention point of view, and the other is to validate method to be used in new business areas and expected results from its use. In both ways validity can be

confirmed not only of method itself but also of fitness of method for intended use. Leave objective evidences of the validation.

5.4.5.2 Use of non-standard methods and the like is out of scope of accreditation by this Center.

5.4.5.3 Strike a balance between cost, risks and technical feasibility and needs of the customer

5.4.6 Estimation of uncertainty of measurement
Prepare uncertainty of measurement based onVLAC-VR103 Policy on measurement traceability if applicable national standard does not exist. Also refer to VLAC-VR105 Policy on uncertainty of measurement

5.4.6.1 Testing laboratory performing its own calibrations shall establish procedure for it by referencing VLAC-VR103 Policy on measurement traceability.

5.4.6.2 Establish procedure for estimation of uncertainty of measurement by referencing VLAC-VR105 Policy on uncertainty of measurement (see 5.4.1). Uncertainty of measurement also applies to 5.6.2.1 of Specific requirements. If test standard specifies rendering format for uncertainty of measurement, follow it.

5.4.6.3 Estimate uncertainty by taking into consideration standard devices used, methods and facilities used, environmental conditions, properties and condition of the item being tested and others.

5.4.7 Control of data
Sending by electronic way or electromagnetic way is prescribed in 5.10.7. It is out of scope of this item.

5.4.7.1 Data transfer here means transcription and processing

5.4.7.2 Commercial off-the-shelf software such as word processors are not subject of this item. Results of processing by macro and spread sheet and the like need validation. Validation of automatic measurement software associated with testing and measurement is treated in 5.5.2 and out of scope in this item. This item covers both software aspect and hardware aspect.

a) validate computer software developed by the user as being adequate for use. Keep a record proving that data filing software in use is as good in integrity as manual filing. Prepare a flowchart designed to help documented software functions to be easily understood

b) is about protection of software (not to cause loss of data) used for testing and measurement. The purpose of maintaining integrity of data transmission and data processing is to prevent data from being lost by input errors, transcription errors and misplacement in filing.

c) version control is prescribed in 5.5.5. Secure personnel with managerial competence and being good at handling environment issues and operation of facilities and equipment

5.5 Equipment

5.5.1 Measurement and test facilities/equipment may be those on lease or rental, but they shall be put under control of the laboratory to be ready for use at all time. The laboratory having custody of such equipment/facilities is held responsible for decision making on their maintenance and calibration (without responsibility taken the laboratory cannot be said to control them). In case test facilities are shared by other department, establish policy and procedure to hold the laboratory responsible for their control.

5.5.2 Validate automated measurement software as ordinarily usable before applying it to real measurement and keep a record on the validation. Confirm conformity of measurement instruments and standard devices to specifications or standards before start using them and leave a record on the confirmation. The same procedure is also applicable to equipment on lease or rental. Requirements in this item are also applicable to site attenuation prescribed in VLAC-VR102 Specific requirements for the competence of EMC testing laboratories. The same goes with RF electromagnetic field immunity testing facilities, sound anechoic chambers for air-borne nose testing and SAR testing facilities as far as accreditation scope of this Center is concerned.

5.5.3 Equipment shall be operated by authorized personnel. Instructions on the use and maintenance of equipment shall be readily available.

5.5.4 Selection of items of equipment and its software used for testing and calibration to go with unique identifiers shall be done by considering the significance of their impact to test results. Also the laboratory shall keep a record on equipment with and without unique identifiers.

5.5.5 Keep a registry of significant facilities/equipment used for testing and calibration. The same goes with software built in the equipment.

a) have procedure for version control

b) (no additional qualification or customization)

c) – e) (no additional qualification or customization)

f) prepare labels and marks for identification (5.5.8 will prescribe procedure for affixing)

g) (no additional qualification or customization)

h) keep a record on repair of facilities/equipment

5.5.6 Establish policy and plan on periodical calibration and maintenance. Either that or establish procedure for actions to be taken based on the result of periodical calibration and maintenance. In certain cases actions to be taken are specified by period or cycle of calibration and maintenance.

