COPPER MOUNTAIN
TECHNOLOGIES

Calibration Laboratory Quality Manual

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DOCUMENT CHANGE RECORD

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18-November-2018	The manual cancels and replaces the QMS.01:2015, which has been technically revised.

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AUTHORIZATION APPROVALS

Electronic authorization approval is the preferred method for approving quality system documents. Signed hardcopies are only available upon request.

Approver:	Laboratory Head
Approver:	Consulting Engineer
Document Reviewer:	Quality Manager
Document Owner:	Quality Manager

DISTRIBUTION

Printed copies of this document are uncontrolled and users must verify the revision is current before use. All previous revisions must be discarded. Current documents and revision index are available on Copper Mountain Technologies network. All documents will have electronic approval. An uncontrolled copy is available to customers via the Copper Mountain Technologies website.

1 SCOPE

This Calibration Laboratory Quality Manual defines or identifies the policies, procedures and requirements for the competence, impartiality and consistent operation that choose to comply with the requirements of ISO/IEC 17025 as a calibration laboratory. This document is applicable to all laboratory activities, regardless of accreditation exists. Any local documents, procedures and policies associated with ISO/IEC 17025 compliance for calibration laboratories must comply with this document.

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.

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

ISO/IEC Guide 99 International vocabulary of metrology – Basic and general concepts and associated terms (VIM, also known as JCGM 200), issued by BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML

ISO/IEC Guide 98-4 Uncertainty of measurement – Part 4: Role of measurement uncertainty in conformity assessment (also known as JCGM 106), issued by BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP and OIML

EURAMET Calibration Guide No. 12 Guidelines on the Evaluation of Vector Network Analyzers (VNA)

3 TERMS AND DEFINITIONS

For the purposes of this document, the relevant terms and definitions given in VIM apply.

4 MANAGEMENT REQUIREMENTS

4.1 Impartiality

4.1.1 Laboratory activities are undertaken impartially and structured and managed so as to safeguard impartiality.

4.1.2 The laboratory management is committed to impartiality.

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

4.1.4 The laboratory identifies risks to its impartiality on an on-going basis. This includes 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 laboratory with a risk to impartiality.

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

4.2 Confidentiality

4.2.1 The laboratory is responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. The laboratory informs the customer in advance, of the information it intends to place in the public domain. Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and is regarded as confidential.

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

4.2.3 Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) is confidential between the customer and the laboratory. The provider (source) of this information is confidential to the laboratory and is not be shared with the customer, unless agreed by the source.

4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

5 STRUCTURAL REQUIREMENTS

5.1 The laboratory is a defined part of Copper Mountain Technologies that is legally responsible for its laboratory activities.

5.2 The laboratory has identified management that has overall responsibility for the laboratory (annex A).

5.3 The laboratory has defined and documented the range of laboratory activities for which it conforms with this document. Copper Mountain Technologies laboratory performs calibration activities. The laboratory only claims conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis. Laboratory whose work includes both accredited and non-accredited calibrations complies to this document, but non-accredited calibrations are not required to fully comply with sections 6.5, 7.6 and reporting requirements of 7.8.

5.4 Laboratory activities are carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition. This includes laboratory activities performed in its permanent facilities.

5.5 The laboratory has (annex B):

a) defined the organization and management structure of the laboratory, its place in parent organization (see also annex A), and the relationships between management, technical operations and support services. The structure is described to a level of detail sufficient to identify key personnel / activities and in order to reveal possible conflicts of interest involving both calibration services and manufacturing activities involving calibration;

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

c) documented its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.

5.6 The laboratory has personnel named as a quality manager who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a) implementation, maintenance and improvement of the management system;

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

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

d) reporting to laboratory management on the performance of the management system and any need for improvement;

e) ensuring the effectiveness of laboratory activities.

NOTE Individuals may be assigned more than one function and it may be impractical to appoint deputes for every function.

5.7 Laboratory management ensures that:

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

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 laboratory has available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

6.2 Personnel

6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities act impartially, are competent and work in accordance with the laboratory's management system.

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

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

6.2.4 The management of the laboratory communicates to personnel their duties, responsibilities and authorities.

6.2.5 The laboratory has procedure (s) and retains records for:

a) determining the competence requirements;

b) selection of personnel;

c) training of personnel;

d) supervision of personnel;

e) authorization of personnel;

f) monitoring competence of personnel.

6.2.6 The laboratory authorizes personnel to perform specific laboratory activities, including but not limited to, the following:

a) development, modification, verification and validation of methods;

b) analysis of results, including statements of conformity or opinions and interpretations;

c) report, review and authorization of results.

6.3 Facilities and environmental conditions

6.3.1 The facilities and environmental conditions are suitable for the laboratory activities and not adversely affect the validity of results.

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

6.3.3 The laboratory monitors, controls and records environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results.

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

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

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

c) effective separation between areas with incompatible laboratory activities.

6.3.5 When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it ensures that the requirements related to facilities and environmental conditions of this document are met.

6.4 Equipment

6.4.1 The laboratory has access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory

activities and that can influence the results.

6.4.2 When the laboratory uses equipment outside its permanent control, it ensures that the requirements for equipment of this document are met.

6.4.3 The laboratory has a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.

6.4.4 The laboratory verifies that equipment conforms to specified requirements before being placed or returned into service.

6.4.5 The equipment used for measurement is capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

6.4.6 Measuring equipment is calibrated when:

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

– calibration of the equipment is required to establish the metrological traceability of the reported results.

6.4.7 The laboratory establishes a calibration program, which is reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

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

a) Laboratory has a procedure stating its policy for establishing and changing calibration intervals for equipment that it controls.

6.4.9 Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, is taken out of service. It is isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly. The laboratory examines the effect of the defect or deviation from specified requirements and initiates the management of nonconforming work procedure (see 7.10).

6.4.10 When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks are carried out according to a procedure.

6.4.11 When calibration and reference material data include reference values or correction factors, the laboratory ensures the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements.

6.4.12 The laboratory takes practicable measures to prevent unintended adjustments of equipment from invalidating results.

6.4.13 Records are retained for equipment which can influence laboratory activities. The records include the following, where applicable:

a) the identity of 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 equipment conforms with specified requirements;

d) the current location. Copper Mountain Technologies use only one location for all calibration activities, thus, as a current location the laboratory is considered (RCD.020 Accommodation data list);

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; Copper Mountain Technologies do not use reference material in its laboratory activities, thus, section 6.4.13 f) is not applicable.

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

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

6.5 Metrological traceability

6.5.1 The laboratory establishes and maintains 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 laboratory ensures that measurement results are traceable to the International System of Units (SI) through:

a) calibration provided by a competent laboratory; or

b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; (Copper Mountain Technologies do not use reference material in its laboratory activities, thus, section 6.5.2 b) is not applicable) or

c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

6.5.3 When metrological traceability to the SI units is not technically possible, the laboratory demonstrates metrological traceability to an appropriate reference, e.g.:

a) certified values of certified reference materials provided by a competent producer. Copper Mountain Technologies do not use reference material in its laboratory activities, thus, section 6.5.3 a) is not applicable;

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

6.6.1 The laboratory ensures that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:

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

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

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

6.6.2 The laboratory has a procedure and retains records for:

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

b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers (annex B.5);

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

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

6.6.3 The laboratory communicates its requirements to external providers for:

a) the products and services to be provided;

b) the acceptance criteria;

c) competence, including any required qualification of personnel;

d) activities that the laboratory, or its customer, intends to perform at the external provider's premises.

6.6.4 When a laboratory subcontracts any part of the calibration, this work is placed with a laboratory complying with the requirements of ISO/IEC 17025 and (or) ANSI/NCSL Z540-1. The laboratory ensures and is able to demonstrate that its subcontractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory with respect to the work being sub-contracted. The laboratory advises the customer of its intention to subcontract any portion of the calibration to another party.

7 PROCESS REQUIREMENTS

7.1 Review of requests, tenders and contracts

7.1.1 The laboratory has a procedure for the review of requests, tenders and contracts. The procedure ensures that:

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

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

c) where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval;

d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.

7.1.2 The laboratory informs the customer when the method requested by the customer is considered to be inappropriate or out of date.

7.1.3 When the customer requests a statement of conformity to a specification or standard for calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule are clearly defined. Unless inherent in the requested specification or standard, the decision rule selected is communicated to, and agreed with, the customer.

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

7.1.5 The customer is informed of any deviation from the contract.

7.1.6 If a contract is amended after work has commenced, the contract review is re-

peated and any amendments are communicated to all affected personnel.

7.1.7 The laboratory cooperates with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed.

7.1.8 Records of reviews, including any significant changes, are retained. Records also are retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities.

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 The laboratory uses appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.

7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, are kept up to date and are made readily available to personnel (see 8.3).

7.2.1.3 The laboratory ensures that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method is supplemented with additional details to ensure consistent application.

7.2.1.4 When the customer does not specify the method to be used, the laboratory selects an appropriate method and informs the customer of the method chosen. Methods 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 equipment, are recommended. Laboratory-developed or modified methods can also be used.

7.2.1.5 The laboratory verifies that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification are retained. If the method is revised by the issuing body, verification is repeated to the extent necessary.

7.2.1.6 When method development is required, this is a planned activity and is assigned to competent personnel equipped with adequate resources. As method development pro-

ceeds, periodic review is carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan is approved and authorized.

7.2.1.7 Deviations from methods for all laboratory activities occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

7.2.2 Validation of methods

7.2.2.1 The laboratory validates non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation is as extensive as is necessary to meet the needs of the given application or field of application.

7.2.2.2 When changes are made to a validated method, the influence of such changes is determined and where they are found to affect the original validation, a new method validation is performed.

