

Edition 10

Revision 00

QUALITY MANUAL



QSWG

NIMT

1 February 2019



FOREWORD TO CURRENT EDITION

This edition is established in order to improve NIMT's management system to comply with the new ISO/IEC 17025:2017 and ISO/IEC 17034:2016. The contents of this QM are developed to correspond to the structure of ISO/IEC 17025:2017 and ISO/IEC 17034:2016.



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1. COMMITMENT TO QUALITY

The National Institute of Metrology, Thailand (NIMT), under administration of the Top Management, guarantees and enhances continuous quality improvement in measurements services provided to its customers. Additionally, the Top Management shall ensure the accomplishment of the stated quality policies as appeared in 9.1.2 of this Quality Manual (QM).

NIMT recognizes the importance of impartiality and confidentiality in promoting confidence when conducting its measurement activities.

NIMT are fully committed to providing all services to the customer in an open, independent and impartial manner.

The NIMT staff and all of its organizational units, which are directly or indirectly involved in providing the measurement services, are herewith bound to carry out their tasks in accordance with the quality policies laid down in this QM.

This QM describes NIMT's quality management structure and organizational processes necessary to fulfill the objective goals in quality assurance for all NIMT's measurement services. It guarantees that organizational and technical activities are planned, supervised and controlled, and that provisions of the contracts, the rules and the guidelines concluded with all accreditation bodies and/or peer-reviewers are complied with.

NIMT as the holder of the NIMT Laboratory declares its willingness to ensure that the impartiality of the NIMT Laboratory's staff is guaranteed for all measurement services certified by accreditation bodies and/or peer-reviewers.

Ajchara Charoensook

Director

National Institute of Metrology (Thailand)



2. DEFINITIONS

a) Terms of quality assurance

This QM uses the term and definitions given in ISO/IEC Guide 99 and ISO/IEC 17000 and the following apply. ISO and IEC maintain terminological databases for use in standardization at the following address:

- ISO Online browsing platform: available at <https://www.iso.org/obp>

- IEC Electropedia: available at <http://electropedia.org/>

and definitions of quality assurance terms in accordance with *the International Vocabulary of Metrology — Basic and General Concepts and Associated Terms (VIM) (JCGM200: 2012)* and series of international standards and guidelines including various applicable ISO standards and EA standards.

Impartiality

Presence of objectivity

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the laboratory (3.6)

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.

(SOURCE: ISO/IEC 17021-1:2015, 3.2, modified-The words “the certification body” have been replaced by “the laboratory” in Note 1 to entry, and the word “independence” has been deleted from the list in Note 2 to entry.)

Complaint

Expression of dissatisfaction by any person or organization to a laboratory (3.6), relating to the activities or results of that laboratory, where a response is expected

(SOURCE: ISO/IEC 17000:2004, 6.5, modified-The words “other than appeal” have been deleted, and the words “conformity assessment body or accreditation body, relating to the activities of that body” have been replaced by “a laboratory, relating to the activities or results of that laboratory”.)

Interlaboratory comparison

organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

(SOURCE : ISO/IEC 17043:2010, 3.4)



Intralaboratory comparison

Organization, performance and evaluation of measurements or tests on the same or similar items within the same laboratory (3.6) in accordance with predetermined conditions

Proficiency testing

Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (3.3)

(SOURCE : ISO/IEC 17043:2010, 3.7, modified – Notes to entry have been deleted)

Laboratory

Body that performs one or more of the following activities:

- testing;
- calibration;
- sampling, associated with subsequent testing or calibration

Note 1 to entry: In the context of this document, “laboratory activities” refer to the three above-mentioned activities.

Decision rule

Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

Verification

provision of objective evidence that a given item fulfils specified requirements

EXAMPLE 1: Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg.

EXAMPLE 2: Confirmation that performance properties or legal requirements of a measuring system are achieved.

EXAMPLE 3: Confirmation that a target measurement uncertainty can be met.

NOTE 1: When applicable, measurement uncertainty should be taken into consideration.

NOTE 2: The item may be, e.g. a process, measurement procedure, material, compound, or measuring system.

NOTE 3: The specified requirements may be, e.g. that a manufacturer's specifications are met.

NOTE 4: Verification in legal metrology, as defined in VIML[53], and in conformity assessment in general, pertains to the examination and marking and/or issuing of a verification certificate for a measuring system.

NOTE 5: Verification should not be confused with calibration. Not every verification is a validation.

NOTE 6 In chemistry, verification of the identity of the entity involved, or of activity, requires a description of the structure or properties of that entity or activity.

(SOURCE: JCGM 200:2012, 2.44)

Validation

verification, where the specified requirements are adequate for an intended use

EXAMPLE A measurement procedure, ordinarily used for the measurement of mass concentration of nitrogen in water, may be validated also for measurement of mass concentration of nitrogen in human serum.

(SOURCE: JCGM 200:2012, 2.45)

b) Fundamental metrological concepts and associated terms calibration (VIM 2.39)

operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

NOTE 1: A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases, it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty.

NOTE 2: Calibration should not be confused with adjustment of a measuring system, often mistakenly called “self-calibration”, nor with verification of calibration.

reference material, RM (ISO Guide 30: 2015, 2.1.1)

material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process

Note 1 to entry: RM is a generic term.

Note 2 to entry: Properties can be quantitative or qualitative, e.g. identity of substances or species.



Note 3 to entry: Uses may include the calibration of a measurement system, assessment of a measurement procedure, assigning values to other materials, and quality control.

Note 4 to entry: ISO/IEC Guide 99:2007 has an analogous definition, but restricts the term “measurement” to apply to quantitative values. However, Note 3 of the definition in ISO/IEC Guide 99:2007 specifically includes qualitative properties, called “nominal properties”.

certified reference material, CRM (ISO Guide 30: 2015, 2.1.2)

reference material (RM) characterized by a metrologically valid procedure for one or more specified properties, accompanied by an RM certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability

Note 1 to entry: The concept of value includes a nominal property or a qualitative attribute such as identity or sequence. Uncertainties for such attributes may be expressed as probabilities or levels of confidence

Note 2 to entry: Metrologically valid procedures for the production and certification of RMs are given in, among others, ISO Guide 35.

Note 3 to entry: ISO Guide 31 gives guidance on the contents of RM certificates.

Note 4 to entry: ISO/IEC Guide 99:2007 has an analogous definition.

reference material producer, RMP (ISO Guide 30: 2015, 2.3.5)

body (organization or company, public or private) that is fully responsible for project planning and management; assignment of, and decision on property values and relevant uncertainties; authorization of property values; and issuance

metrological traceability, traceability (VIM 2.41)

property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

NOTE 1: For this definition, a ‘reference’ can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.

NOTE 2: Metrological traceability requires an established calibration hierarchy.

NOTE 3: Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.