5.5.7 Establish policy and procedure for the handling of equipment a part or the whole of which is functionally defective. It is required in VLAC-VR102 Specific requirements for the competence of EMC testing laboratories. In addition it shall be applied to accreditation scope other than EMC as well. Defective equipment shall be clearly labelled or marked as being out of service. If defective equipment has been used without being noticed the laboratory shall investigate the validity of results of tests performed in the past.

5.5.8 Affix a label or mark to equipment needing calibration to indicate status of calibration of that equipment

5.5.9 Is about equipment which went outside the direct control of the laboratory. Before starting use them again the laboratory shall check function and carry out calibration of them. As long as equipment are under control of the laboratory their conformity to 5.2.3 (adherence to management system) is regarded as retained even if the equipment were made available to contractors (or personnel).

5.5.10 Establish procedure on checking out calibration status of facilities/equipment before starting using them in order to maintain facilities/equipment in the state of being calibrated. It is required in VLAC-VR102 Specific requirements for the competence of EMC testing laboratories. In addition it shall be applied to accreditation scope other than EMC as well except when method of checking is specifically prescribed in standards etc.

5.5.11 If correction becomes necessary as a result of calibration, establish procedure to update the correction

5.5.12 Adjustment to self-correction feature of facilities and equipment shall be safeguarded from being disabled. Otherwise there is possibility that testing and calibration results will be invalidated. This measure applies to software too.

5.6 Measurement traceability

Refer also to VLAC-VR103 Policy on measurement traceability.

5.6.1 General

The laboratory shall have procedure for maintaining departmental standard on in-house calibration. Also have calibration procedure for facilities and equipment which may influence the results of testing.

5.6.2 Specific requirements

This section is meant for calibration machineries. However, this section is also applicable to laboratories carrying out their own calibration. In this case, follow 5.6.2.1 below and 4.1.e) of VLAC-V103.

5.6.2.1 Calibration

In case calibration service is provided by a department of a company or organization of which testing laboratory is also a part, use of that calibration service by the testing laboratory is not in-house calibration but external calibration. In this case the calibration department shall be qualified as certified calibration machinery (JSCC certification included). If the department in question is not so certified then the laboratory shall confirm that calibration done by that department is traceable according to VR103.

5.6.2.1.1 Have policy to ascertain that calibration done is at the end of unbroken chain of traceability up to SI. For procedure to do so see VLAC-VR103 Policy on measurement traceability.

5.6.2.1.2 Is not applicable to this Center because traceability to standard materials in the field of analysis testing etc. is out of scope of this Center.

5.6.2.2 Testing

5.6.2.2.1 To what degree the prescription in 5.6.2.1 Calibration and VLAC-VR103 Policy on measurement traceability shall be observed depends on requirements of testing method and the degree of adherence to specifications.

5.6.2.2.2 (no additional qualification or customization)

5.6.3 Reference standards and reference materials

5.6.3.1 Reference standards

Establish procedure on the use of reference standards only for in-house calibration unless special procedure on their use is available.

5.6.3.2 Reference materials

Not applicable to this Center

5.6.3.3 Intermediate checks

Requirements here are set on the assumption that standards change with time. Establish procedure on intermediate checks.

5.6.3.4 Transport and storage

(no additional qualification or customization)

5.7 Sampling

Out of scope of this Center

5.8 Handling of test and calibration items

5.8.1 Procedure manual shall be created to cover identification of items, status confirmation, indication of test completed or not, packaging, delivery date and, if necessary, identification of test results.

5.8.2 Establish procedure to identify test items. This identification shall be harmonized with procedure for a series of tests

5.8.3 Keep record on anomaly identified on test items with regard to the state specified by testing method. Follow 5.4.1 for departure from test method to be used.

5.8.4 Have procedures for use of storage facilities and for preventing test items from getting deteriorated, lost or damaged during storage. “Integrity” here means that there is no failure occurring which is attributable to the laboratory (it is different from “Safety.”)