7.2.2.3 The performance characteristics of validated methods, as assessed for the intended use, is relevant to the customers' needs and consistent with specified requirements.

7.2.2.4 The laboratory retains the following records of validation:
a) the validation procedure used;
b) specification of the requirements;
c) determination of the performance characteristics of the method;
d) results obtained;
e) a statement on the validity of the method, detailing its fitness for the intended use.

7.3 Sampling

Copper Mountain Technologies accredited measurement facilities do not sample. Thus, section 7.3 of ISO/IEC 17025 is not applicable.

7.4 Handling of calibration items

7.4.1 The laboratory has a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of calibration items, including all provisions necessary to protect the integrity of the calibration item, and to protect the interests of the laboratory and the customer. Precautions are taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for calibration. Handling instructions provided with the item are followed.

7.4.2 The laboratory has a system for the unambiguous identification of calibration items. The identification is retained while the item is under the responsibility of the laboratory. The system ensures that items will not be confused physically or when referred to in records or other documents. The system, if appropriate, accommodates a sub-division of an item or groups of items and the transfer of items.

7.4.3 Upon receipt of the calibration item, deviations from specified conditions are recorded. When there is doubt about the suitability of an item for calibration, when anti-tamper seals are present but broken, or when an item does not conform to the description provided, the laboratory consults the customer for further instructions before proceeding and records the results of this consultation. When the customer requires the item to be calibrated acknowledging a deviation from specified conditions, the laboratory includes a disclaimer in the report indicating which results may be affected by the deviation.

7.4.4 When items need to be stored or conditioned under specified environmental conditions, these conditions are maintained, monitored and recorded.

7.5 Technical records

7.5.1 The laboratory ensures that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations are recorded at the time they are made and are identifiable with the specific task.

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

7.6 Evaluation of measurement uncertainty

7.6.1 Laboratory identifies the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, are taken into account using appropriate methods of analysis.

7.6.2 A laboratory performing calibrations, including of its own equipment, evaluates

the measurement uncertainty for all calibrations.

7.6.3 Copper Mountain Technologies has accredited measurements facilities to perform a calibration. Testing is not performed under accreditation. Thus, section 7.6.3 of ISO/IEC 17025 is not applicable.

7.7 Ensuring the validity of results

7.7.1 The laboratory has a procedure for monitoring the validity of results. The resulting data are recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results. This monitoring is planned and reviewed and includes, where appropriate, but not be limited to:

a) use of reference materials or quality control materials. Copper Mountain Technologies do not use reference material in its laboratory activities, thus, section 7.1.1 a) is not applicable;

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

c) functional check(s) of measuring and testing equipment;

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

e) intermediate checks on measuring equipment;

f) replicate calibrations using the same or different methods;

g) recalibration of retained items;

h) correlation of results for different characteristics of an item;

i) review of reported results;

j) intralaboratory comparisons;

k) testing of blind sample(s).

7.7.2 The laboratory monitors its performance by comparison with results of other laboratories, where available and appropriate. This monitoring are planned and reviewed and includes, but not be limited to, either or both of the following:

a) participation in proficiency testing;

b) participation in interlaboratory comparisons other than proficiency testing.

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

NOTE Laboratory develops schedule for monitoring the validity of results – technical record that would reflect key planned measurement events according to the scope of accreditation, data to be kept, appropriate methods, evaluation analysis with predefined criteria.

According to the schedule, during equipment lifetime, monitoring the obtained measurement result trends is performed in purpose of:

- identification of possible deterioration or aging of a standard;

- making decision for initial adjustment of a standard;

- making decision for replacing or repairing of a standard, or purchasing another one;

- making decision to upgrade a standard;

- making decision for using automation programs or techniques for more effective operations with a standard (where applicable);

- making decision to change monitoring interval in case of a doubt;

- making decision to appoint actions to prevent incorrect results in case of data are close to pre-defined criteria;

- making decision to correct the scope of accreditation.

For collecting and analysis of the measurement results, one should adhere to methods given in this section. The most important of them are proficiency testing activity as a part of interlaboratory comparison, intermediate check, reviewing and investigation of reported results, comparison analysis of measurements obtained with the same type equipment.

It is also recommended to use statistical software for treatment of the results.

Laboratory carries out corrective actions (in accordance with 8.7) if the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria.

Results of the analysis are considered into management reviews.

7.8 Reporting of results

7.8.1 General

7.8.1.1 The results are reviewed and authorized prior to release.

7.8.1.2 The results are provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. calibration certificate), and include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports are retained as technical records.

7.8.1.3 When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer are readily available.

7.8.2 Common requirements for reports

7.8.2.1 Each report includes at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse:

a) a title (e.g. “Calibration Certificate”);

b) the name and address of the laboratory;

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

d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;

e) the name and contact information of the customer;

f) identification of the method used;

g) a description, unambiguous identification, and, when necessary, the condition of the item;

h) the date of receipt of the calibration item(s), where this is critical to the validity and application of the results;

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

j) the date of issue of the report;

k) reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results;

l) a statement to the effect that the results relate only to the items tested, calibrated or sampled;

m) the results with, where appropriate, the units of measurement;

n) additions to, deviations, or exclusions from the method;

o) identification of the person(s) authorizing the report;

p) clear identification when results are from external providers;

q) a statement, that the calibration certificate shall not be reproduced except in full, without written approval of the laboratory.

7.8.2.2 The laboratory is responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer are clearly identified. In addition, a disclaimer is put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it states in the report that the results apply to the sample as received.

7.8.3 Specific requirements for test reports

All accredited Copper Mountain Technologies measurement facilities perform calibrations and issue calibration certificates. Thus, section 7.8.3 of ISO/IEC 17025 dealing with Test Reports is not applicable.

7.8.4 Specific requirements for calibration certificates

7.8.4.1 In addition to the requirements listed in 7.8.2, calibration certificates include the following:

a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);

b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;

c) a statement identifying how the measurements are metrologically traceable;

d) the results before and after any adjustment or repair, if available. Certificates or reports designate any special limitations of use;

e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);

f) where appropriate, opinions and interpretations (see 7.8.7);

g) the following or a similar statement on its issued certificates: “Reported uncertainties (where applicable) represent expanded uncertainties expressed at approximately the 95% confidence level using a coverage factor of 2 (k=2)”;

h) the measurement uncertainty unless it has been established and documented during contract review that only a statement of compliance to a specification is required by the customer;

i) when a customer requests only a statement of compliance without data and measurement uncertainty (as evidenced in contract review records), contract review records indicate

the customer was notified that the calibration is not intended to be used in support of further dissemination of metrological traceability (i.e., to calibrate another device);

j) at specific customer request (as documented in contract review records), the laboratory may issue a statement of compliance without taking the measurement uncertainty into consideration. In this case, are the results and measurement uncertainty included in the calibration certificate and is the following statement included in the certificate: "The statement of compliance in this certificate was issued without taking the uncertainty of measurement into consideration. The customer shall assess the results and uncertainty when determining if the results meet their needs." This is considered "shared responsibility";

k) the laboratory maintain records of measurement uncertainty for all accredited calibrations;

l) the uncertainties reported to, at most, two significant digits, where feasible;

m) the laboratory ensures it does not report a smaller uncertainty of measurement on its issued accredited certificates than the CMC on the scope of accreditation.

7.8.4.2 Where the laboratory is responsible for the sampling activity, calibration certificates meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results.

7.8.4.3 A calibration certificate or calibration label does not contain any recommendation on the calibration interval, except where this has been agreed with the customer.

7.8.5 Reporting sampling – specific requirements

All accredited Copper Mountain Technologies measurement facilities perform calibrations and issue calibration certificates. Thus, section 7.8.5 of ISO/IEC 17025 dealing with Sampling Report is not applicable.

7.8.6 Reporting statements of conformity

7.8.6.1 When a statement of conformity to a specification or standard is provided, the laboratory documents the decision rule employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule.

NOTE Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.

7.8.6.2 The laboratory reports on the statement of conformity, such that the statement clearly identifies:

a) to which results the statement of conformity applies;

b) which specifications, standards or parts thereof are met or not met;

c) the decision rule applied (unless it is inherent in the requested specification or standard).

NOTE When reporting statements of conformity, laboratory has chosen the next approach for defining a decision rule based on ISO/IEC Guide 98-4 and EURAMET Calibration Guide No. 12.

Two main cases should be considered:

- Statement of conformity applies to parameters which are covered by the scope of accreditation, and laboratory establishes a sequence of uncertainty calculation for them (for more details refer to traceability guide).

EURAMET Calibration Guide No. 12 (Annex E) prescribes decision rule and way of uncertainty accounting for S-parameters in accordance with scalar case of quantitative verification criteria. S-parameters are named into the scope as “Reflection Magnitude”, “Reflection Phase”, “Transmission Magnitude”, and “Transmission Phase”.

For other parameters into the scope such as “RF Absolute Power - Measure” and “Frequency” the decision rule is “simple acceptance” described into the ISO/IEC Guide 98-4 (refer to 8.2) and based on TUR of 3:1 or best. Under such a rule, the producer and user (consumer) of the measurement result agree to accept as conforming (and reject otherwise) an item whose property has a measured value in the tolerance interval.

- Statement of conformity applies to parameters which are not included into the scope of accreditation. The unaccredited material, where applicable, is indicated by an asterisk (*) or confined to clearly marked sections. Uncertainty of such measurements is not calculated and cannot be taken into account. Thus, a measured value is accepted as pass decision if it is in the tolerance interval and rejected as fail decision when it is out of the tolerance.

7.8.7 Reporting opinions and interpretations

7.8.7.1 When opinions and interpretations are expressed, the laboratory ensures that only personnel authorized for the expression of opinions and interpretations release the respective statement. The laboratory documents the basis upon which the opinions and interpretations have been made.

