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General requirements for the competence of verification laboratories

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Contents

Page

Foreword

Rwanda Standards are prepared by Technical Committees and approved by Rwanda Standards Board (RSB) Board of Directors in accordance with the procedures of RSB, in compliance with Annex 3 of the WTO/TBT agreement on the preparation, adoption and application of standards.

The main task of technical committees is to prepare national standards. Final Draft Rwanda Standards adopted by Technical committees are ratified by members of RSB Board of Directors for publication and gazettment as Rwanda Standards.

DRS 438 was prepared by Technical Committees RSB/TC 014, Quality management and quality assurance and RSB/TC 46 RSB/TC 46 Metrology and physical phenomena

In the preparation of this standard, reference was made to the following standard:

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories

The assistance derived from the above source is hereby acknowledged with thanks.

Committee membership

The following organizations were represented on the Technical Committee on *Tourism and Hospitality* (RSB/TC 014) in the preparation of this standard.

Act Business Solutions

Rwanda Development Board (RDB)

University of Rwanda-HQs

Standards for Sustainability

Life Long Education Group Ltd

Rwanda Mines, Petroleum and Gas Board (RMB)

Meteo Rwanda

Societe Petrolier (SP) Ltd

Sulfo Rwanda Industries Ltd

Cleaner Production and Climate Innovation Centre (CPCIC)

E^{se}URWIBUTSO

Rwanda Standards Board (RSB) – Secretariat

General requirements for the competence of verification laboratories

1 Scope

1.1 This Committee Draft specifies the general requirements for the competence of laboratories to carry out the verification of measuring instruments and prepackages. It covers type evaluation, initial, subsequent and in-service verification of measuring instruments and metrological supervision activities and prepackages control.

1.2 This Committee Draft applies to all verification laboratories that perform verification of measuring instruments and pre-packages regardless of the number of personnel or the extent of the scope of the verification activities.

1.3 This Committee Draft provides requirements for development, maintenance and implementation of management systems of verification laboratories.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

RS ISO 9001 Quality management systems — Requirements

ISO Guide 33 Reference materials — Good practice in using reference materials

RS ISO 17020 Conformity assessment — Requirements for the operation of various types of bodies performing inspection

3 Definitions

For the purposes of this standard, the following terms and definitions apply.

3.1

appeal

request by the client or responsible party to the verification body for reconsideration of a decision it has made relating to the verification

3.2

complaint

expression of dissatisfaction, other than appeal, by any person or organization to a verification laboratory relating to the activities of that verification laboratory, where a response is expected

3.3

permanent facility

verification laboratory used or intended for use as a permanent base, with an address that is used in the quality documentation of the relevant organization

3,4

prepackage

single item for presentation as such to a consumer, consisting of a product and its packing material, made up before being offered for sale and in which the quantity of product has a predetermined value, whether the packing material encloses the product completely or only partially, but in any case in such a way that the actual quantity of product cannot be altered without the packing material either being opened or undergoing a perceptible modification

NOTE 1 For the purpose of this document, prepackages include prepackages marked with a constant nominal quantity or random nominal quantities. The term "predetermined value" refers to the value determined prior to the prepackage being offered for sale.

NOTE 2 The actual quantity of some products may change after packing due to desiccation or chemical reactions

3.5

reference material

any material that is stable and used in the place of verification standards, and the quantity of which has been determined on a suitable instrument that has been calibrated or verified with standards traceable to national or international standards before such determination, for the purpose of verifying instruments

3.7

rejection mark

mark that is applied to a measuring instrument to indicate that it doesn't comply with the requirements for such instrument in terms of the relevant national legislation and Standard

3.7

verification

set of actions of inspecting and testing measuring instruments or prepackages in order to ascertain that such measuring instruments or prepackages comply with national standard and legislation

NOTE this includes stamping, sealing or marking instruments with a stamp, seal or mark and issuing a certificate of verification in writing.

3.8

verification laboratory

Any competent verification laboratory that is approved by the national responsible body to verify prepackages or measuring instruments for use in trade, medical, law enforcement, safety and environmental protection in terms of the relevant national legislation from a permanent facility or on site

3.9

verification mark

mark that is applied to a measuring instrument or prepackage to indicate that it complies with all the requirements for such instrument or product in terms of the relevant national standard and legislation

3.10

verification officer

any person appointed by the national responsible body to verify measuring instruments or prepackages in terms of the relevant national legislation and standard

3.11

verification standard

equipment or document that is used by a verification officer to verify measuring instruments or prepackages

4 General requirements

4.1 Impartiality

4.1.1 Verification laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.

4.1.2 The verification laboratory top management shall be committed to impartiality.

4.1.3 The verification laboratory shall be responsible for the impartiality of its verification laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.

4.1.4 The verification laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a verification laboratory with a risk to impartiality.

NOTE A relationship that threatens the impartiality of the verification laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

4.1.5 If a risk to impartiality is identified, the verification laboratory shall be able to demonstrate how it eliminates or minimizes such risk.

4.2 Confidentiality

4.2.1 The verification laboratory shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of verification laboratory activities.