5.9 Assuring the quality of test and calibration results

5.9.1 Procedure manual shall contain related documents and technical data which indicate the method to demonstrate the competency of the laboratory. Also it shall contain proofs of technical adequacy of tests to be administered by the laboratory.

a) out of scope of this Center

b) follow VLAC-VR106 Policy on proficiency testing when participating in a program

c) (no additional qualification or customization)

d) (no additional qualification or customization)

e) pay attention to the fact that things to be clarified differs from test item to test item

5.9.2 is related to 4.9 Control of nonconforming testing and/or calibration work, 4.10 Improvement, 4.11 Corrective action, and 4.12 Preventive action

5.10 Reporting the results

5.10.1 General

Test report (or calibration certificate) shall be prepared in such a way that it has sufficient technical content not to induce misunderstanding when interpreted without explanation or not to get its validity lost. If a test which is out of accreditation scope is included in the report or certificate there shall be an unmistakable statement that the laboratory is not accredited to perform that specific test. Establish a method to use accreditation symbols and follow the rule set by the accreditation body. For these purposes refer to VLAC-VR100 Rules for accreditation of

EMC testing laboratories and VLAC-VR107 Policy on use of accreditation symbol and reference to accreditation. If requirements in this standard in 5.10.2, 5.10.3 and 5.10.4 are satisfied a test report (or calibration certificate) is issued either in hardcopy or electronically. Issuance in electronic way is described in 5.10.7.

5.10.2 Test reports and calibration certificates
All the eleven items specified here shall be included in the test report (or calibration certificate) unless there is a valid reason for omission. There shall be a note to the effect that making a copy of all part of the report or certificate is permissible but partial copy is not. Refer also to VLAC-VR100 Rules for accreditation of EMC testing laboratories. Items which can be added to test report include those described in test standards, if any, within the scope of accreditation on top of those described in 5.10.3

a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory.

a) (no additional qualification or customization)

b) the name and street address of the laboratory shall be the same as those used in accreditation certificate. Abbreviation of company name and department name is not desirable.

c) print page number and the number of total pages on each page

d) omit them if the customer desires to omit them

e) include date of issuance of the standards

f) include the name, type and number among others

g) (no additional qualification or customization)

h) out of scope of this Center

i) (no additional qualification or customization)

j) test report (or calibration certificate) shall bear a signature of the personnel responsible for the report (or certificate) (it is not a condition that the signatory is able to explain details of the content)

k) (no additional qualification or customization)

5.10.3 Test reports
5.10.3.1 deals with items to be included in test reports as necessary in addition to items enumerated in 5.10.2

a) describe departures, if any, from standards and measurement methods

b) state judgment on compliance/non-compliance with requirements, if relevant

c) state estimated uncertainty of measurement if applied standards and measurement method require consideration on it for better judgment on compliance

d)(no additional qualification or customization)

e) (no additional qualification or customization)

5.10.3.2 Sampling is out of scope of this Center

5.10.4 Calibration certificates
This item is good also for certificates issued for internal calibration (calibration carried out on facilities/equipment to be used by the laboratory themselves)

5.10.4.1 Certificate is invalid if items specified here are not included in addition to the statement of compliance.

a) – c) (no additional qualification or customization)

5.10.4.2 is applicable also to internal calibration

5.10.4.3 (no additional qualification or customization)

5.10.4.4 (no additional qualification or customization)

5.10.5 Opinions and interpretations

This is not applicable to internal calibration. When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. (Note 2 gives examples of opinions and interpretations)

5.10.6 Testing and calibration results obtained from subcontractors

In the case conditions stated in 4.5.3 are met, if subcontractor refused to take responsibility for the subcontracted work, this fact shall be noted. Test report on tests performed by subcontractors shall be clearly identifiable.

5.10.7 Electronic transmission of results

This item is about communication on test results by electronic means including e-mail and downloading from Internet site. See 4.1.5c) for requirements for documentation and 5.4.7.2b)for safeguarding against loss.

5.10.8 Format of reports and certificates

Design forms for test report (and calibration certificate) with layout good for avoiding misunderstanding or misuse and careful wordings so that the report/certificate will no invite questions afterwards.

5.10.9 Amendments to test reports and calibration certificates

Amendments to a test report or calibration certificate after issue shall be made only in the form of a further document. When issuing a completely new test report or calibration certificate, this shall contain a reference to the original that it replaces and a note to the effect that the original report or certificate is void.