7.8.7.2 The opinions and interpretations expressed in reports are based on the results

obtained from the calibrated item and are clearly identified as such.

7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue is retained.

7.8.8 Amendments to reports

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

7.8.8.2 Amendments to a report after issue are made only in the form of a further document, or data transfer, which includes the statement "Supplement to Calibration Certificate, serial number... [or as otherwise identified]", or an equivalent form of wording.

Such amendments shall meet all the requirements of this document.

7.8.8.3 When it is necessary to issue a complete new report, this is uniquely identified and contains a reference to the original that it replaces.

7.8.8.4 If any event, such as the identification of defective laboratory calibration equipment, casts doubt on the validity of results given in any prior calibration report or certificate or amendment to a report or certificate, the calibration laboratory notify the customer promptly in writing. Such notification quantifies the magnitude of error created in the calibration results. The customer promptly notified when any customer's measuring and test equipment is found significantly out of tolerance during the calibration/verification process. Measurement data reported so that appropriate action can be taken.

7.9 Complaints

7.9.1 The laboratory has a documented process to receive, evaluate and make decisions on complaints. Where applicable, complaints are promptly resolved.

7.9.2 A description of the handling process for complaints is available to any interested party on request. Upon receipt of a complaint, the laboratory confirms whether the complaint relates to laboratory activities that it is responsible for and, if so, deal with it. The laboratory is responsible for all decisions at all levels of the handling process for complaints.

7.9.3 The process for handling complaints includes at least the following elements and

methods:

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

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

c) ensuring that any appropriate action is taken.

7.9.4 The laboratory receiving the complaint is responsible for gathering and verifying all necessary information to validate the complaint.

7.9.5 Whenever possible, the laboratory acknowledges receipt of the complaint, and provides the complainant with progress reports and the outcome.

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

7.9.7 Whenever possible, the laboratory gives formal notice of the end of the complaint handling to the complainant.

7.10 Nonconforming work

7.10.1 The laboratory has a procedure that is implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). Out of tolerance calibration standards are considered to be nonconforming calibration work. The procedure ensures 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 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.

7.10.2 The laboratory retains records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).

7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that

there is doubt about the conformity of the laboratory's operations with its own management system, the laboratory implements corrective action.

7.11 Control of data and information management

7.11.1 The laboratory has access to the data and information needed to perform laboratory activities.

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

NOTE 1 In this document “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.

7.11.3 The laboratory information management system:

a) is protected from unauthorized access;

b) is safeguarded against tampering and loss;

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

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

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

7.11.4 When a laboratory information management system is managed and maintained off-site or through an external provider, the laboratory ensures that the provider or operator of the system complies with all applicable requirements of this document.

7.11.5 The laboratory ensures that instructions, manuals and reference data relevant to the laboratory information management system are made readily available to personnel.

7.11.6 Calculations and data transfers are checked in an appropriate and systematic manner.

8 MANAGEMENT SYSTEM REQUIREMENTS

8.1 Options

8.1.1 General

The laboratory establishes, documents, implements and maintains a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of Clauses 4 to 7, the laboratory implements a management system in accordance with Option A.

8.1.2 Option A

The management system of the laboratory address the following:

– management system documentation (see 8.2);
– control of management system documents (see 8.3);
– control of records (see 8.4);
– actions to address risks and opportunities (see 8.5);
– improvement (see 8.6);
– corrective actions (see 8.7);
– internal audits (see 8.8);
– management reviews (see 8.9).

8.1.3 Option B

Copper Mountain Technologies have chosen Option A. Thus, section 8.1.3 of ISO/IEC 17025 is not applicable.

8.2 Management system documentation (Option A)

8.2.1 Laboratory management, under the direction of top management, establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization (annex C).

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

8.2.3 Laboratory management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness. The laboratory management, under the direction of top management, ensures the integrity of the management system when changes are planned or implemented to the laboratory management system.

8.2.4 All documentation, processes, systems, records, related to the fulfilment of the requirements of this document are included in, referenced from, or linked to the management system (annex D).

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

8.3 Control of management system documents (Option A)

8.3.1 The laboratory controls the documents (internal and external) that relate to the fulfilment of this document.

8.3.2 The laboratory ensures 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 laboratory establishes and retains legible records to demonstrate fulfilment of the requirements in this document.

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

8.5 Actions to address risks and opportunities (Option A)

8.5.1 The laboratory considers the risks and opportunities associated with the 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 laboratory;

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

d) achieve improvement.

8.5.2 The laboratory plans:

a) actions to address these risks and opportunities;

b) how to:

– integrate and implement these actions into its management system;

– evaluate the effectiveness of these actions.

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

8.6 Improvement (Option A)

8.6.1 The laboratory identifies and selects opportunities for improvement and implements any necessary actions.

8.6.2 The laboratory seeks feedback, both positive and negative, from its customers. The feedback is analyzed and used to improve the management system, laboratory activities and customer service.

8.7 Corrective actions (Option A)

8.7.1 When a nonconformity occurs, the laboratory:

a) reacts to the nonconformity and, as applicable:

– takes action to control and corrects it;

– addresses the consequences;

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

– reviewing and analyzing the nonconformity;

– determining the causes of the nonconformity;

– determining if similar nonconformities exist, or could potentially occur;

c) implements any action needed;

d) reviews the effectiveness of any corrective action taken;

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

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

8.7.2 Corrective actions are appropriate to the effects of the nonconformities encountered.

8.7.3 The laboratory retains 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 laboratory conducts internal audits at planned intervals to provide information on whether the management system:

a) conforms to:

– the laboratory's own requirements for its management system, including the laboratory activities;

– the requirements of this document;

b) is effectively implemented and maintained.

The cycle for internal audit will be completed annually.

8.8.2 The laboratory:

a) plans, establishes, implements and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which is taken into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;

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

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

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

e) retains records as evidence of the implementation of the audit program and the audit results.

8.9 Management reviews (Option A)

8.9.1 The laboratory management reviews 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. The management review is

conducted at a minimum annually.

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

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

i) customer and personnel feedback;

j) complaints;

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 record all decisions and actions related to at least:

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

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

c) provision of required resources;

d) any need for change.

9 USE OF ACCREDITATION BODY SYMBOL

9.1.1 The laboratory, when reporting accredited results uses either the accreditation body symbol or the following statement (edited as appropriate): “This calibration/test is accredited under the laboratory’s ISO/IEC 17025 accreditation issued by [Accreditation Body Name]. Refer to certificate and scope of accreditation [insert accreditation number here]”.

9.1.2 The accreditation body symbol is being used properly (if being used) when making reference to the laboratory’s accreditation in communication media such as the internet, documents, brochures, or advertising.

9.1.3 The laboratory uses the accreditation body symbol only within its scope of accreditation except where accredited and non-accredited results are on the same report/certificate. In such cases, non-accredited results are to be clearly defined and a footnote to acknowledge that the report/certificate includes non-accredited work.

9.1.4 The laboratory ensures that:

a) it does not make any misleading or unauthorized statements regarding its accreditation;

b) reports or certificates containing the accreditation body symbol are not used in a misleading manner;

c) it does not use its accreditation to imply that a product, process, system, or person is approved by accreditation body;

d) it does not use the accreditation body symbol on cover sheets for sub-contracted calibrations.

9.1.5 If the laboratory uses the ILAC mark:

a) it ensures to use it only in conjunction with the accreditation body symbol;

b) the laboratory has obtained permission from accreditation body;

c) the accreditation number (for example XX-XXXX) included with the accreditation body symbol;

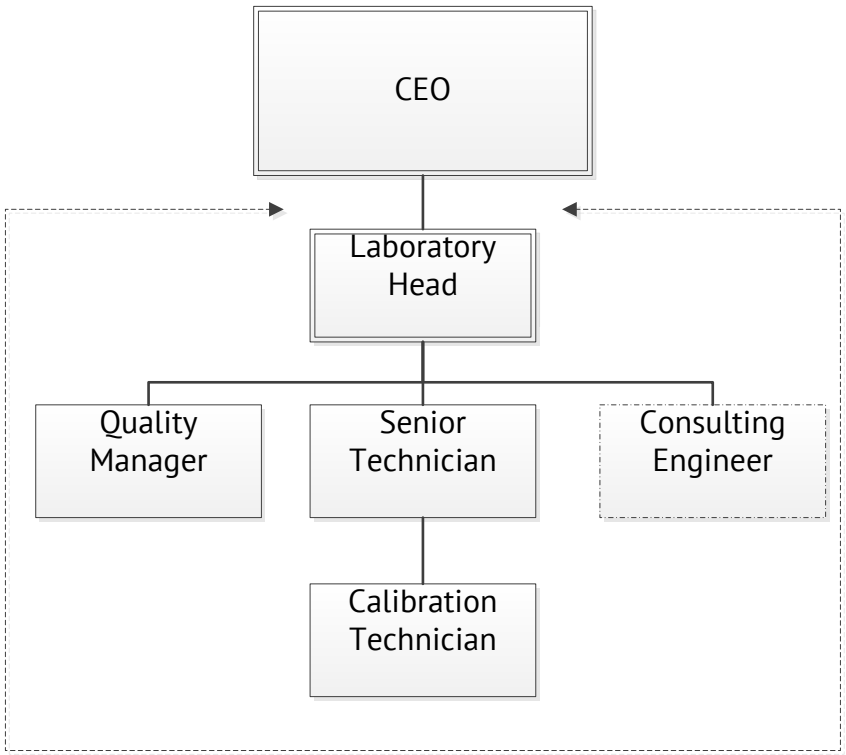
d) it does not use the ILAC mark on business cards;

e) it ensures that requirements of ILAC and accreditation body are met.