NOTE 4: For measurements with more than one input quantity in the measurement model, each of the input quantity values should itself be metrologically traceable and the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity value should be commensurate with its relative contribution to the measurement result.

national measurement standard, national standard (VIM 5.3)

measurement standard recognized by national authority to serve in a state or economy as the basis for assigning quantity values to other measurement standards for the kind of quantity concerned

reference measurement standard, reference standard (VIM 5.6)

measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location

working measurement standard, working standard (VIM 5.7)

measurement standard that is used routinely to calibrate or verify measuring instruments or measuring systems

NOTE 1: A working measurement standard is usually calibrated with respect to a reference measurement standard.

NOTE 2: In relation to verification, the terms “check standard” or “control standard” are also sometimes used.

measurement uncertainty, uncertainty of measurement, uncertainty (VIM 2.26)

non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

NOTE 1: Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated.

NOTE 2: The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

NOTE 3: Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from series of measurements and can be characterized by standard deviations. The other components, which may be evaluated by Type B evaluation of measurement uncertainty, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information.

NOTE 4: In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

best measurement capability, BMC (EA-4/02 M:2013)

The smallest uncertainty of measurement that a laboratory can achieve within its scope of accreditation, when performing more or less routine calibrations of nearly ideal measurement standards intended to define, realize, conserve, or reproduce a unit of that quantity or one or more of its values, or when performing more or less routine calibrations of nearly ideal measuring instruments designed for the measurement of that quantity.

calibration and measurement capability, CMC (Joint arrangement of CIPM/MRA and ILAC)

a CMC is a calibration and measurement capability available to customers under normal conditions:

- i) as published in the BIPM key comparison database (KCDB) of the CIPM MRA; or
- ii) as described in the laboratory's scope of accreditation granted by a signatory to the ILAC Arrangement.

NOTE 1: The meanings of the terms Calibration and Measurement Capability, CMC, (as used in the CIPM MRA), and Best Measurement Capability, BMC, (as used historically in connection with the uncertainties stated in the scope of an accredited laboratory) are identical. The terms BMC and CMC should be interpreted similarly and consistently in the current areas of application.

NOTE 2: Under a CMC, the measurement or calibration should be:

- performed according to a documented procedure and have an established uncertainty budget under the management system of the NMI or the accredited laboratory;
- performed on a regular basis (including on demand or scheduled for convenience at specific times in the year); and available to all clients.

NOTE 3: The ability of some NMIs to offer “special” calibrations, with exceptionally low uncertainties which are not “under normal conditions,” and which are usually offered only to a small sub-set of the NMI's clients for research or for reasons of national policy, is acknowledged.



These calibrations are, however, not within the CIPM MRA, cannot bear the equivalence statement drawn up by the JCRB, and cannot bear the logo of the CIPMMRA. They should not be offered to clients who then use them to provide a commercial, routinely available service. Those NMIs which can offer services with a smaller uncertainty than stated in the database of Calibration and Measurement Capabilities in the KCDB of the CIPM MRA, are, however, encouraged to submit them for CMC review in order to make them available on a routine basis where practical.

NOTE 4: Normally there are four ways in which a complete statement of uncertainty may be expressed (range, equation, fixed value and a matrix). Uncertainties should always comply with the JCGM 100:2008 “Evaluation of Measurement Data Guide to the Expression of Uncertainty in Measurement” and should include the components listed in the relevant key comparison protocols of the CIPM Consultative Committees. These can be found in the reports of comparisons published in the CIPM MRA KCDB as a key or supplementary comparison.

NOTE 5: Contributions to the uncertainty stated on the calibration certificate and which are caused by the client’s device before or after its calibration or measurement at a laboratory or NMI, and which would include transport uncertainties, should normally be excluded from the uncertainty statement. Contributions to the uncertainty stated on the calibration certificate include the measured performance of the device under test during its calibration at the NMI or accredited laboratory. CMC uncertainty statements anticipate this situation by incorporating agreed-upon values for the best existing devices. This includes the case in which one NMI provides traceability to the SI for another NMI, often using a device which is not commercially available.

NOTE 5a: Where NMIs disseminate their CMCs to customers through services such as calibrations or reference value provision, the uncertainty statement provided by the NMI should generally include factors related to the measurement procedure as it will be carried out on a sample, i.e., typical matrix effects, interferences etc. must be considered. Such uncertainty statements will not generally include contributions arising from the stability or in homogeneity of the material. However, the NMI may be requested to evaluate these effects, in which case an appropriate uncertainty should be stated on the measurement certificate. As the uncertainty associated with the stated CMC cannot anticipate these effects, the CMC uncertainty should be based on an analysis of the inherent performance of the method for typical stable and homogeneous samples.

NOTE 5b: Where NMIs disseminate their CMCs to customers through the provision of certified reference materials (CRMs) the uncertainty statement accompanying the CRM, and as claimed in the CMC, must indicate the influence of the material (notably the effect of instability, inhomogeneity and sample size) on the measurement uncertainty for each certified property value. The CRM certificate should also give guidance on the intended application and limitations of use of the material.



NOTE 6: The NMI CMCs which are published in the KCDB provide a unique, peer reviewed traceability route to the SI or, where this is not possible, to agreed - upon stated references or appropriate higher order standards. Assessors of accredited laboratories are encouraged always to consult the KCDB (<http://kcdb.bipm.org>) when reviewing the uncertainty statement and budget of a laboratory in order to ensure that the claimed uncertainties are consistent with those of the NMI through which the laboratory claims traceability.

NOTE 7: National measurement standards supporting CMCs from an NMI or DI are either themselves primary realizations of the SI or are traceable to primary realizations of the SI (or, where not possible, to agreed - upon stated references or appropriate higher order standards) at other NMIs through the framework of the CIPM MRA. Other laboratories that are covered by the ILAC Arrangement (i.e. accredited by an ILAC Full Member Accreditation Body) also provide a recognized route to traceability to the SI through its realizations at NMIs which are signatories to the CIPM MRA, reflecting the complementary roles of both the CIPM MRA and the ILAC Arrangement.



c) Specific terms of NIMT

work instructions

instruction related to the place of work which describe working processes and supplement other working documents (e.g. drawings, orders)

d) Abbreviation used

QSWG	Quality System Working Group
QM	Quality Manual
QP	Quality Procedure
DQM / GQM	Department Quality Manual / Group Quality Manual
CP / PP	Calibration Procedure / Production Procedure
SOP	Standard Operating Procedure
WI	Work Instruction
QA	Quality Assurance
EA	European Cooperation for Accreditation
CRM	Certified Reference Material
UUC	Unit Under Calibration
BIPM	International Bureau of Weights and Measures
CIPM	International Committee on Weights and Measures
RMO	Regional Metrological Organization
NMI	National Metrology Institute
CIPM MRA	CIPM Mutual Recognition Arrangement,
VIM	International Vocabulary of Metrology – Basic and General Concepts and Associated Terms
ILAC	International Laboratory Accreditation Cooperation