4.2.2 The verification laboratory shall inform the customer in advance, of the information it intends to place in the public domain.

4.2.3 Except for information that the customer makes publicly available, or when agreed between the verification laboratory and the customer (e.g. for the purpose of responding to complaints and appeals), all other information is considered proprietary information and shall be regarded as confidential.

4.2.4 When the verification laboratory is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned shall, unless prohibited by law, be notified of the information provided.

4.3 Independence

The verification laboratory shall be independent to the extent that is required with regard to the conditions under which it performs its services. Depending on these conditions, it shall meet the minimum requirements stipulated in Annex A, as outlined below:

a) A verification laboratory providing third-party verifications shall meet the type A requirements of Clause A.1 (third-party verification laboratory).

b) A verification laboratory providing first-party verifications, second-party verifications, or both, which forms a separate and identifiable part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the items it verifies and which supplies verification services only to its parent organization (in-house verification laboratory) shall meet the type B requirements of Clause A.2.

c) A verification laboratory providing first-party verifications, second-party verifications, or both, which forms an identifiable but not necessarily a separate part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the items it verifies and which supplies verification services to its parent organization or to other parties, or to both, shall meet the type C requirements of Clause A.3.

5 Structural requirements

5.1 The verification laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for verification of measuring instrument and prepackages.

NOTE For the purposes of this standard, a governmental verification laboratory is deemed to be a legal entity on the basis of its governmental status.

5.2 The verification laboratory shall identify management that has overall responsibility for the verification laboratory.

5.3 The verification laboratory shall define and document the range of verification laboratory activities for which it conforms with this document.

5.4 The verification laboratory shall only claim conformity with this document for this range of verification laboratory activities, which excludes externally, provided verification laboratory activities on an ongoing basis.

5.5 Verification laboratory activities shall be carried out in such a way as to meet the requirements of this standard, national legislation, and organizations providing recognition. This shall include verification laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.

5.6 The verification laboratory shall:

a) define the organization and management structure of the verification laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;

b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of verification laboratory;

c) document its procedures to the extent necessary to ensure the consistent application of its verification laboratory activities and the validity of the verification results; and

d) provide adequate supervision of verification officers; trainee verification officers shall be supervised by qualified verification officers;

5.7 The verification laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

e) follow up the development, implementation, maintenance and improvement of the management system;

f) identification of deviations from the management system or from the procedures for performing verification laboratory activities;

g) initiation of actions to prevent or minimize such deviations;

h) reporting to highest level of verification laboratory management on the performance of the management system and any need for improvement;

i) ensuring the effectiveness of verification laboratory activities.

5.8 Verification laboratory management shall ensure that:

a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers satisfaction; and

b) the integrity of the management system is maintained when changes to the management system are planned and implemented.

6 Resource requirements

6.1 General

The verification laboratory shall have personnel, facilities, standard equipment, systems and support services necessary to manage and perform its verification laboratory activities.

6.2 Personnel

6.2.1 All personnel of the verification laboratory that could influence the verification laboratory activities shall act impartially, be competent and work in accordance with the verification laboratory's management system.

6.2.2 The verification laboratory shall document the competence requirements for each function influencing the results of verification laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.

6.2.3 The verification laboratory shall ensure that the personnel have the competence to perform verification laboratory activities for which they are responsible and to evaluate the significance of deviations.

6.2.4 The top management of the verification laboratory shall communicate to personnel their duties, responsibilities and authorities.

6.2.5 The verification laboratory shall have procedure(s) and retain records for:

a) determining the competence requirements;

b) selection of personnel;

c) training of personnel;

d) supervision of personnel;

e) authorization of personnel; and

f) monitoring competence of personnel.

6.3 Facilities and environmental conditions

6.3.1 The facilities and environmental conditions shall be suitable for the verification laboratory and shall not adversely affect the validity of results.

NOTE Influences that can adversely affect the validity of results can include, but are not limited to, microbial contamination, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound and vibration.

6.3.2 The requirements for facilities and environmental conditions necessary for the performance of the verification laboratory activities shall be documented.

6.3.3 The verification laboratory shall monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.

6.3.4 Tests and verifications shall be stopped when the environmental conditions jeopardize the results of the tests or verifications.

6.3.5 Measures to control facilities shall be implemented, monitored and periodically reviewed and shall include, but not be limited to:

a) access to and use of areas affecting verification laboratory activities;

b) prevention of contamination, interference or adverse influences on verification laboratory activities;

c) effective separation between areas with incompatible verification laboratory activities.

6.3.6 Measures shall be taken to ensure good housekeeping in the verification laboratory. Special procedures shall be prepared where necessary.

6.3.7 When the verification laboratory performs verification activities at sites or facilities outside its permanent control, it shall ensure that the requirements related to facilities and environmental conditions of this standard are met.

6.4 Standard Equipment

6.4.1 The verification laboratory shall be equipped with standard equipment (including, but not limited to, measuring instruments, software, reference materials, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results. ISO Guide 33 provides guidance on the selection and use of reference materials and ISO Guide 80 provides guidance to produce in-house quality control materials.