ANNEX A
ORGANIZATION CHART

QMS.01.1

ORGANIZATION CHART

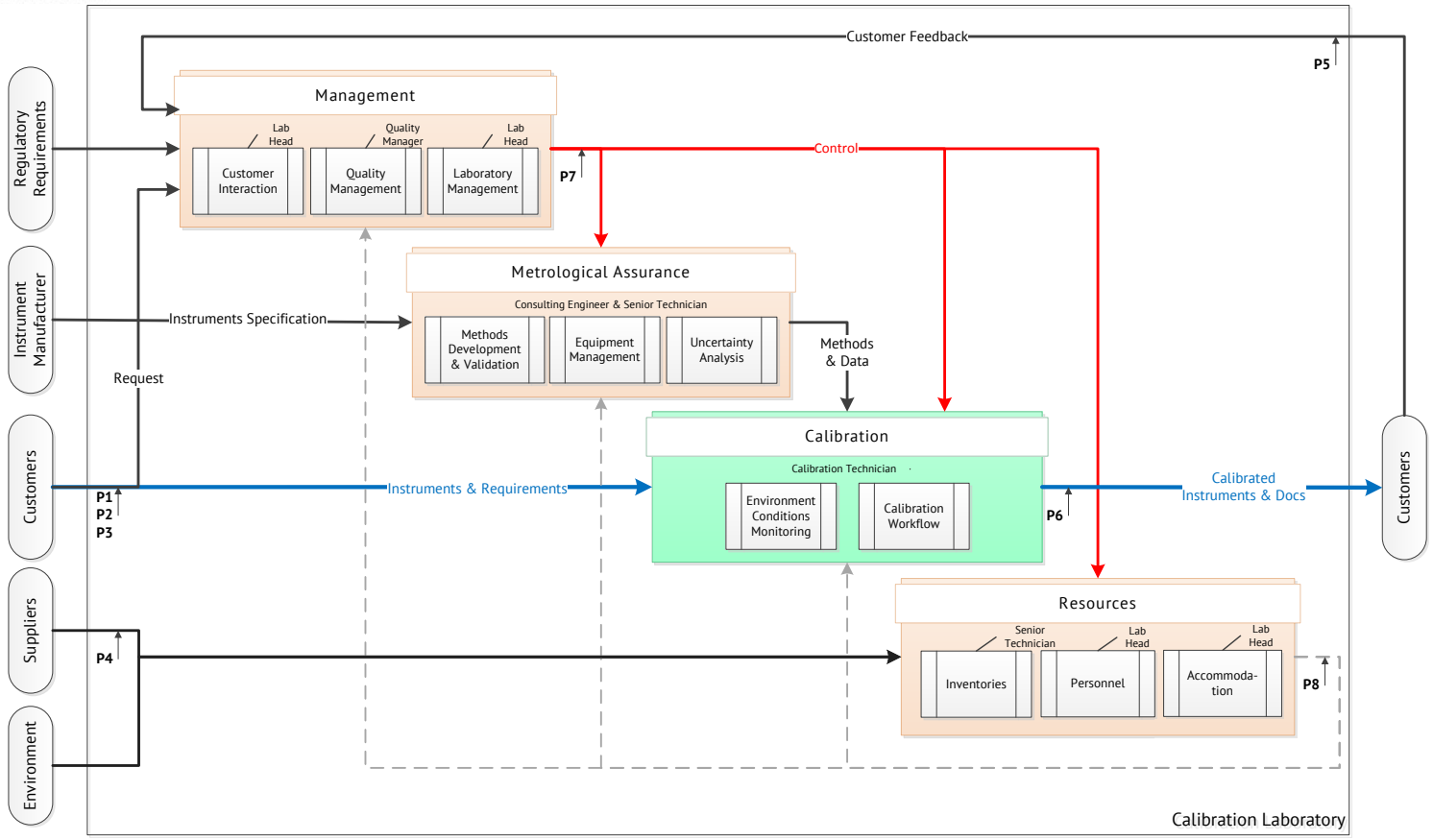


Calibration Laboratory

ANNEX B
PROCESSES INTERACTION CHART

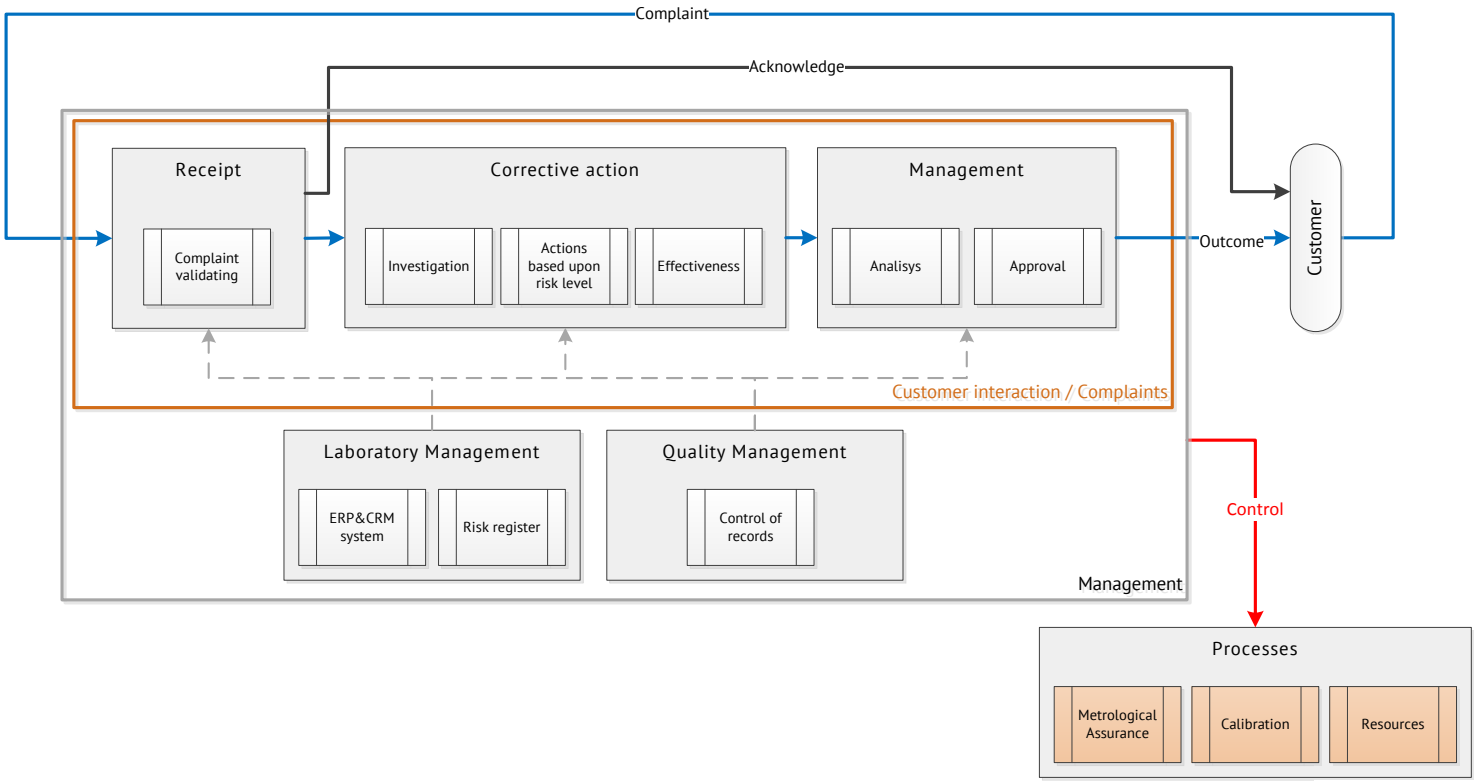
QMS.01.2

PROCESSES INTERACTION CHART



QMS.01.2.2

COMPLAINT HANDLING



B.1 Processes Interaction Chart shows:

– relationships between quality management, technical operations, and support services (see 5.5 a). Four main processes are defined: Management, Calibration, Metrological Assurance and Resourses, including the subprocesses;

– responsibility of all personnel who manage, perform or verify work affecting the quality of the calibrations (see 5.5 b) and performance of management system (see 5.6);

– interaction lines between main processes. Lines demonstrate both flows of instruments, requirements and resources (direction of the flow is shown with arrow) and communication activity (communication is bi-directional, its direction is not shown. If interaction line exists then communication is made);

– and policies (P1…P8) as the control gates of processes or the special rules for ingoing or outgoing process data. This new approach is applied to find the proper place for the policy statements in daily laboratory work. The policies are under laboratory head supervision.

B.2 Policy Statements:

P1: Copper Mountain Technologies ensures the protection of its customers' confidential information and proprietary rights, including protecting the electronic storage and transmission of results (see 4.2).

P2: Copper Mountain Technologies avoids involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity (see 4.1).

P3: All requests, tenders and contracts are considered in detail even if the requirements exceed the capabilities of laboratory (see 7.1).

P4: Any deviations from requested services and supplies are discussed with the laboratory head (see 6.6). Services and supplies with deviations deemed significant to the calibration work are rejected. Corrective action will be initiated as deemed appropriate.

P5: All complaints received from customers or other parties are considered in detail (see 7.9).

P6: When any aspect of calibration work, or the results of this work, do not conform to laboratory procedures or the agreed requirements of the customer an information about it immediately passes to quality manager (see 7.10).

P7: When nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified the correction action is im-

plemented immediately together with a decision about the acceptability of the nonconforming work (see 8.7).

P8: For identifying training needs and providing training of personnel the verbal communication is used, and captured in RCD.010 Personnel Record (see 6.2).

B.3 Processes Description:

In this document the process approach for describing the quality management system is implemented. Processes and subprocesses are defined, authorities are assigned. Because of size of the calibration laboratory an employee at certain position participates at several main processes. Therefore it is impractical to document the procedures separately. Under the conditions the best solution is to describe process steps for every employee at certain position. The steps are in annex E.