3. INTRODUCTION

3.1 DESCRIPTION

This QM describes general policies and guidelines that NIMT Laboratory has to meet in order to demonstrate its compliance to the following international standards and/or guidelines:

- a) ISO/IEC 17025: *General Requirements for the Competence of Testing and Calibration Laboratories.*
- b) ISO 17034: *General Requirements for the Competence of Reference Material Producers.*
- c) Guidelines provided by the accreditation bodies employed by NIMT Laboratory.
- d) JCGM 200:2012, *International vocabulary of metrology - Basic and general concepts and associated terms (VIM).*
- e) ISO/IEC 17000, *conformity assessment - Vocabulary and general principles.*

3.2 SCOPE

The quality system described in this manual covers measurement services (calibration, testing, analysis and RM production) provided to customers both internal and external to NIMT. In general, the scope of the NIMT quality system for measurement services encompasses all services listed in the pricelist announced at www.nimt.or.th. **to ensure the competence, impartiality and consistent operation of NIMT laboratory.** However, the implementation of the quality system covers only parameter listed in the monthly report of the quality system status according to the ISO/IEC 17025 and the relevant requirements of ISO 17034 which are submitted to NIMT's Strategy and Evaluation Group.



4. GENERAL REQUIREMENTS

4.1 IMPARTIALITY

- 4.1.1 It is the policy and the code of ethics of NIMT that all activities shall be impartially undertaken and structured and managed in order to safeguard impartiality.
- 4.1.2 All staff is free from any internal and external commercial, financial and other pressures which might adversely affect the quality of their work, in case of such influences or inducements are taken, the staff shall immediately report, in writing to the Head of Department.
- 4.1.3 NIMT shall identify risks to the impartiality as an ongoing basis, which shall include those risks that arise from the activities, or from the relationships, or from the relationships of the personnel either internal or external one.
- 4.1.4 If a risk to impartiality is identified, the laboratory shall follow QP-08: Procedure for addressing the risk and opportunities.

4.2 CONFIDENTIALITY

- 4.2.1 NIMT has policies to protect the customer's confidential information and proprietary rights including the protection of the electronic storage and the transmission of results. NIMT shall inform the customer in advance about the information intended to be placed in the public domain and avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;
- 4.2.2 When the NIMT is required by law or authorized by contractual arrangements to release confidential information, the individual or the body concerned shall, unless prohibited by law, be notified of the information provided.
- 4.2.3 The following procedures shall be implemented;
- When the customer identifies information or equipment as confidential or proprietary, the laboratory staff shall not copy or reproduce any documents. Information or equipment that is received by the laboratory shall not be discussed outside of NIMT.
 - Confidential data shall be stored. If the information is stored on the NIMT's computer network, it shall be password protected. Only authorized laboratory staff with the need to access such information will be given access to confidential or proprietary information by the Head of Department. Confidential information, data,

and/or proprietary documents shall be physically returned to the customer in person or sent by registered mail to the customer provided address. Facsimiles, telephone conversations, and transmission via normal postal mails and electronic mails (e-mails) are prohibited.

- c) All staff shall not disclose any customer's information.
- d) All staff shall not engage in any activities that may endanger the trust in its independence of judgment and integrity in relation to its measurement services.
- e) The Head of **Group** is responsible for protecting and monitoring the customer's information or equipment or proprietary rights and those activities respectively.

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

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



5. STRUCTURAL REQUIREMENTS

5.1 ORGANIZATION

5.1.1 BACKGROUND AND MISSION

NIMT has been established under the legislation of the National Metrology Development Act B.E. 2540. NIMT has primary responsibilities to establish and maintain the national measurement standards which are metrologically traceable to SI units.

NIMT Laboratory is the part of NIMT that carries out all scientific work, including measurement services and technological supports in all areas of metrology and the Director is acting as the Head of NIMT Laboratory.

NIMT Laboratory composes of several laboratories to cover measurements in different areas. Each laboratory is led by the Head of Group.

NIMT Laboratory Management System covers work carried out in the NIMT Laboratory's permanent facilities at the address shown in [5.1.2](#) as well as work carried out at a customer's facility (on-site calibration work).

The measurement services provided by NIMT Laboratory aim to establish the unbroken chain of measurements to the calibration and testing laboratories including those in the industrial section.

5.1.2 PHYSICAL LOCATIONS

NIMT Laboratory has two permanent physical locations at the addresses shown below:

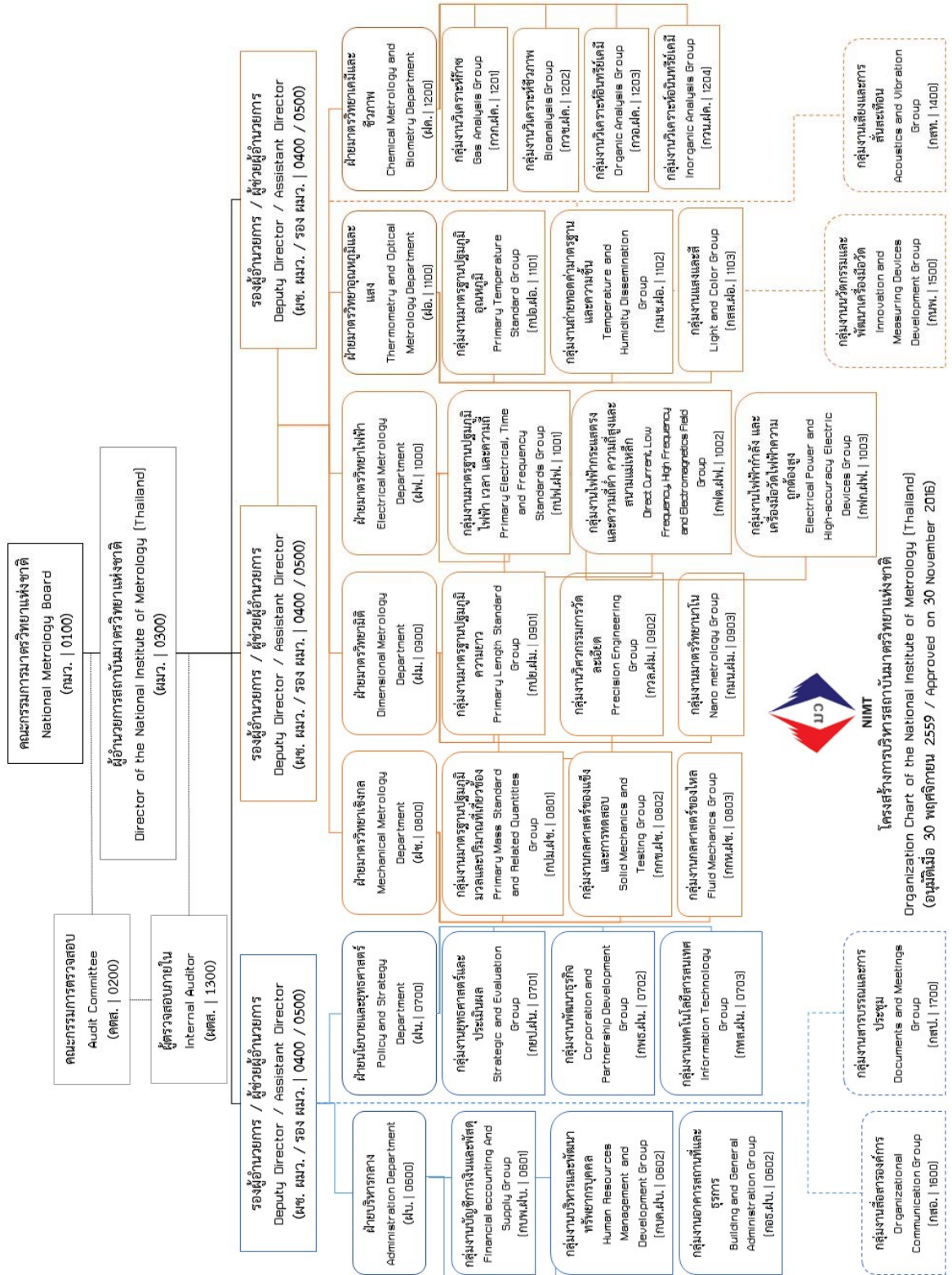
National Institute of Metrology (Thailand)
3/4-5Moo 3, Klong 5, KlongLuang
Pathumthani, 12120 THAILAND
Telephone: 66 2577 5100