6.4.2 When the verification laboratory needs to use standard equipment outside its permanent control, it shall ensure that the applicable requirements of this standard are met.

6.4.3 Standard equipment used for verification and sampling, and its software shall be capable of achieving the accuracy required and shall comply with the specifications relevant to the verification concerned.

6.4.4 Standard equipment that requires specialized instructions to operate shall be operated only by authorized personnel.

6.6.5 Up-to-date instructions on the use and maintenance of standard equipment (including any relevant manuals provided by the manufacturer of the standard equipment) shall be readily available for use by the appropriate authorized verification laboratory personnel.

6.4.6 The verification laboratory shall have a procedure for safe handling, transport, storage, use and planned maintenance of standard equipment in order to ensure proper functioning, prevent contamination or deterioration and to protect calibration integrity.

6.4.7 There shall be an issue register or comparable arrangement for issuing standard equipment, verification marks (stamps/stickers), sealing pliers, reports and certificate forms/books, etc. to individual verification officers.

6.4.8 Where standard equipment, not issued to an individual verification officer, is removed from the verification laboratory, the relevant verification officer shall sign an issue register (or comparable arrangement) on removal, and a member of staff shall check for proper functioning and sign the said register on the return of the standard equipment.

6.4.9 The verification laboratory shall verify that standard equipment conforms to specified requirements before being placed or returned into service.

6.4.10 The standard equipment used for verification activities shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

6.4.11 Standard equipment shall be calibrated when:

a) the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or

b) calibration of the standard equipment is required to establish the metrological traceability of the reported results.

NOTE Types of standard equipment having an effect on the validity of the reported results can include:

1) those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement;

2) those used to make corrections to the measured value, e.g. temperature measurements;

3) those used to obtain a measurement result calculated from multiple quantities.

6.4.12 The verification laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

6.4.13 All standard equipment requiring calibration or which has a defined period of validity shall be labelled, coded or otherwise identified to allow the user of the standard equipment to readily identify the status of calibration or period of validity.

6.4.14 Standard equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The verification laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure.

6.4.15 When intermediate checks are necessary to maintain confidence in the performance of the standard, these checks shall be carried out according to a procedure.

6.4.16 When calibration of standard equipment and reference material data require the use of reference values or correction factors, the verification laboratory shall ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

6.4.17 The verification laboratory shall take practicable measures to prevent unintended adjustments of standard equipment from invalidating results.

6.4.18 Records shall be retained for standard equipment which can influence verification activities. The records shall include the following, where applicable:

a) the identity of standard equipment, including software and firmware version;

b) the manufacturer's name, type identification, and serial number or other unique identification;

c) evidence of verification that standard equipment conforms with specified requirements;

d) the current location;

e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;

f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;

g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the standard;

h) details of any damage, malfunction, modification to, or repair of, the standard equipment.

6.4.19 The sealing pliers and stamps or stickers for applying as verification marks shall be formally issued to verification officers and controlled to prevent fraudulent use.

6.5 Metrological traceability

6.5.1 The verification laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

6.5.2 The verification laboratory shall ensure that measurement results are traceable to National measurement standards or the International System of Units (SI) through:

a) calibration provided by a competent laboratory; or

NOTE Laboratories fulfilling the requirements of current version of ISO 17025 are considered to be competent.

b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or

NOTE Reference material producers fulfilling the requirements of current version of ISO 17034 are considered to be competent.

6.5.3 When metrological traceability to the national measurement standards or the International System of Units (SI units) is not technically possible, the verification laboratory shall demonstrate metrological traceability to an appropriate reference, e.g.:

a) certified values of certified reference materials provided by a competent producer;

b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

6.6 Externally provided products and services or supplies

6.6.1 The verification laboratory shall ensure that only suitable externally provided products and services or supplies that affect verification laboratory activities are used, when such products and services:

a) are intended for incorporation into the verification laboratory's verification activities;

b) are provided, in part or in full, directly to the customer by the verification laboratory, as received from the external provider;

c) are used to support the operation of the verification laboratory.

NOTE Products can include, for example, measurement standards, auxiliary standard equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and standard maintenance services, proficiency testing services and assessment and auditing services.

6.6.2 The verification laboratory shall have a procedure and retain records for:

a) defining, reviewing and approving the verification laboratory's requirements for externally provided products and services;

b) ensuring that externally provided products and services conform to the verification laboratory's established requirements, or when applicable, to the relevant requirements of this standard, before they are used or directly provided to the customer;

c) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

7 Process requirements

7.1 Review of requests, tenders and contracts

7.1.1 The verification laboratory shall have a procedure for the review of verification requests. This procedure shall ensure that:

a) the verification requirements are adequately defined, documented and understood;

b) the verification laboratory has the capability and resources to meet the verification requirements;

c) Where external verification laboratory are to be used to perform verification work, the verification laboratory shall advise or inform the customer of the specific verification laboratory work to be performed by the external verification laboratory and any matters required for the success of verification work in writing;

NOTE It is recognized that externally verification laboratory activities can occur when:

1) the verification laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full;

2) the verification laboratory does not have the resources or competence to perform the activities.

d) the appropriate verification methods or procedures are selected and are capable of meeting the relevant national standard and legislation.