To guarantee the proper implementation for all of processes that are covered with quality management system and described in this manual the brief instructions (comments) are provided for each of documents or folders with that the employee must work. Comments are part of the document and additional identification is not needed.

Implementation of all processes, subprocesses and procedures is guaranteed and is confirmed by documents maintenance and compliance with requirements to structure and rules of access to the laboratory documentation. All documentation is divided between employees and is used and is managed by them in daily work.

B.4 Procedures Matrix

Parent Process	Parent Subprocess	Procedure Title	Procedure Description	Instructions	Related Documents and Records
Laboratory Head					
Management	Customer Interaction	Impartiality	4.1	1 Define personal responsibility for every activity. 2 Define deputy for every position. 3 Provide full access to information linked with laboratory activity. 4 Systematically conduct trainings. 5 Use semi-automatic calibration software. 6 Monitor risks to impartiality (see procedure 8.5).	P2 RCD.010 RCD.110
		Confidentiality	4.2	1 Define rules of access for employees. 2 Provide data security through internal networking systems that are installed behind an Internet firewall. 3 Define Privacy policy and publish it in Web-site.	P1 Privacy Policy
		Review of requests, tenders and contracts	7.1	1 Define and understand the requirements (together with senior technician). 2 Analyze resources and opportunities using scope of accreditation and current workload. 3 Communicate with customer if external provider performs specific lab activities, gain customer's approval. External provider should be evaluated as 6.6. 4 Select appropriate calibration method. Inform customer of the method chosen. Communicate with customer when method requested is inappropriate or out of date.	P3 Scope of accreditation RCD.040 RCD.042 RCD.044 RCD.060 RCD.062 EPR&CRM system

B.4 Procedures Matrix

Parent Process	Parent Subprocess	Procedure Title	Procedure Description	Instructions	Related Documents and Records
				5 Define both the specification or standard and the corresponding decision rule if statement of conformity is requested. Decision rule selected should be agreed with customer. 6 Document in any way the review, including any significant changes. 7 Inform customer of any deviation from the contract. 8 Repeat contract review and communicate to all affected person when any amendments. 9 Be in touch with customer.	
		Improvement (Option A)	8.6	1 Accept every request, feedbacks in different ways (website, phone, e-mail, etc). Use and analyze it to improve work processes. 2 Identify needed improvements and potential sources of non-conformities. 3 Allow to visit calibration facilities. 4 Maintain Contact Us webpage.	EPR&CRM system Web-site RCD.070 (OFI type)
		Complaints	7.9	1 Receive and document the complaint according to company's information system rules. 2 Validate the complaint: check that described case is exactly related with laboratory activity. 3 Perform cause analysis (together with quality manager).	EPR&CRM system RCD.061 RCD.070 RCD.071 RCD.110

B.4 Procedures Matrix

Parent Process	Parent Subprocess	Procedure Title	Procedure Description	Instructions	Related Documents and Records
				4 Implement corrective actions (together with quality manager) if necessary. Pay attention, the actions should be based upon risk level (see RCD.110 Risk Register for potential complaints cases). 5 Ensure that the actions taken will resolve the complaint. 6 Save all records, including actions undertaken. 7 Communicate outcome to customer. 8 Be in touch with customer.	
	Laboratory Management	Management reviews (Option A)	8.9	1 Analyze information (see 8.9.2). 2 Define weaknesses. 3 Define changes or improvements. 4 Fix the results (see 8.9.3). 5 Check for implementation.	RCD.090 RCD.091
		Actions to address risks and opportunities (Option A)	8.5	1 Analyze results of reviews and define and classify risks and opportunities for next key directions: - lab and company essence; - lab activities including risk to its impartiality; - management system effectiveness. 2 Plan actions to prevent risks achieved and improve opportunities defined. 3 Evaluate the effectiveness of these actions during management review.	RCD.110

B.4 Procedures Matrix

Parent Process	Parent Subprocess	Procedure Title	Procedure Description	Instructions	Related Documents and Records
Resourses	Personnel	Personnel	6.2	1 Monitor actuality of competence requirements. Redefine if needed. 2 Assess the competence of personnel once a year or before new authorization. Assessment methods to be used: - direct supervision; - classroom discussion; - 1-on-1 training, etc. Use competence requirements when new worker is being accepted for employment. 3 Perform training if needed: - Assess needs for training. - Define training topic and training schedule. - Perform training. - Assess effectiveness of training in follow-up audit. 4 Ensure supervision of how personnel work in daily routine. 8 Assign the authorization and deputy authorization for every person. 9 Monitor the competence of personnel. Reassess immediately if there is found competence's decline.	P8 RCD.010 Annex E

B.4 Procedures Matrix

Parent Process	Parent Subprocess	Procedure Title	Procedure Description	Instructions	Related Documents and Records
	Accommodation	Facilities and environmental conditions	6.3	QMS.CAL.01, QMS.GNR.02	RCD.020
Quality Manager					
Management	Quality Management	Documents and Records	7.5, 7.11, 8.3, 8.4	1 Use rules of access for employees. 2 Use semi-automatic calibration software. 3 Use data security through internal networking systems that are installed behind an Internet firewall. To control the documents and records in the proper way it is necessary to fill in the RCD.050 record. 1 Define list of all laboratory documents. 2 Check current revision status of document. 3 Enter the change to document and identified it if necessary (together senior technician if needed). 4 Approve document, put into folder. 5 Assign the last actualization date.	EPR&CRM system G-Suite RCD.050 RCD.051 RCD.052

B.4 Procedures Matrix

Parent Process	Parent Subprocess	Procedure Title	Procedure Description	Instructions	Related Documents and Records
				6 Assign document owner and storage folder. 7 Perform back up where applicable. 8 Perform periodically review.	
		Nonconforming work	7.10	To manage the non-conforming calibration work in the proper way it is necessary to fill in the RCD.070. 1 Fix the nonconforming work and, as applicable: - takes action to control and corrects it; - addresses the consequences. 2 Assign responsible person. 3 Evaluate significance of nonconformity work including an impact analysis on previous results based on risk-oriented approach. Take a decision on the possibility of continuing calibration (together with laboratory head if needed). 4 Perform cause analysis to evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: - reviewing and analyzing the nonconformity; - determining the causes of the nonconformity; - determining if similar nonconformities exist, or could potentially occur. 5 Take a decision about the acceptability of nonconformity work.	P6 RCD.070

B.4 Procedures Matrix

Parent Process	Parent Subprocess	Procedure Title	Procedure Description	Instructions	Related Documents and Records
				6 Notify customer and recall work if needed. 7 Implement corrective action if evaluation indicates possibility of recursion and / or nonconformity with management system requirements. 8 Give info gathered to lab head to take his/her permission on work resumption.	
		Corrective actions (Option A)	8.7	To manage the corrective action in the proper way it is necessary to fill in the RCD.071 record. 1 Collect all complaints and non-conformity records. 2 Perform cause analysis. 3 Prepare correction action plan. 4 Monitor plan fulfillments. 5 Review the effectiveness of any corrective action taken. 6 Update risks and opportunities determined during planning, if necessary. 7 Make changes to the management system, if necessary. 6 Perform audit (see 8.8) if necessary.	P7 RCD.061 RCD.070 RCD.071

B.4 Procedures Matrix

Parent Process	Parent Subprocess	Procedure Title	Procedure Description	Instructions	Related Documents and Records
		Internal audits (Option A)	8.8	To manage the internal audit in the proper way it is necessary to fill in the RCD.080 and RCD.081 records. 1 Define internal audit schedule. 2 Define processes to be controlled, audit criteria relayed. 3 Carry out internal audit. Methods used during audit are next: interview, observe and docs review. Take into consideration the importance of lab activities concerned, changes affecting and results of previous audits. 4 Assess effectiveness of corrective actions. 5 Bring audit data to laboratory head. 6 Implement appropriate correction and corrective actions without undue delay. 7 Verify audit data (corrective action implementation, effectiveness, etc) in follow-up audit.	RCD.080 RCD.081

B.4 Procedures Matrix

Parent Process	Parent Subprocess	Procedure Title	Procedure Description	Instructions	Related Documents and Records
Senior Technician					
Metrological Assurance	Equipment Management	Equipment, Metrological traceability	6.4, 6.5	QMS.EQP.01, QMS.TRC.01 (Traceability chains) Establishing and changing of calibration interval: 1 Define equipment manufacturer recommendations. 2 Analyze intensiveness of equipment exploitation, data of previous calibrations, maintenance and repair. 3 Establish interval according manufacturer recommendations if analysis data are satisfactory and exploitation is performed on regular base. 4 When analytical data are suspicious, reduce interval to the next. Interval is defined as 6, 12, 18 or 24 months, or other interval as deemed appropriate. 5 When analysis data are satisfactory and exploitation is performed rarely, increase interval to the next. Interval is defined as 6, 12, 18 or 24 months, or other interval as deemed appropriate.	RCD.030 RCD.032 RCD.033
	Uncertainty Analysis	Evaluation of measurement uncertainty	7.6	QMS.TRC.01	Scope of accreditation

B.4 Procedures Matrix

Parent Process	Parent Subprocess	Procedure Title	Procedure Description	Instructions	Related Documents and Records
		Ensuring the validity of results	7.7	1 Define schedule for monitoring the validity of results: - take a part in proficiency testing in regular base; - perform functional check(s) and/or intermediate checks on equipment; - use one from different methods and/or different equipment (where applicable); - review and investigate reported results. 2 Determine criteria for each discipline in accordance with the scope. 3 Analyze results obtained during monitoring, including trend behavior. 4 Use statistical software (where applicable). 5 Implement corrective actions if needed. 6 Present the monitoring analysis data in management review.	Calibration data Proficiency testing results RCD.120
	Methods Development & Validation	Selection, verification and validation of methods	7.2	1 Define an instrument specification to be checked during calibration. 2 Define a method for calibration from RCD.043 or develop a new method. 3 Fill in RCD.043 for new method. 4 If parameter defined by new method is used or planned to be used in lab scope of accreditation:	RCD.043 QMS.CAL.01 QMS.GNR.01 QMS.TRC.01