National Institute of Metrology (Thailand)
Acoustics and Vibration Group
Technological Metrology Building
75/7 Rama VI Road, Thungphayathai, Rachathewi
Bangkok, 10400 THAILAND
Telephone: 66 2354 3700

5.1.3 ORGANIZATION STRUCTURE

5.1.3.1 Organization Chart

Diagram below shows the organization chart of NIMT.



โครงสร้างการบริหารสถาบันมาตรวิทยาแห่งชาติ
Organization Chart of the National Institute of Metrology (Thailand)
(อนุมัติเมื่อ 30 พฤศจิกายน 2559 / Approved on 30 November 2016)



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- 5.1.3.2 NIMT consists of two core parts. The first part is known internally as the Technical Metrology Part which corresponds to the NIMT Laboratory and the second part is known as the Technical Support Part. Both parts are shown in the organization chart above.
- 5.1.3.3 The NIMT Laboratory composes of five technical departments and one technical group, namely:
- a) Mechanical Metrology Department
 - b) Dimensional Metrology Department
 - c) Electrical Metrology Department
 - d) Thermometry and Optical Metrology Department
 - e) Chemical Metrology and Biometry Department
 - f) Acoustics and Vibration Group
- 5.1.3.4 The Technical Support Part, which consists of the Policy and Strategy Department, the Administration Department and Information Technology Group, is ISO 9001:2015 certified by Management System Certification Institute (Thailand), abbreviated as MASCI. The Technical Support Part establishes, implements, and maintains its management system appropriate to the scope of its activities. The sections within the Technical Support Part that have functions that impact in some way the provision of the measurement services are listed below together with brief summaries of their functions.
- a) Financial accounting and Supply Group : Accounting and Finance Section which is under the Administrative Department has the function to handle customers' billings and payments for all measurement services;
 - b) Financial accounting and Supply Group : Procurement Section which is under the Administrative Department has the function to provide support for procurement of equipment and materials and shipping and receiving;
 - c) Human Resources Management and Development Group : Human Resource Section which is under the Administrative Department has the function to provide assistance with hiring, training, position classification, and personnel records;
 - d) Building and General Administration Group : Building and Maintenance Section which is under the Administrative Department has the function to provide and maintain the physical facilities and laboratory environment;
 - e) Corporation and Partnership Development Group which is under the Policy and Strategy Department has the function to plan for customer services both before and after services, to establish and maintain good relationships with customers, to collaborate with all laboratories regarding their capabilities, to update pricelist, to

provide quotations, schedule services, and to coordinate between laboratories and customers;

- f) Information Technology Group **which is under the Policy and Strategy Department** has the function to provide facilities and support critical to operation of all NIMT's information and infrastructure.

5.1.3.5 The Audit Committee and the Internal Auditor are not related to the management system that governs the operations of NIMT Laboratory. Their responsibility and authority are as follows:

- a) Audit Committee review and ensure that the financial statement of the NIMT including the disclosure of financial information, burden bound and contingent liability which submitted to the executive is reliable, traceable and transparent.
- b) They also ensure that the operation within the NIMT is conducted according to the NIMT's regulations, codes, and ethics. The internal control shall be maintained efficiently and without fraud and conflict of interest.
- c) Internal Auditor is responsible for internal audit on the relevant matters mentioned above and report of the Audit committee. He or she verifies the accounting and financial information and the maintenance of fixed asset, etc.

LEGAL BASIS

NIMT Laboratory is an organizational unit within NIMT. NIMT is a juristic person under the supervision of the Ministry of Science and Technology. Responsibilities and tasks of the organization are listed under the National Metrology Development Act B.E. 2540.

More details regarding additional legal obligations to accreditation bodies and per reviewers can be found in the record entitled "Accreditation: xx" where "xx" is a reference to various accreditation bodies or peer reviewers. The records locate in the Quality Manager's office.

5.1.4 RESPONSIBILITIES AND AUTHORITIES

5.1.4.1 NIMT Laboratory is entitled to issue certificates that can bear the logos of the appropriate accreditation bodies and relevant organizations based on CIPM MRA. The list of parameters accredited by each accreditation body or reviewed by each peer-reviewer is continuously updated and reported monthly in "The monthly report of the quality system status according to the ISO/IEC 17025 and/or the relevant requirements of ISO 17034" which is submitted to NIMT's Strategy and Evaluation Group.

NIMT has the managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties

including the implementation, maintenance and improvement of the management system, and to identify occurrences of departures from the management system or from the procedures for performing measurement works, and to initiate actions to prevent or minimize such departures.

5.1.4.2 NIMT technical management is responsible for ensuring compliance with ISO/IEC 17025:2017 and/or the relevant requirements of ISO 17034. They are nominated as the NIMT Technical Management Team. The appointments of NIMT Technical Management Team's members are based on their academic qualifications and managerial experiences. The members are listed below:

Title	Management
Deputy Directors /Assistant Directors of NIMT	Executive Member
Head of Mechanical Metrology Department	Member
Head of Dimensional Metrology Department	Member
Head of Electrical Metrology Department	Member
Head of Thermometry and Optical Metrology Department	Member
Head of Chemical Metrology and Biometry Department	Member
Head of Acoustics and Vibration Group	Member

5.1.4.3 Director – Top Management

The Director is appointed by the Board of Director of NIMT, he is responsible for NIMT's policies and the resources needed to carry out the activities in such a way as to meet the requirements of ISO/IEC 17025 and ISO 17034 to satisfy the needs of the customers, and the accreditation bodies as well as the peer-reviewers as applied.