7.1.2 The verification laboratory shall cooperate with customers or their representatives in clarifying the customer's request and during verification work.

NOTE 1 Such cooperation can include:

a) providing reasonable access to relevant areas of the verification laboratory to witness verification results

b) preparation, packaging, and dispatch of verification items needed by the customer for verification purposes

c) where necessary, the customer may provide needed transportation , equipment, materials and manpower for easy of verification work.

NOTE 2 Clients value good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the client, especially in large assignments, should be maintained throughout the work. The laboratory should inform the client of any delays or major deviations in the performance of the verification activities.

7.1.3 The verification laboratory shall inform the customer when the method requested by the customer is considered to be inappropriate or out of date.

7.1.4 Any differences between the request or tender and the contract shall be resolved before verification laboratory activities commence. Each contract shall be acceptable both to the laboratory and the customer. Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results.

7.1.5 The customer shall be informed of any deviation from the contract.

7.1.6 If a contract is amended after work has commenced, the contract review shall be repeated and any amendments shall be communicated to all affected personnel.

7.1.7 Records of request reviews including any significant changes shall be retained. Records shall also be retained of pertinent discussions with a customer relating to the customer's requirements or the results of the verification laboratory activities.

7.2 Subcontracting of verification work

7.2.1 The verification laboratory shall only subcontract work that is within its scope of accreditation. When a laboratory subcontracts work, the laboratory to which the work is subcontracted shall be accredited to verify the instrument concerned and shall issue the verification certificate.

7.2.2 The verification laboratory shall advise the client and gain the client's approval for the arrangement, in writing or verbally.

7.2.3 The verification laboratory is responsible to the client for the subcontractor's work, except in the case where the client specifies which subcontractor shall be used.

7.2.4 The verification laboratory shall maintain a register of all subcontractors that it uses for verification and a record of the evidence of compliance with this standard for the work in question.

7.3 Purchasing, services and supplies

7.3.1 The verification laboratory shall have a policy and procedure(s) for the selection and procuring of services and suppliers of the calibrated verification standards it uses that affect the quality of the verification activities.

7.3.2 The verification laboratory shall ensure that the purchased supplies and verification standards that affect the quality of verification are not used until they have been inspected or otherwise verified as complying with standard specifications, approvals or requirements, and have been calibrated or verified. Records of actions taken to check compliance shall be maintained.

7.4 Verification methods

7.4.1 General

7.4.1.1 The verification laboratory shall use the appropriate methods and procedures as prescribed in terms of the relevant national standard and legislation for all verification within its scope.

NOTE These include sampling, handling, transport, storage and preparation of verification items to be verified, and, where appropriate, the specified maximum permissible error, as well as statistical techniques for analysis of verification data.

7.4.1.2 The verification laboratory shall have instructions on the use and operation of all relevant standard equipment, and on the handling and preparation of items for verification (or both), where the absence of such instructions could jeopardize the results of verification.

7.4.1.3 All instructions, standard equipment, manuals and reference data relevant to the work of the verification laboratory shall be maintained up to date and be made readily available to personnel.

7.4.1.4 Deviation from verification methods shall occur only if the deviation has been documented, technically justified and authorized, and accepted by the national responsible body.

7.4.1.5 Where the relevant national legislation or international, national or regional standards or specifications which are recognized by the national responsible body contain sufficient and concise information on how to perform the verification, they do not need to be supplemented or re-written as internal procedures if they can be used as published by the verification officer in the verification laboratory.

7.4.2 Selection of methods

7.4.2.1 The verification laboratory shall select the appropriate methods and procedures as prescribed in terms of the relevant national standard and legislation for all verification within its scope.

7.4.2.2 The verification laboratory shall ensure that it uses the latest valid edition of a standard document unless it is not appropriate or possible to do so. When necessary, the standard document shall be supplemented with additional details to ensure consistent application.

7.4.2.3 When the governing technical regulations as specified in the relevant national legislation do not specify the method to be used, the verification laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the standard equipment after approval thereof by the national responsible body.

7.4.2.4 The verification laboratory shall confirm that it can properly operate standard methods before performing the verifications. If the standard method changes, the confirmation shall be repeated.

7.5 Sampling

7.5.1 The verification laboratory shall have a sampling plan and procedure when it carries out sampling for verification. The sampling procedure shall address the factors to be controlled to ensure the validity of verification results.

7.5.2 The sampling plan and procedure shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.

7.5.3 The sampling procedure shall describe:

a) the selection criteria of samples or sites;

b) the sampling plan;

c) the preparation and treatment of sample(s) from a substance, material or product to yield the required item for verification.