B.4 Procedures Matrix

Parent Process	Parent Subprocess	Procedure Title	Procedure Description	Instructions	Related Documents and Records
				a) Save obtained verification / validation / proficiency test data for new method; b) Compare data with specified requirements in scope of accreditation (or in project of scope); c) Define uncertainty and traceability requirements in QMS.TRC.01 for new method. 5 Add new issue into QMS.CAL.01 and QMS.GNR.01.	
Resourses	Inventories	Externally provided products and services	6.6	1 Monitor actuality of laboratory requirements. Redefine if needed. 2 Select type, specs and manufacturer if required for absent inventories (equipment, consumable materials, etc) or define requirements for externally provided services. 3 Use EPR&CRM system to place order for absent inventories or services required, together with detailed description and/or bring the information to lab head. 4 Monitor current status of request to ensure that it was reviewed and approved or to be able correct or cancel it promptly. Communicate with lab head if necessary. 5 If item requested should be bought from supplier which is absent in list of approved suppliers the sufficient approving should be performed before.	P4 RCD.030 RCD.032 RCD.033 RCD.043 RCD.050 RCD.100 FM2015 EPR&CRM system Annex B.5

B.4 Procedures Matrix

Parent Process	Parent Subprocess	Procedure Title	Procedure Description	Instructions	Related Documents and Records
				6 Discuss any actions arising from approving with lab head. 7 Communicate with supplier to clearance lab requirements. 8 Receive requested item. 9 Verify item and its docs. If the item is not comply with its specs and lab requirements, do not use it in laboratory activities. 10 Fill in RCD.030, RCD.032, RCD.033, RCD.043, RCD.050, RCD.100, if applicable. 11 Deliver item to work places or directly provide to customer.	
Calibration Technician					
Calibration	Calibration Workflow	Calibration Procedure	7.5, 7.8	QMS.CAL.01 Fill in RCD.040 record for calibration data (technical records).	P6 RCD.040 RCD.041 Calibration data
		Handling of calibration items	7.4	QMS.GNR.01	EPR&CRM system QMS.GNR.01.1

B.4 Procedures Matrix

Parent Process	Parent Subprocess	Procedure Title	Procedure Description	Instructions	Related Documents and Records
	Environment Conditions Monitoring	Environment Conditions Monitoring	6.3.3	QMS.GNR.01	RCD.020, Logger data, QMS.GNR.01.1

B.5 Criteria for evaluation, selection, monitoring of performance and re-evaluation of external providers

	Original equipment (tool) manufacturer	Equipment (tool) dealers	National metrology institute	Calibration laboratory	Proficiency test provider	Others
Evaluation						
Method	Q*	Q	Q*	Q & A*	Q & A*	Q & A*
Criteria:						
Competencies in manufacturing	O					P
Competencies in services (exc. calibration)		O			O	O
Competencies in calibration		P	O	O		
Maintenance and repair	P	P		P		P
Competencies in quality management				P	P	P
Selection						
CIPM MRA participant			O			
Accreditation for ISO/IEC 17025	P	P		O		P
Accreditation for ISO/IEC 17043					O	
Monitoring of performance						
Period & method	NA	3Q	3Q	3Q&A*	3Q&A*	3Q&A*
Re-Evaluation						
Period & method	NA	6Q	6Q	6Q	6Q	6Q
Method (in case of quality discrepancy)	NA	A	A	A	A	A

Comments:
Method: NA – not applicable; Q – questionnaire; I – incoming inspection; A – audit; S – site visits; * - if necessary;
Period: 1 time in number of years;
Selection marks: O – obligatory requirement, P - permitted, could be qualified as an advantage.

ANNEX C
POLICY STATEMENTS

QMS.01.3

COPPER MOUNTAIN TECHNOLOGIES

QUALITY POLICY STATEMENT

Copper Mountain Technologies is committed to continual improvement of services to achieve ongoing customer satisfaction. The purpose of the Copper Mountain Technologies calibration laboratory Quality System is to ensure that our measurement instruments meet or exceed their published specifications.

The objectives of the quality system are to guarantee the:

a) Permanently provide quality of calibration and verification procedures which conform to customer and regulatory requirements.

b) Accuracy and reliability of all delivered test results are achieved by the most modern, proven and fully validated calibration methods.

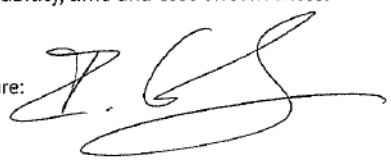
c) Laboratory standards and equipment are fit for purpose, properly maintained and calibrated and where possible, measurements are traceable to recognized standards.

d) Quality documents and the relevant procedures are well-known and implemented in the workflow by suitable trained and qualified personnel that are provided with tools and special software to perform laboratory operations with high precision and in an acceptable time frame.

e) Consistently comply with ISO/IEC 17025 to ensure quality calibration services, and to continually improve the effectiveness of the Quality Management System.

Copper Mountain Technologies will continually strive to improve the quality of our services through membership in the international conference covering RF and microwave sphere, and try to use and develop unique measurement techniques satisfying even the most demanding customers in terms of accuracy, reliability, time and cost effectiveness.

Irena Goloschokin, CEO Signature:



QMS.01.3.2

IMPARTIALITY POLICY

The purpose of this policy is to give confidence to all participants who engage with the Copper Mountain Technologies (CMT) laboratory that CMT understands the importance of ensuring impartiality in implementation of their professional activities and strictly adheres to International standard ISO/IEC 17025:2017 and Accreditation Body requirements.

Commitment

The laboratory is an integral part of CMT and has explicit vertical organization structure. CMT guarantees that all laboratory activity is carried out without any kind of management pressures or discrimination. For this reason, the company management, in particular the CEO, strive to create professional environment and culture that prevent preferential treatment or conflict of interests when interacting with both internal and external parties.

The laboratory does not engage in any activities that may diminish confidence in its competence, independence of judgment and integrity in relation to its professional activities.

The laboratory follows its established policies and procedures equally with regard to all its customers and suppliers, and services are available to all companies in equal manner. All points of interaction are registered and controlled by the internal ERP and CRM system and may be reviewed at any time by company management for identifying and preventing any potential conflict of interest.

In the event that customers or other interested parties are concerned about impartiality or objectivity, the company performs procedures for handling complaints and appeals without discrimination.

QMS.01.3.2

The laboratory provides its staff the knowledge required to operate impartially and asks its staff to promptly inform management of any circumstances which may constitute a conflict of interests.

The laboratory provides a mechanism in a form of supplementary metrological software to conduct its professional activities and safeguard the impartiality for both customers and staff. Unified software for all customers without prevalence of individual interests is utilized. Additionally, the laboratory utilizes multi-level internal controls when reviewing all technical records prior to issuance.

The laboratory develops and follows an impartiality risk assessment strategy. If a risk to impartiality is identified, the laboratory takes appropriate measures to eliminate or minimize it by providing specific direction to laboratory staff in accordance with the company's policies. Results of the risk analysis are presented at annual management review meeting for clear understanding of services provided and impartiality issues encountered.

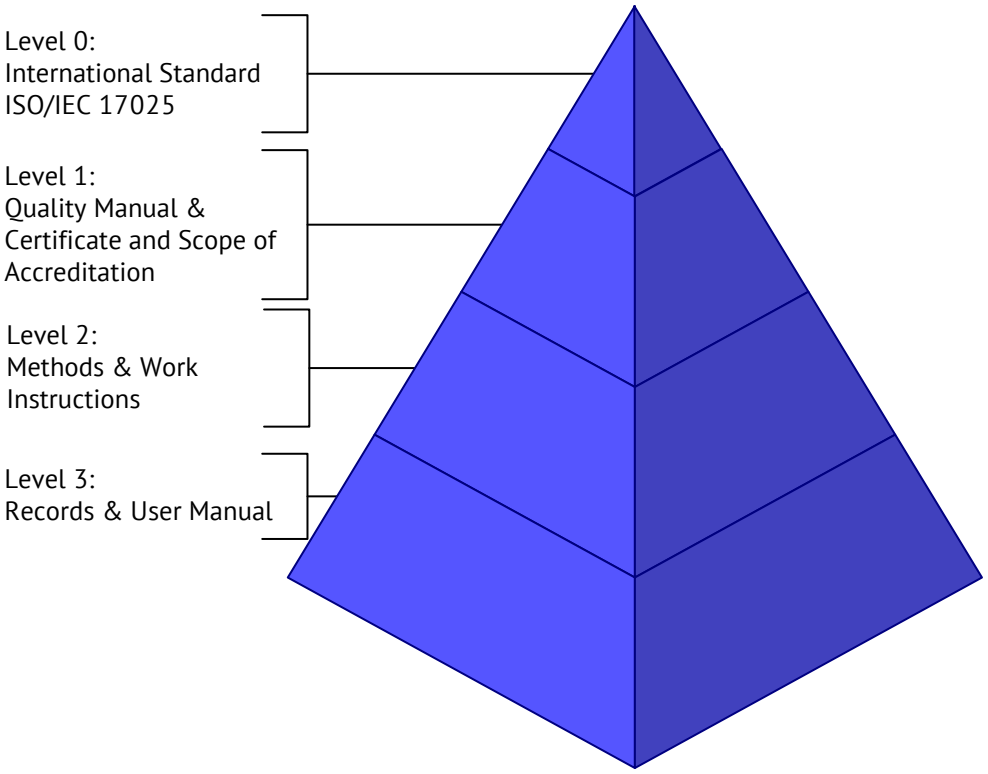
If you need any clarification on the impartiality policy covered here, please contact the company's technical support service group at support@coppermountaintech.com.