5.1.4.4 Deputy Director / Assistant Director – Executive Member of the Technical Management Team

The Deputy Director / Assistant Director is the person that is appointed by the Director under the approval of the Board of Director of NIMT. He / She has overall responsibility and authority based on the policy for the technical operations of NIMT (i.e., to review and to screen the resources needed to carry out the activities in 5.1.4.2).

Deputy Directors / Assistant Directors are appointed to cover 5 technical departments and Acoustics and Vibration Group within NIMT.

The responsibilities of the Deputy Director / Assistant Director include:

- taking control operation of NIMT Laboratory to ensure that NIMT Laboratory operates according to NIMT's policies;
- review of the personnel planning and training;
- NIMT Laboratory's cost control;
- reporting the departures from the NIMT's policies to the Director; and
- any other duties as required by the Director.

5.1.4.5 Quality Manager

Flg.Off. Uthai Norranim is the person entrusted by NIMT Management to act as the Quality Manager of NIMT who irrespective of other duties and responsibilities, has the responsibility to ensure that the quality system is at all times. The Quality Manager shall have direct access to the Top Management on the matters related to the quality system. With regard to the quality, the Quality Manager is also responsible for:

- a) preparation, maintenance, review and control of the QM and QP;
- b) initiation, supervision and improvement on a continuing basis of the management system;
- c) planning and organizing the internal audits and management reviews and ensuring that corrective actions and preventive actions are executed in effective manners and within appropriate time;
- d) maintaining filing and recording system of all general quality documents; and
- e) external representation (contacts with customers) by acting as the contact person to handle the cases of complaints and feedbacks.

5.1.4.6 Deputy Quality Manager

In the absence of the Quality Manager, Ms. Rugkanawan Wongpithayadisai and Ms. Ratirat Sinweeruthai are authorized to act on behalf of the Quality Manager.

5.1.4.7 Head of Department

The Head of Department reports to the supervise Deputy Director / Assistant Director. He / she has overall responsibility for technical operation within the corresponding department. The scopes of duties are the followings:

- a) to supervise all plans proposed from all individual groups and merge them into departmental plans;
- b) additionally, to overlook, monitor, and control all operational activities; resource management and financial spending of all groups and central unit;
- c) to give advice on all relevant technical operations within the responsible department on a continuing basis that compile to the requirements of ISO/IEC 17025 or ISO17034;
- d) to approve the improvement proposal from HG and support funding for implementation of the approved plan;
- e) to approve proposed projects and submitted departmental research plan to the Research Committee for final approval;
- f) to approve the annual comparison plan and support the approved ones for funding;

- g) to give advice on all activities related to comparisons and proficiency testings;
- h) to give advices when any dispute issue regarding QA and QC arise;
- i) to approve the dissolution proposal proposed by HG and support for funding if necessary;
- j) After implementation of the dissolution plan, evaluate the effectiveness of the implementation and give suggestions for preventive and improvement to minimize the occurrence of NC;
- k) to overlook the allocation and distribution of works of all individuals within the department and find resolution if the distribution of work is not suitable;
- l) to give advice and justification for any dispute issue regarding the measurement / production / certification method;
- m) to discipline any metrologists who do not perform their duties regarding technical record maintenance.

5.1.4.8 Head of Group

The Head of the Group under each department in the organization chart reports to the Head of Department. He / she has overall responsibility for technical operation within the corresponding group. The scopes of duties are the followings:

- a) to plan, manage, control and monitor strategic operation and activities of the responsible group (preparing strategic and operational group plan, proposing annual budget request, controlling and monitoring KPI, and managing and developing human and other resources);
- b) to supervise all relevant technical operations within the responsible group on a continuing basis that compile to the requirements of ISO/IEC 17025 or ISO17034;
- c) to propose suitable improvement plan to the technical management within the responsible group;
- d) to review and perform initial project analysis on all projects submitted within the responsible group;
- e) to offer possible aggregation of some projects that can utilize resource sharing or share common delivery targets;
- f) to prioritize all projects and submit them together with comments and suggestions from project analysis to the Head of Department;
- g) to evaluate the output, outcome, impact of participating in or organizing a comparison or proficiency testing within the responsible group;
- h) to propose annual comparison and proficiency testing plan to the Head of Department for appropriate funding;
- i) to approve the comparison protocol if the laboratory within the responsible group is the pilot laboratory;

- j) to review and approve or disapprove justification proposed by Head of Laboratory;
- k) to justify the significance of the NC and propose dissolution of the NC for approval to the Head of Department and assign an appropriate metrologist to perform the corrective action;
- l) to prepare the Training Program, of all personnel within the group based on the Training Needs gathered from subordinate laboratories;
- m) to ensure the allocation of works comply to the competence of the assigned staff based on existing evidence such as training evaluation, etc.;
- n) to approve the written measurement / production / certification procedures;
- o) to review and maintain all technical records.

5.1.4.9 Head of Laboratory

The Head of Laboratory under each department in the organization chart reports to the Head of Group. He / she is responsible for the technical operation within the corresponding laboratory. The scopes of duties are the followings:

- a) to establish and maintain relevant technical operations within the responsible laboratory on a continuing basis that compile to the requirements of ISO/IEC 17025 or ISO 17034;
- b) to collect proposed research projects from metrologists within the laboratory and submit to Head of Group with comments and suggestions;
- c) to coordinate the international and/or domestic comparisons of the responsible laboratory;
- d) to review the comparison protocol if the laboratory is the pilot laboratory;
- e) to perform data analysis for QA and QC, make report and propose justification to Head of Group;
- f) to consider raising NC;
- g) to gather needs from individuals within the responsible laboratory and formulate the laboratory Training Needs;
- h) to prepare the staff authorization and propose to Head of Group for approval;
- i) to review and validity of the method and the relevant written procedures and instructions;
- j) to prepare the calibration program and monitor technical records and report to Head of Group if records are not maintained appropriately.



5.1.4.10 Metrologist

The scopes of duties are the followings:

- a) to initiate a research and/or development project within the metrological area of interest;
- b) to perform measurement works related to the relevant inter-laboratory comparison;
- c) to prepare the protocol if the laboratory is the pilot laboratory;
- d) to collect data and information for QA and QC;
- e) to report to the relevant Head of Laboratory when any problems arise that can lead to NC;
- f) to inform training needs to Head of Laboratory;
- g) to maintain the responsible training record;
- h) to prepare the training evaluation for the Head of Group;
- i) to establish appropriate measurement / production / certification methods and prepare related procedures based on the approved funded projects;
- j) to prepare and maintain all technical records such as equipment records, environmental records, calibration / measurement / production / certification records;
- k) to perform routine maintenance and calibration and production of Certified reference material etc.