7.5.4 The verification laboratory shall retain records of sampling data that forms part of the verification that is undertaken. These records shall include, where relevant:

a) reference to the sampling method used;

b) date and time of sampling;

c) data to identify and describe the sample (e.g. number, amount, name);

d) identification of the personnel performing sampling;

e) identification of the standard used;

f) environmental or transport conditions;

g) diagrams or other equivalent means to identify the sampling location, when appropriate; and

h) deviations, additions to or exclusions from the sampling method and sampling plan.

7.6 Handling of verification items

7.6.1 The verification laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of verification items, including all provisions necessary to protect the integrity of the verification item, and to protect the interests of the verification laboratory and the customer.

7.6.2 Precautions shall be taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for verification. Handling instructions provided with the item shall be followed.

7.6.3 The verification laboratory shall have a system for the unambiguous identification of verification items.

7.6.4 The identification shall be retained while the item is under the responsibility of the verification laboratory.

7.6.5 The system shall ensure that items will not be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.

7.6.6 Upon receipt of the verification item, deviations from specified conditions shall be recorded.

7.6.7 When there is doubt about the suitability of an item for verification, or when an item does not conform to the description provided, the verification laboratory shall consult the customer for further instructions before proceeding and shall record the results of this consultation.

7.6.8 When the customer requires the item to be verified acknowledging a deviation from specified conditions, the verification laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.

7.6.9 When verification items need to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

7.7 Technical records

7.7.1 The verification laboratory shall ensure that technical records are retained, such as records of original observations (raw data), derived data and sufficient information to establish an audit trail, verification and calibration records, staff records and a copy of each verification certificate issued for a defined period. Technical records, such as forms, contracts, raw data sheets, workbooks, verification certificates and shall be kept in prescribed format.

NOTE 1 Records of observations may be in the form of a verification officer's note, which contains sufficient information to establish an audit trail.

NOTE 2 Technical records are accumulations of data and information which result from carrying out verification and which indicate whether specified quality or process parameters are achieved.

7.7.2 Observations, data and calculations shall be recorded at the time they are made and be identifiable to the specific task.

7.7.3 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value shall be entered alongside. All such alterations to records shall be signed or initialled and dated by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

7.7.4 The verification laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations.

7.8 Assuring the validity of verification results

7.8.1 The verification laboratory shall have a procedure for monitoring the validity of verification results.

7.8.2 The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results.

7.8.3 This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:

a) use of reference materials or quality control materials;

b) use of alternative instrumentation that has been calibrated to provide traceable results;

c) functional check(s) of standard equipment;

d) use of check or working standards with control charts, where applicable;

e) intermediate checks on measuring equipment;

f) replicate verification using the same or different methods;

g) re-verification of retained verification items;

h) review of reported verification results;

7.8.4 The verification laboratory may monitor its performance by comparison with results of other laboratories, where available and appropriate.

7.8.5 Data from monitoring activities shall be analyzed, used to control and, if applicable, improve the verification laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside predefined criteria, appropriate action shall be taken to prevent incorrect results from being reported.

7.8.6 Records shall be kept of actions taken to monitor the validity of the verification undertaken.

7.9 Reporting of verification results

7.9.1 General

7.9.1.1 The results of each verification activity carried out by the verification laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the verification methods and procedure.

7.9.1.2 The results shall be reported in a verification report or the verification or rejection certificate, and shall include all the information as prescribed in the national standard and legislation and that is necessary for the interpretation of the verification results, and all the information required by the method used.

7.9.1.3 A verification certificate shall not be combined with a rejection certificate.

7.9.2 Verification certificate

7.9.2.1 Each verification certificate shall include at least the following information, unless the verification laboratory has valid reasons for not doing so:

a) the title "Verification Certificate";

b) the name and address of the verification laboratory;

c) the location of performance of the verification laboratory activities, performed at a customer facility or at sites away from the verification laboratory’s permanent facilities, or in associated temporary or mobile facilities;

d) the unique identification number of the verification certificate on all its pages to identify that each page is recognized as a part of the verification certificate;

e) page numbers and a clear identifier of the number of pages in the verification certificate, e.g. page 1 of 1 or a statement at the beginning of the certificate “This certificate consists of 1 page” or a statement at the end of the certificate “End of Certificate”;

f) the name and address of the customer;

g) the identification of the verification procedure used by the verification laboratory;

h) a description, metrological parameters and unambiguous identification of the items verified including the serial number and the type approval number, if the instrument requires type approval in terms of the relevant national legislation.

i) the date(s) of performance of the verification laboratory activity;

j) identification of the person(s) authorizing the report or certificate;

k) a statement that will serve as proof that the standard equipment directly related to the reading or obtaining of the results of measurement is traceable to a national standard. The following data shall be included as a minimum:

   1) calibration certificate number;

   2) date of calibration of standard equipment;

   3) date of next calibration of standard equipment

   4) identification of standard equipment, e.g. serial numbers, description, set number, etc.; and

NOTE Standard Equipment for auxiliary measurements, such as hydrometers, thermometers and pressure gauges, need not be included in the statement of traceability provided that they are calibrated in accordance with clause 6.5 of this standard.

l) the latest security intervention value, which shall be indicated on the certificate if the instrument being verified is secured by means of a software or physical seal. If the security intervention value indicated on the instrument differs from the security intervention value indicated on the certificate, this means that an unlawful intervention was made on the measuring instrument and, in terms of the relevant national legislation, the instrument shall not be used for the prescribed purpose;

m) expiry date of the verification certificate, if a verification period has been prescribed for the measuring instrument concerned;

n) the initials, surname and signature of the verification officer responsible for the verification, date of verification and a seal number used for identification of the responsible verification officer and the verification laboratory; and

o) the following statement: "The verification item(s) (whatever named) was/were tested or verified and found to comply in all respects with the requirements of the national Legislation or national Standards and may be used for a prescribed purpose as governed by the national Legislation.