Irena Goloschokin, CEO Signature: 

ANNEX D
STRUCTURE OF DOCUMENTATION

QMS.01.4

STRUCTURE OF DOCUMENTATION



ANNEX E
PERSONNEL COMPETENCE

E.1 Competence requirements QMS.01.5

	Laboratory head	Quality manager	Senior technician	Calibration technician
Education				
Technical	X	X	X	X
Qualification				
Electrical Engineering or a related field	X		X	X
Trainings				
ISO/IEC 17025 external training	X	X		
Internal training “Introduction to ISO/IEC 17025 and ANSI/NSCL Z540-1”			X	X
Internal training “Quality management system (NC, CA, PA)”			X	X
Internal training “Complaints”			X	X
Internal training “Conducting Audit”			X	X
Internal training “Proficiency testing: what it is and why it’s important”			X	X
Technical knowledge				
Frequency measurements and uncertainty calculations	X		X	X
Reflection measurements and uncertainty calculations	X		X	X
Transmission measurements and uncertainty calculations	X		X	X
RF power measurements and uncertainty calculations	X		X	X
Skill				
Receipt and handling of equipment and accessories			X	X
Housekeeping, access control, PC maintenance, environmental conditions			X	X
Packaging, return shipment			X	X
Experience				
Ability to process orders, quoting, review of RFQ (Odoo)	X		X	
Ability to use Google Drive (QMS), understanding of its organization, permissions existing	X		X	
Ability to perform document control	X		X	

	Laboratory head	Quality manager	Senior technician	Calibration technician
Ability to determine equipment to purchase, managing suppliers list	X		X	
Ability to perform equipment maintenance, its intermediate checking, understanding traceability requirements	X		X	
Ability to install and use VNAPT, *.prf files, printing test reports and certificates	X		X	X
Ability to compile and control workflow checklist, understanding CAL and GNR documents	X		X	X

E2 Relevant authorization

Laboratory personnel are authorized to perform specific laboratory activities:

- *calibration activity* includes calibration procedure together with reporting; handling of test or calibration items; environment conditions monitoring (see annex B.4);

- *equipment maintenance activity* includes equipment management, metrological traceability; evaluation of measurement uncertainty; ensuring the validity of results; selection, verification and validation of methods; externally provided products and services (see annex B.4);

- *certificate issuing activity* includes reviewing and authorization of calibration results and continuing analysis of results, including statements of conformity or opinions and interpretations.

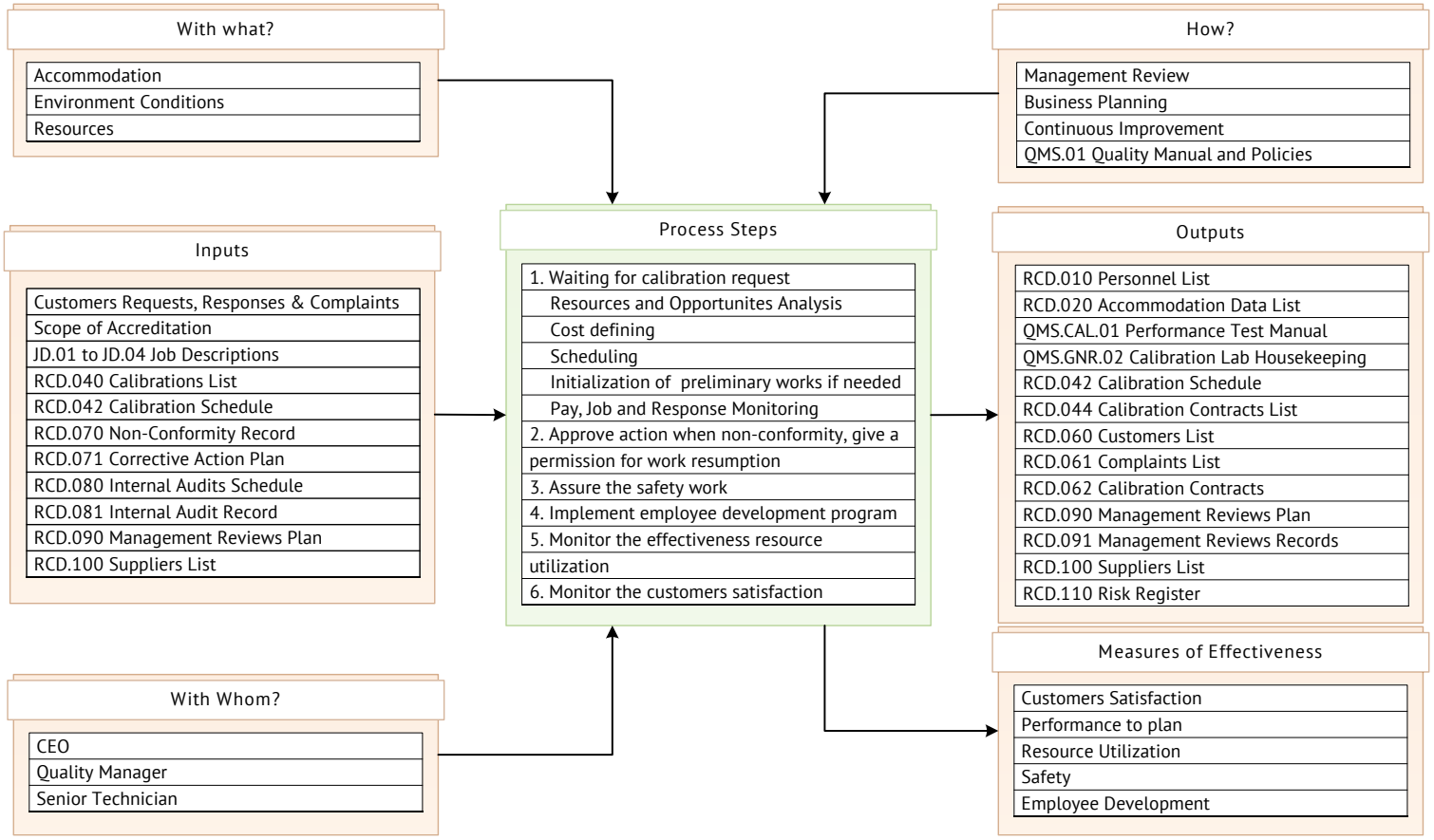
E.3 Personnel job descriptions

LABORATORY HEAD JOB DESCRIPTION

JD.01 Version 3

The Laboratory Head reviews incoming work requests and clarifies discrepancies. He/She reviews laboratory data with respect to the calibration laboratory quality system and calibration standards and for accuracy and conformance to customer and/or specification requirements. The Laboratory Head oversees maintenance of lab equipment. He/She must report to the Quality Manager and CEO about the data which falls outside the quality acceptance criteria. The Laboratory Head shall notify the Quality Manager of any quality problem. The Laboratory Head reports directly to the CEO.

Direct work is management of laboratory activities, including customer interaction, and observance of laboratory objectives and policies.