6. RESOURCE REQUIREMENTS

6.1 PERSONNEL

- 6.1.1 All measurements shall be performed by laboratory personnel who are competent and authorized by the Head of Department. The staff evaluation shall be done prior to the authorization based on the required qualification (i.e., competence, education and professional educations, training, skills and experience) particular to the specific calibration and measurement to be performed by using the staff evaluation form. Any particular personnel who are undergoing training shall not be used unless appropriate supervision is provided.
- 6.1.2 The Head of Department shall formulate the goals with respect to the education, training and skills of laboratory personnel. Training needs and training program shall be identified and formulated for relevant laboratory personnel to ensure the required competence and the effectiveness of the present and anticipated tasks. The Head of Department shall ensure that personnel received training as required by the training program. The effectiveness of the training actions taken will be evaluated by the Head of Group. Details of Procedure for Staff's Training and Authorization are described in QP-11.
- 6.1.3 NIMT shall use personnel permanently employed by NIMT if possible. In case where personnel under contract are required, these shall be approved by the Director and shall also fulfill the requirements of the quality system.
- 6.1.4 The up-to-date job descriptions of managerial, technical and key support personnel are defined in the document called "Job Description (JD)" and each (JD) shall contain:
- a) the responsibilities with respect to performing calibrations ;
 - b) the responsibilities with respect to method modification and development and validation of new methods ;
 - c) expertise and experience required ;
 - d) qualifications and training programs ; and
 - e) managerial duties.

The original record of the Job Descriptions of all positions employed by NIMT is maintained in the Human Resources Management and Development Group. The Quality Manager maintains a duplicate record of all JDs.



- 6.1.5 Records of the authorizations, competence, education and personnel qualifications, training, skills and experience of all technical personnel shall be maintained by the Laboratory. They shall be readily available and shall include the data on which authorization and / or competence is confirmed.



6.2 FACILITIES AND ENVIRONMENTAL CONDITIONS

6.2.1 GENERAL

- 6.2.1.1 All NIMT laboratories will have appropriate accommodation and environment in order to facilitate correct performance of all measurements.
- 6.2.1.2 Such accommodation and environment shall be maintained to ensure that the activities undertaken do not invalidate the results or adversely affect the required accuracy of measurements.
- 6.2.1.3 When measurements are undertaken at sites other than a permanent laboratory facility, the effect of the environmental conditions shall take into account in the measurement result and shall be recorded in the measurement record.

6.2.2 CONTROL MONITORING AND RECORDING

- 6.2.2.1 All NIMT laboratories shall have facilities for control, monitoring, and recording of environmental conditions.
- 6.2.2.2 Monitoring and recording instrument shall be calibrated and metrologically traceable to corresponding SI units.
- 6.2.2.3 The required facilities and environmental conditions for each laboratory are defined in the individual DQM / GQM.

6.2.3 RESPONSIBILITY

- 6.2.3.1 The Metrologist is responsible for ensuring that the controlled conditions are properly maintained and examining the effects of the environmental conditions to the measurement / calibration results and taking actions as necessary.

In case where a deficiency exists which might adversely affect the proper performance of the measurement, the measurement shall be stopped. The Head of Laboratory shall take immediate action to correct the problem.

6.2.4 CONTROL ACCESS

- 6.2.4.1 All areas of NIMT's laboratories are subjected to be controlled. Only NIMT staff is permitted to access and use all areas of NIMT's laboratories.
- 6.2.4.2 None of other parties may access to NIMT's laboratories without permission from the Head of Department. Visitors are to be accompanied by the assigned laboratory staff.
- 6.2.4.3 Door access to laboratory shall be locked when leaving unattended. None of laboratory staff or other parties may access to the laboratory without permission from the Head of Department after office hours.



- 6.2.4.4 There shall be effective separation between neighboring areas when the activities there are incompatible.
- 6.2.4.5 Activities that can affect the laboratory environment such as smoking, eating and drinking are not allowed in the laboratory.
- 6.2.4.6 All laboratory staff is responsible for maintaining good housekeeping throughout the laboratory.
- 6.2.5 **RECORDS**
- 6.2.5.1 Records of environmental conditions shall be maintained by the laboratory for the period of at least 10 years.



6.3 EXTERNALLY PROVIDED PRODUCTS AND SERVICES

6.3.1 For calibration and analysis, it is the policy of NIMT that NIMT Laboratory will not use externally provided service for any works whether because of some unforeseen reasons or on a continuing basis.

6.3.2 For reference material production, Head of Department must ensure that the competences of the selected external providers comply with the technical requirements of NIMT.

Details of Procedure for Selecting and Maintaining the Competence of External Provider are described in QP-17.



6.4 PROVISION OF PRODUCTS, SERVICES AND SUPPLIES

- 6.4.1 All products, services and supplies that could affect the quality of the measurements shall be provided through a suppliers and/or subcontractor who either has satisfactory evaluated or can demonstrate its compliance to the specified requirements.
- 6.4.2 In case of the necessity to use any external measurement services, NIMT shall select only measurement services from the BIPM, or another national metrology institute (NMI) or designated institute (DI) having relevant CMCs published in the KCDB or in a special circumstance, an accredited laboratory according ISO/IEC17025.
- 6.4.3 Requisition for services and supplies shall contain data describing the services and supplies required and shall be reviewed and approved by the Head of Department prior to release.
- 6.4.4 All services and supplies provided shall be inspected or otherwise verified as confirming with purchase specification prior to acceptance and being placed into services. Preferably, the verification should be done before payment is made (except the case where prepayment is required by the supplier).
- 6.4.5 NIMT shall evaluate and maintain the list of suppliers of services and supplies and subcontractors (if applicable) which affect the quality of measurement services.
- 6.4.6 Records of verification of the provided items and supplier evaluation results shall be maintained by the Procurement Section of NIMT. These record shall include quality assurance approval of the suppliers and/or subcontractors hold.

Details of Procedure for Provision of Products, Services and Supplies are described in QP-04.