7.9.2.2 The verification laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified.

7.9.2.3 In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results.

7.9.2.4 Where the verification laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.

7.7.2.5 Any additional information that may be required by specific verification methods should be added.

7.9.3 Rejection certificates

7.9.3.1 A rejection certificate shall be issued for measuring instrument or prepackage that is false, inaccurate or defective and that is not immediately repaired and verified.

7.9.3.2 Results of any tests conducted need not be attached to the rejection certificate but shall be recorded.

7.9.3.3 The rejection certificate shall contain at least the following:

a) the title "Rejection Certificate" and identification number;

b) the name and address of the verification laboratory;

c) the name and address of the customer;

d) description and unambiguous identification of the item(s) rejected;

e) statement that will serve as proof that the standard equipment directly related to the reading or obtaining of the results of measurement is traceable to a national standard when the rejection is related to the inaccuracy of the instrument. The following data shall be included as a minimum:

   1) calibration certificate number;

   2) date of calibration of standard equipment;

   3) date of next calibration of standard equipment

   4) identification of standard equipment, e.g. serial numbers, description, set number etc.; and

f) date of rejection;

g) reason for rejection of the measuring instrument;

h) initials, surname and signature of the verification officer responsible for the rejection and a seal number used for identification of the responsible verification officer; and

i) the following statement: "The verification item(s) has/have been rejected and may not be used for a prescribed purpose in terms of the national legislation until they have been verified as complying to all requirements of the national legislation and standard."

7.9.4 Amendments to reports

7.9.4..1 When an issued verification report or certificate needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.

7.9.4..2 Amendments to a verification report or certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement “Amendment to Report, serial number... [or as otherwise identified]”, or an equivalent form of wording. Such amendments shall meet all the requirements of this document.

7.9.4..3 When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.

7.9.5 Electronic transmission of results

In the case of transmission of verification results by facsimile or other electronic or electromagnetic means, data shall be safeguarded to protect confidentiality.

7.9.6 Format of reports and certificates

7.9.6.1 The format shall be designed to accommodate each type of verification carried out and to minimize the possibility of misunderstanding or misuse and these formats shall be designed and used in accordance with national legislation.

7.9.6.2 Attention shall be given to the layout of the verification or rejection certificate, especially with regard to the presentation of the verification data and ease of assimilation by the reader.

7.9.6.3 The headings shall be standardized as far as possible.

7.10 Complaints and appeals

7.10.1 The verification laboratory shall have a documented process to receive, evaluate and make decisions on complaints and appeals from customers and other parties.

7.10.2 A description of the handling process for complaints and appeals shall be available to any interested party on request. Upon receipt of a complaint, the verification laboratory shall confirm whether the complaint or appeal relates to verification laboratory activities that it is responsible for and, if so, shall deal with it. The

verification laboratory shall be responsible for all decisions at all levels of the handling process for complaints and appeals.

7.10.3 The process for handling complaints and appeals shall include at least the following elements and methods:

a) description of the process for receiving, validating, investigating the complaint or appeal, and deciding what actions are to be taken in response to it;

b) tracking and recording complaints and appeals, including actions undertaken to resolve them;

c) ensuring that any appropriate action is taken.

7.10 4 The verification laboratory receiving the complaint or appeal shall be responsible for gathering and verifying all necessary information to validate the complaint or appeal

7.10.5 Whenever possible, the verification laboratory shall acknowledge receipt of the complaint or appeal, and provide the complainant or appellant with progress reports and the outcome.

7.10.6 The outcomes to be communicated to the complainant or appellant shall be made by, or reviewed and approved by, individual(s) not involved in the original verification laboratory activities in question.

NOTE This can be performed by external personnel.

7.10.7 Whenever possible, the verification laboratory shall give formal notice of the end of the complaint or appeal handling to the complainant and appellant.

7.10.8 Records shall be maintained of all complaints and appeals and of the investigations and corrective actions taken by the verification laboratory.

7.11 Nonconforming work

7.11.1 The verification laboratory shall have a procedure that shall be implemented when any aspect of its verification laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. standard or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure shall ensure that:

a) the responsibilities and authorities for the management of nonconforming work are defined;

b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the verification laboratory;

c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;

d) a decision is taken on the acceptability of the nonconforming work;

e) where necessary, the customer is notified and work is recalled;

f) the responsibility for authorizing the resumption of work is defined.