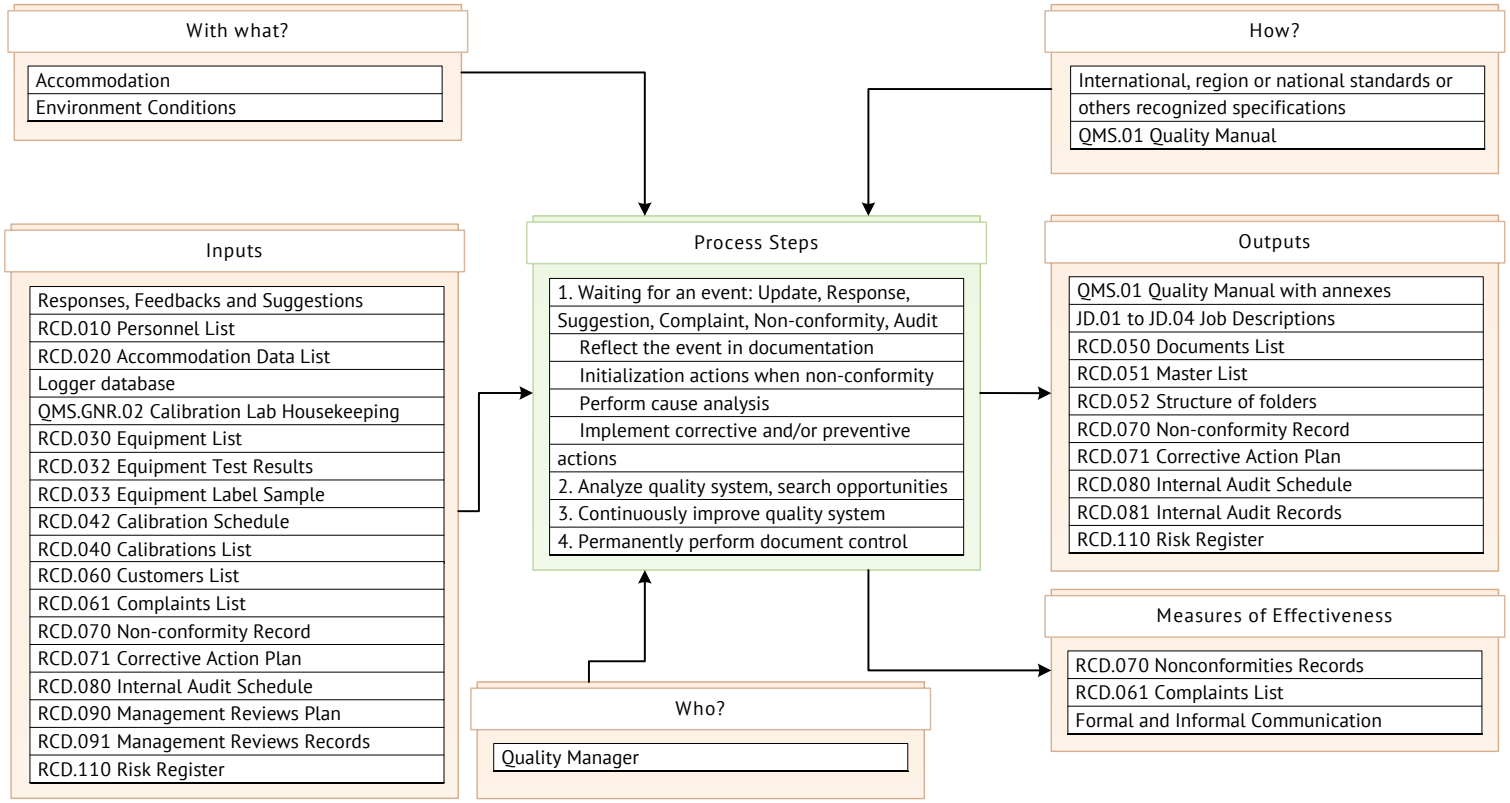


QUALITY MANAGER JOB DESCRIPTION

JD.02 Version 3

The Quality Manager manages the calibration laboratory operating systems such as quality systems and laboratory report formats. He/She documents, implements, and reviews quality procedures and monitors the quality system to ensure compliance with the Copper Mountain Technologies objectives and ISO/IEC 17025. He/She reports the status of quality programs to the Laboratory Head and CEO through formal and informal communication. The Quality Manager issues corrective actions when required. The Quality Manager is authorized to review all laboratory data with respect to the calibration laboratory quality system. The Quality Manager has the authority to require that procedures be amended or discontinued, or analysis suspended or repeated.

Direct work is the assuring the effectiveness of quality system and documents management.

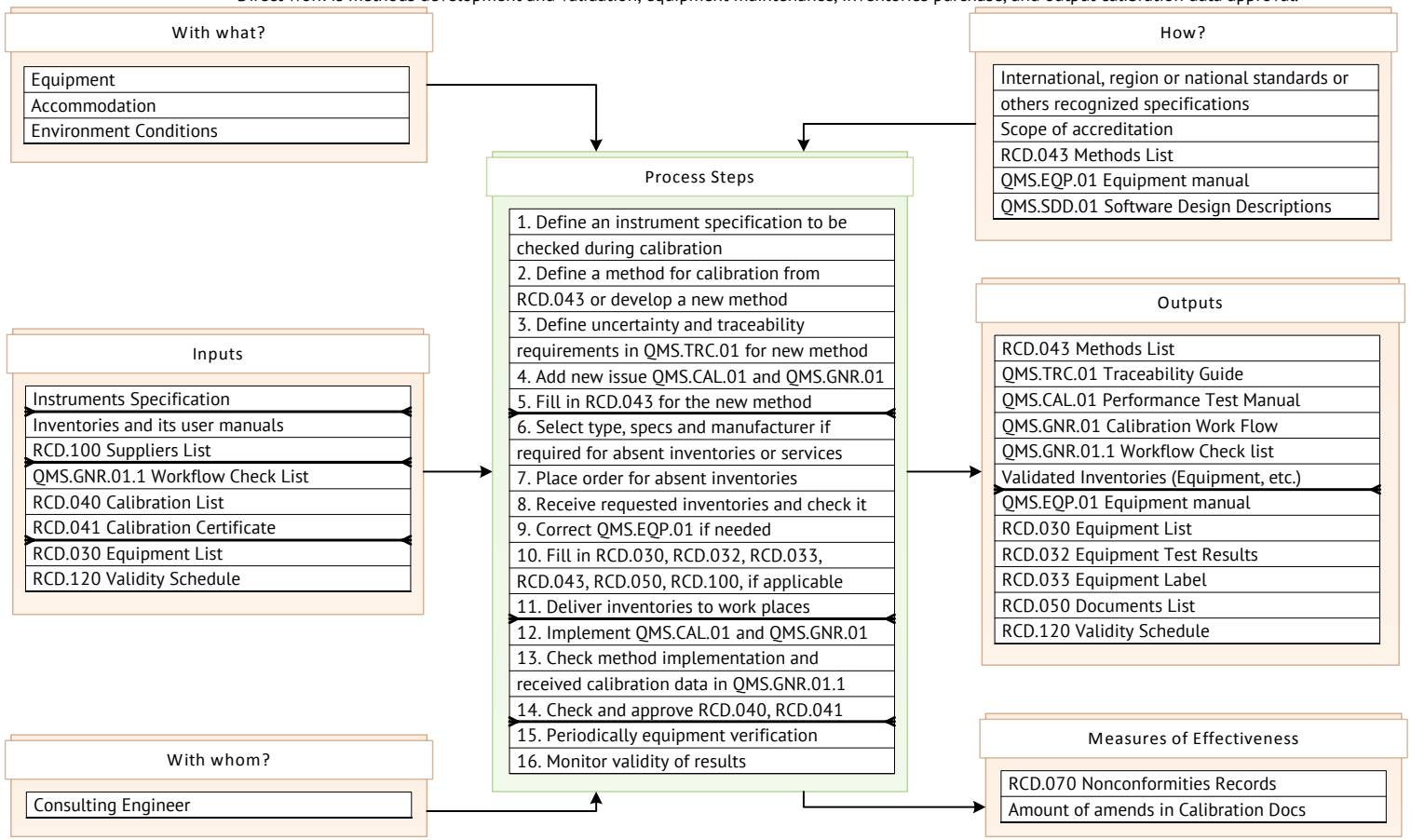


SENIOR TECHNICIAN JOB DESCRIPTION

JD.03 Version 3

These technicians conduct assigned laboratory work in his/her area of responsibility and also perform maintenance, when possible, of laboratory equipment in his/her area of responsibility and maintain the appropriate maintenance logs. These technicians shall notify the Laboratory Head when data falls outside the quality acceptance criteria. These technicians shall also notify the Quality Manager of any quality problems. The technicians report to Laboratory Head.

Direct work is methods development and validation, equipment maintenance, inventories purchase, and output calibration data approval.

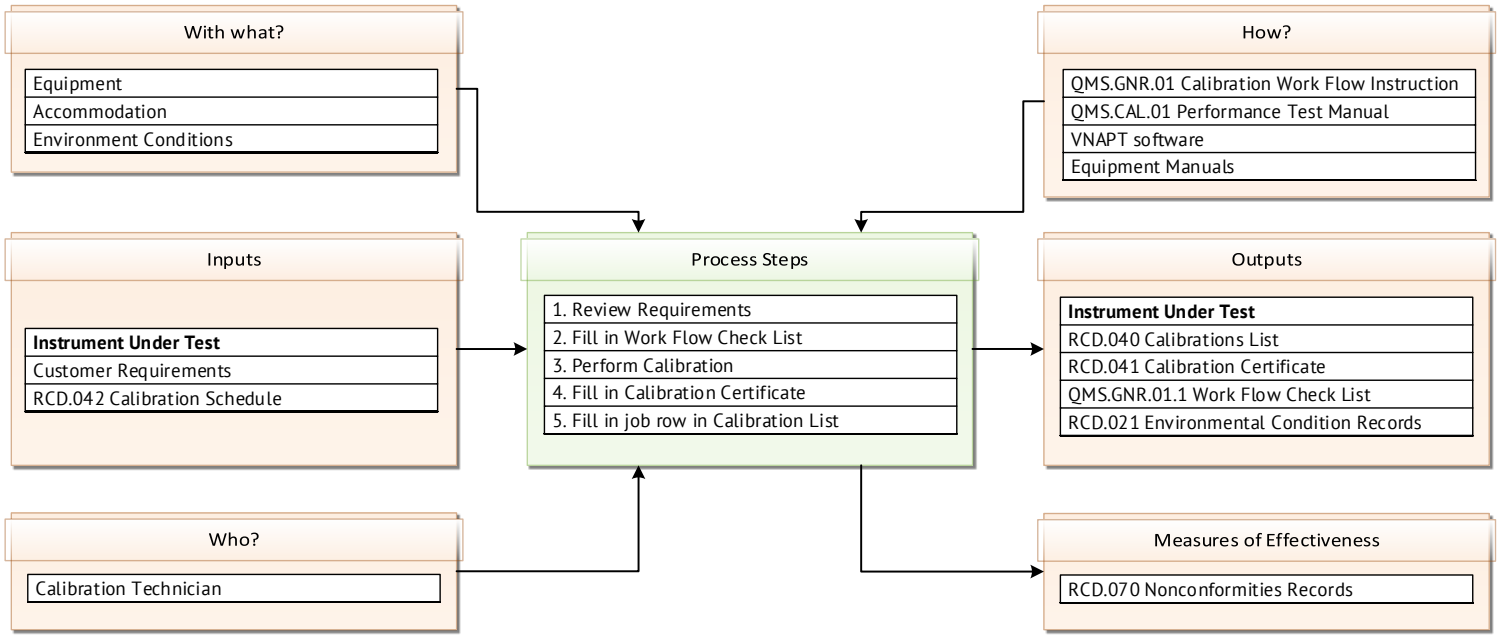


JD.04 Version 1

CALIBRATION TECHNICIAN JOB DESCRIPTION

These technicians conduct assigned laboratory work in his/her area of responsibility. These technicians shall notify the Senior Technician when data falls outside the acceptance criteria. These technicians shall also notify the Quality Manager of any quality problems. The technicians report to the Senior Technician.

Direct work is an instrument calibration and maintenance of output calibration data.



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