6.5 EQUIPMENT

6.5.1 POLICY

- 6.5.1.1 Appropriate equipment (including, measuring instrument, software, measurement standards, reference materials, reference data, reagents, consumable or auxiliary apparatus) and facility shall be accessed in order to ensure that it is sufficient to effectively and correctly perform all of the measurement services provided by the laboratory.
- 6.5.1.2 NIMT equipment shall be kept fully maintained in an operational condition and calibrated in accordance with the defined procedures.
- 6.5.1.3 New items of equipment will not be used for servicing until they have been properly commissioned, validated and/or calibrated if necessary.
- 6.5.1.4 Each item of equipment having significant effect to the quality will have laboratory staff assigned to be responsible for maintaining it in a fully functional condition and with a current calibration status.
- 6.5.1.5 Equipment outside the permanent control of the laboratory is not normally used for providing measurement services. However if it is necessary to do so the authorization of the Head of Group is to be sought and the Head of Group must ensure that all necessary calibration and verification procedures have been carried out.
- 6.5.1.6 Each item of equipment and its software used for calibration and significance to the results shall be uniquely identified.
- 6.5.1.7 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

6.5.2 CALIBRATION, PERFORMANCE CHECKS AND OPERATION OF EQUIPMENT

- 6.5.2.1 Calibration programs shall be established, reviewed and adjusted as necessary according to the procedure in QP-12 for key quantities or values of the instruments where these properties have a significant effect on the results.
- 6.5.2.2 All equipment requiring regular calibration will display a calibration sticker, in a clearly visible position if applicable, indicating when it was calibrated and when the next calibration is due.

6.5.2.3 Any equipment that has calibration settings that are risky to be accidentally altered must be checked prior to use to ensure that the correct calibration settings are used. Any calibration method that utilizes such equipment must include a setting procedure. In all cases, calibration equipment including the software used shall be safeguarded from adjustments which would invalidate the results.

6.5.2.4 When calibrations and reference material data include reference values or correction factors, the laboratory staff shall ensure that all relevant records and computer software related to the evaluation of final measurement results are updated and implemented accordingly.

6.5.3 REFERENCE STANDARDS AND REFERENCE MATERIALS

6.5.3.1 All reference standards and reference materials shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.

6.5.3.2 Where applicable, the laboratory shall have procedures and schedules for intermediate checks to maintain confidence status of reference, primary measuring equipment and reference materials between calibrations.

The results of the intermediate checks shall be recorded.

6.5.3.3 Procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity shall be described in sufficient details in individual DQM / GQM.

6.5.4 HANDLING OF EQUIPMENT

6.5.4.1 Equipment shall be protected from deterioration and abuse and maintenance shall be carried out regularly to ensure proper functioning. Handling of major equipment affecting the result of measurement work are described or referred to in individual DQM / GQM.

6.5.4.2 Measuring equipment and standards that are overdue for calibration or not calibrated shall be labeled or segregated to prevent from their inadvertent use.

6.5.4.3 Equipment that has either been subjected to overloading or mishandling gives suspect results or has been shown to be defective or outside specified limits shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration to perform correctly.

6.5.4.4 The laboratory shall examine the effect of this defect on previous calibration and take action as required.



6.5.5 EQUIPMENT RECORDS

6.5.5.1 Each laboratory maintains its own Equipment List (Fr-EQU-02).

6.5.5.2 Records of each item of equipment significant to the measurement performed are maintained in the Equipment Record (Fr-EQU-03). The record shall include at least the followings:

- a) Name of the item of equipment, including software and firmware version;
- b) The manufacture's name, type, serial number or other unique identification;
- c) Date received and date of placed in to service (where appropriate);
- d) Current location;
- e) Results of verification to check that the equipment complies with the specification;
- f) Manufacturer's manual (if available);
- g) References and information regarding calibration status such as dates, results and scans the approved certificate of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
- h) Documentation of reference materials;
- i) Maintenance program (where appropriate);
- j) History of any damage, malfunctions, modification or reparation.

6.5.5.3 All equipment records shall be kept for life of equipment.

6.5.6 AUTHORIZATION OF USE

6.5.6.1 Only staff members who have been trained in the use of each item of equipment and authorized by the Head of Group are permitted to use the equipment in the laboratory. Training records for each individual staff member indicate their capability to operate major items of laboratory equipment.

6.5.7 MONITORING

6.5.7.1 Some items of equipment that may require intermediate checks to maintain confidence in its calibration status, these checks shall be carried out according to defined procedure (including schedules and pre-defined criteria). The results of the intermediate checks shall be documented and maintained.

The Head of Group is responsible for developing procedures for intermediate checking of the items in question and taking appropriate



6.6 METROLOGICAL TRACEABILITY

6.6.1 POLICY

6.6.1.1 All measuring equipment including reference standards and reference materials having a significant effect on the accuracy and validity of the result of measurement shall be calibrated before putting into service.

6.6.2 TRACEABILITY

6.6.2.1 Traceability to SI units **shall be ensured** by:

- a) NIMT's owns primary standards, which may be primary realization of the SI units of measurement or agreed representations of SI units based on fundamental physical constants, or
- b) Other standards that are calibrated by the BIPM, another national metrology institute (NMI) or designated institute (DI) having relevant CMCs published in the KCDB.
- c) **Direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.**

6.6.2.2 When it is necessary to use external calibration services from another organization apart from NMI or DI, NIMT will use only calibration services from the laboratories that have been accredited to the ISO/IEC 17025 or equivalent.

6.6.2.3 Where traceable to the SI Units is not possible, NIMT will establish traceability through the use of certified reference materials provided by a competent supplier or the use of specified methods and/or consensus standards **and ensured by suitable comparison.**

6.6.2.4 The Head of Department is responsible to ensure that the laboratory establishes and maintains the traceability to SI units through the use of appropriate primary and/or other standards.

6.6.2.5 Details of Procedure for Maintaining Measurement Traceability are described in QP-12.



7. PROCESS REQUIREMENTS

7.1 REVIEW OF REQUESTS, TENDERS AND CONTRACTS

7.1.1 A customer shall submit measurement service inquiry to NIMT via the Cooperation and Partnership Development Group NIMT shall review the customer's inquiry before starting the measurement service in order to ensure that :

- a) the customer' requirements are adequately defined, documented, and understood ;
- b) NIMT has sufficient capabilities and resources to fulfill the customer' requirements ; and
- c) an appropriate method is selected.

Any differences between the request or tender and the contract shall be resolved and accepted both to NIMT and the customer. **Deviations requested by the customer shall not impact the integrity of NIMT or the validity of the results.**

7.1.2 **In case NIMT accept to state the statement of conformity to a specification or standard, the customer's requested statement of conformity and decision rule shall be clearly, defined and agreed with the customer.**

7.1.3 **The review process shall be conducted by those who will carry out the contracted work and only in writing.**

7.1.4 **Any decision that is resulted from the review leading to a contract shall be signed by the relevant Head of Department.**

7.1.5 **NIMT shall inform the customer when there are any deviations from the contract.**

7.1.6 **NIMT shall review the process when the contract need to be amended due to some unforeseen circumstance such as the customer's requirements are changed or a technical problem arise after the contracted work has been commenced. The result of such amendment shall be communicated to all affected personnel.**

7.1.7 **When it has been defined in the contract or by the agreement with NIMT, NIMT shall cooperate with the customer or the customer's representative to clarify the customer's**



requests and to witness NIMT Laboratory's performance in relation to the work performed for that customer.