7.11.2 The verification laboratory shall retain records of nonconforming work and actions as specified in 7.11.1, bullets b) to f).

7.11.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the verification laboratory's operations with its own management system, the verification laboratory shall implement corrective action.

7.12 Control of data and information management

7.12.1 The verification laboratory shall have access to the data and information needed to perform verification laboratory activities.

7.12.2 The verification laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the verification laboratory information management system(s) by the verification laboratory before introduction. Whenever there are any changes, including verification laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.

NOTE 1 In this standard “verification laboratory information management system(s)” includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems.

NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.

7.12.3 The verification laboratory information management system(s) shall:

a) be protected from unauthorized access;

b) be safeguarded against tampering and loss;

c) be operated in an environment that complies with provider or verification laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

d) be maintained in a manner that ensures the integrity of the data and information;

e) include recording system failures and the appropriate immediate and corrective actions.

7.12.4 When a verification laboratory information management system is managed and maintained off-site or through an external provider, the verification laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this standard.

7.12.5 The verification laboratory shall ensure that instructions, manuals and reference data relevant to the verification laboratory information management system(s) are made readily available to personnel.

7.12.6 Calculations and data transfers shall be checked in an appropriate and systematic manner.

8 Management system requirements.

8.1 Options

8.1.1 General

The verification laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this standard and assuring the quality of the verification laboratory results. In addition to meeting the requirements of Clauses 4 to 7, the verification laboratory shall implement a management system in accordance with option A or option B.

8.1.2 Option A

As minimum, the management system of the verification laboratory shall address the following:

a) management system documentation;

b) control of management system documents;

c) control of records;

d) actions to address risks and opportunities;

e) improvement;

f) corrective actions;

g) internal audits;

h) management reviews.

8.1.3 Option B

A verification laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7 of this draft standard, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9 of this standard.

8.2 Management system documentation (Option A)

8.2.1 Verification laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purposes of this standard and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the verification laboratory organization.

8.2.2 The policies and objectives shall address the competence, impartiality and consistent operation of the verification laboratory.

8.2.3 Verification laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

8.2.4 All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.

8.2.5 All personnel involved in verification laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

8.3 Control of management system documents (Option A)

8.3.1 The verification laboratory shall control the documents (internal and external) that relate to the fulfilment of this standard.

NOTE In this context, “documents” can be policy statements, procedures, specifications, manufacturer’s instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.

8.3.2 The verification laboratory shall ensure that:

a) documents are approved for adequacy prior to issue by authorized personnel;

b) documents are periodically reviewed, and updated as necessary;

c) changes and the current revision status of documents are identified;

d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;

e) documents are uniquely identified;

f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

8.4 Control of records (Option A)

8.4.1 The verification laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this standard.

8.4.2 The verification laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The verification laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.

NOTE Additional requirements regarding technical records are given in 7.7.

8.5 Actions to address risks and opportunities (Option A)

8.5.1 The verification laboratory shall consider the risks and opportunities associated with the verification laboratory activities in order to:

a) give assurance that the management system achieves its intended results;

b) enhance opportunities to achieve the purpose and objectives of the verification laboratory;

c) prevent, or reduce, undesired impacts and potential failures in the verification laboratory activities;

d) achieve improvement.

8.5.2 The verification laboratory shall plan:

a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement these actions into its management system;

2) evaluate the effectiveness of these actions.

NOTE Although this document specifies that the verification laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Verification Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.

8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of verification laboratory results.

NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to expanding the scope of the verification laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.

8.6 Improvement (Option A)

8.6.1 The verification laboratory shall identify and select opportunities for improvement and implement any necessary actions.

NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.

8.6.2 The verification laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be analysed and used to improve the management system, verification laboratory activities and customer service.

NOTE Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.

8.7 Corrective actions (Option A)

8.7.1 When nonconformity occurs, the verification laboratory shall:

a) react to the nonconformity and, as applicable:

   1) take action to control and correct it;

   2) address the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

   1) reviewing and analysing the nonconformity;

   2) determining the causes of the nonconformity;

   3) determining if similar nonconformities exist, or could potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) update risks and opportunities determined during planning, if necessary;

f) make changes to the management system, if necessary.

8.7.2 Corrective actions shall be appropriate to the effects of the nonconformities encountered.

8.7.3 The verification laboratory shall retain records as evidence of:

a) the nature of the nonconformities, cause(s) and any subsequent actions taken;

b) the results of any corrective action.

8.8 Internal audits (Option A)

8.8.1 The verification laboratory shall conduct internal audits at planned intervals to provide information on whether the management system:

a) conforms to:

1) the verification laboratory's own requirements, for its management system, including the verification laboratory activities;

2) the national legislation;

3) the requirements of this standard;

b) is effectively implemented and maintained.

8.8.2 The verification laboratory shall:

a) plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the verification laboratory activities concerned, changes affecting the verification laboratory, and the results of previous audits;

b) define the audit criteria and scope for each audit;

c) ensure that the results of the audits are reported to relevant management;

d) implement appropriate correction and corrective actions without undue delay;

e) retain records as evidence of the implementation of the audit programme and the audit results.

NOTE ISO 19011 provides guidance for internal audits.

8.9 Management reviews (Option A)

8.9.1 The verification laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.

8.9.2 The inputs to management review shall be recorded and shall include information related to the following:

a) changes in internal and external issues that are relevant to the verification laboratory;

b) fulfilment of objectives;

c) suitability of policies and procedures;

d) status of actions from previous management reviews;

e) outcome of recent internal audits;

f) corrective actions;

g) assessments by external bodies;

h) changes in the volume and type of the work or in the range of verification laboratory activities;

i) customer and personnel feedback;

j) complaints and appeals;

k) effectiveness of any implemented improvements;

l) adequacy of resources;

m) results of risk identification;

n) outcomes of the assurance of the validity of results; and

o) other relevant factors, such as monitoring activities and training.

8.9.3 The outputs from the management review shall record all decisions and actions related to at least:

a) the effectiveness of the management system and its processes;

b) improvement of the verification laboratory activities related to the fulfilment of the requirements of this document;

c) provision of required resources;

d) any need for change.

Annex A
(Normative)
Independence requirements for verification laboratories

A.1 Requirements for verification laboratories (Type A)

The verification laboratory referred to in 4.1.6 a) shall meet the requirements below:

a) The verification laboratory shall be independent of the parties involved.
b) The verification laboratory and its personnel shall not engage in any activities that may conflict with their independence of judgment and integrity in relation to their verification activities. In particular, they shall not be engaged in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items verified.

NOTE 1 This does not preclude exchanging technical information between the client and the verification laboratory (e.g. explanation of findings or clarifying requirements or training).

NOTE 2 This does not preclude the purchase, ownership or use of verified items that are necessary for the operations of the verification laboratory, or the purchase, ownership or use of the items for personal purposes by the personnel.

c) A verification laboratory shall not be a part of a legal entity that is engaged in design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items verified.

NOTE 1 This does not preclude exchanging technical information between the client and any other part of the same legal entity of which the verification laboratory is a part (e.g. explanation of findings or clarifying requirements or training).

NOTE 2 This does not preclude the purchase, ownership, maintenance or use of verified items that are necessary for the operations of another part of the same legal entity, or for personal purposes by the personnel.

d) The verification laboratory shall not be linked to a separate legal entity engaged in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items verified by the following:

1) common ownership, except where the owners have no ability to influence the outcome of a verification;

EXAMPLE 1 A cooperative type of structure where there are large numbers of stakeholders, but they (individually or as a group) have no ability to influence the outcome of a verification.

EXAMPLE 2 A holding company consisting of several separate legal entities (sister companies) under a common mother company, where neither the sister companies nor the mother company can influence the outcome of a verification.

2) common ownership appointees on the boards or equivalent of the organizations, except where these have functions that have no influence on the outcome of a verification;

EXAMPLE A bank financing a company insists on an appointee to the board who will overview how the company is managed but will not be involved in any decision-making.

3) directly reporting to the same higher level of management, except where this cannot influence the outcome of a verification;

NOTE Reporting to the same higher level of management is permitted on matters other than design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items verified.

4) contractual commitments, or other means that may have an ability to influence the outcome of a verification.

A.2 Requirements for verification laboratories (Type B)

The verification laboratories referred to in 4.1.6 b) shall meet the requirements below.

a) Verification services shall only be supplied to the organization of which the verification laboratory forms a part.
b) b) A clear separation of the responsibilities of the verification personnel from those of the personnel employed in the other functions shall be established by organizational identification and the reporting methods of the verification laboratory within the parent organization.
c) The verification laboratory and its personnel shall not engage in any activities that may conflict with their independence of judgment and integrity in relation to their verification activities. In particular, they shall not be engaged in the design, manufacture, supply, installation, use or maintenance of the items verified.

NOTE 1 This does not preclude exchanging technical information between the verification laboratory and the other parts of the organization of which the verification laboratory forms a part, e.g. explanation of findings or clarifying requirements or training.

NOTE 2 This does not preclude the purchase, ownership or use of verified items that are necessary for the operations of the verification laboratory, or the purchase, ownership or use of the items for personal purposes by the personnel.

A.3 Requirements for verification laboratories (Type C)

The verification laboratory referred to in 4.1.6 c) shall meet the requirements below.

a) The verification laboratory shall provide safeguards within the organization to ensure adequate segregation of responsibilities and accountabilities between verification and other activities.
b) The design/manufacture/supply/installation/servicing/maintenance and the verification of the same item carried out by a Type C verification laboratory shall not be undertaken by the same person. An exception to this is where a regulatory requirement explicitly allows an individual person from a Type C verification laboratory to undertake both the design/manufacture/supply/installation/servicing/maintenance and the verification of the same item, as long as this exception does not compromise the verification results.

NOTE Verifications carried out by Type C verification laboratory cannot be classified as third party verifications for the same verification activities because they do not meet the requirements of independence of operations for Type A verification laboratories.

Bibliography

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