7.1.8 NIMT shall maintain records of reviews, including any significant changes that are obtained from the pertinent discussion with the customer regarding the customer's requirements or the results of the work during the period of execution of the contract.

7.1.9 The review shall include any work that needs to be subcontracted.

Details of Procedure for Reviews of Requests, Tenders, and Contracts are described in QP-03.



7.2 SAMPLING

For calibration and testing, sampling process is not applied.



7.3 HANDLING OF MEASUREMENT SERVICES

The handlings of measurement services are defined according to the nature and process of services as follows:

7.3.1 CALIBRATION, TESTING AND ANALYSIS

7.3.1.1 GENERAL

7.3.1.1.1 All items received for measurement service shall be handled in a manner not to cause any confusion regarding the identity and to prevent damage and deterioration of such items at any time.

7.3.1.2 IDENTIFICATION

7.3.1.2.1 Each item submitted for measurement service including its accompanied sub-items shall be uniquely identified in a secure manner by using service tag that is tied to the equipment, or its container, or any other appropriate place. The service tag shall contain the data that is traceable to the relevant work order issued for the items. The service tag shall remain with the item throughout the measurement process.

7.3.1.3 CONDITION ON RECEIPT

7.3.1.3.1 Upon receipt, the relevant NIMT staff must examine the item to determine if it is suitable for the agreed measurement service. Any abnormality observed shall be recorded on to the work order and if the item is not suitable for the measurement service, the Head of Group shall inform the customer for further instruction. The contract review process may also be repeated again.

7.3.1.4 HANDLING, TRANSPORTING AND STORAGE

7.3.1.4.1 All measurement items shall be handled and transported with caution. The manufacturer's instruction shall be followed. Items requiring transportation by hands should be done by persons who are responsible for that specific work.

7.3.1.4.2 Suitable storage facilities shall be provided, before and after measurement process. Where items are to be stored or conditioned under specified environmental conditions these shall be maintained, recorded and monitored at all times.

7.3.1.4.3 Details of Procedure for Processing of Measurement Service Items are described in QP-13.



7.3.1.5 DISPOSAL

- 7.3.1.5.1 After completion, the items are to be returned to the customer under the customer's responsibility. Any time or part of the item that needs to be disposed by the laboratory, they should be segregated and placed outside the measurement areas in order that the cleanliness and integrity of the laboratory are assured at all times.

7.3.2 REFERENCE MATERIAL

Head of Group must ensure that NIMT staff understand the importance of proper handling, are properly trained, and consistently handle reference materials appropriately. If specific procedures for identifying, preparing, packaging, handling, storing and shipping of reference materials are required, these are documented in the DQM of Chemical Metrology and Biometry Department.



7.4 METHODS AND MEASUREMENT PROCEDURES

7.4.1 POLICY AND SCOPE

- 7.4.1.1 It is the policy of NIMT Laboratory to perform all measurements in accordance with standards or specifications required by the customer. The measurements will normally be performed in accordance with internationally recognized methods chosen by the responsible laboratory. Where these are not available or are not appropriate, in-house developed methods or manufactures recommended methods may be used provided that these have been fully documented and validated.
- 7.4.1.2 The version of standard method being applied must explicitly be stated and the latest version of standard method shall be used whenever technically possible except when otherwise required by the customer.
- 7.4.1.3 The Head of Group is responsible for ensuring that all relevant specifications and standards are available and up-to-date by following QP-02.
- 7.4.1.4 When it is necessary to modify or amplify the standard methods in order to enable staff to be able to use the standard as a detailed calibration procedure, the calibration procedures detailed in the amplified method must be consistent with the details in the standard method.

7.4.2 PREPARATION AND AUTHORIZATION OF MEASUREMENT METHODS

- 7.4.2.1 The Head of Group is responsible for selection, preparation and validation of measurement method for use within each laboratory. The approved method shall be documented in sufficient details in the Calibration Procedure
- 7.4.2.2 If the selected method is a standard method, the Head of Group has to confirm that the laboratory has sufficient resources to perform the method and if the standard method is changed or updated, the confirmation process shall be repeated.
- 7.4.2.3 All Calibration Procedures are subjected to document control as described in QP-02.

7.4.3 METHOD VALIDATION

- 7.4.3.1 In-house developed methods, non-standard methods and amplification of standard methods shall be validated before using as the laboratory methods.
- 7.4.3.2 The techniques used for validation which should be one of, or a combination of, the following:
- calibration using reference standards or reference materials;
 - comparison with other methods;
 - inter-laboratory comparison;

- d) calibration with examination of the influence quantities; and/or
- e) reasonable estimation of the uncertainties of the results.

7.4.3.3 The range and accuracy of the values obtainable from validated methods, as assessed for intended use, shall be relevant to the customers' need.

7.4.4 ESTIMATION OF UNCERTAINTY IN MEASUREMENT

7.4.4.1 The uncertainties of measurement results will be quoted at approximately 95% confidence level, which generally corresponds to the coverage factor $k = 2$. The method for use in estimate of uncertainty of the measurements is based on the EA Publication EA-4/02 M: 2013 "*Evaluation of the Uncertainty of Measurement in Calibration*", or JCGM 100:2008 "*Evaluation of Measurement Data Guide to The Expression of Uncertainty in Measurement*".

7.4.5 CONTROL OF DATA

7.4.5.1 All calculations and data transfers carried out during measurement and reporting will be checked by Head of Group who is familiar with the methods and calculations involved. Calibration records must be countersigned by the person performing the checking.

7.4.5.2 If user-developed software is used for data acquisition and/or processing, it must be documented in sufficient details such as software identification, version in use, flow diagram, etc.

Such software must be validated to ensure that both data acquisition and processing are being performed correctly. The minimum level of checking must be the processing of a set of standard data from which the results have been manually calculated. The validation result shall be recorded.

7.4.5.3 Where automatic data acquisition is used, every effort must be made to ensure the integrity of the data.

7.4.5.4 Records of data shall be maintained according to policies stated in section 8.3 of this manual.

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

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



7.5 REPORTING THE RESULTS

7.5.1 POLICY

7.5.1.1 Measurement results shall be reported in a certificate entitled "Certificate of Calibration" or "Certificate of Analysis". The certificate shall contain only factual information and in accordance with the measurement that has been performed by the laboratory. In the case of measurement performed for internal customers, the results shall be reported in a similar way that is used for customers.

7.5.1.2 The certificates shall contain only measured quantities and the results of the functions measured. **NIMT has a policy not to include any statement of compliance in the certificate unless with written customer's request that is justified to be scientifically sound and feasible.** However, if a statement of compliance with a specification has to be made to comply with any particular standards, the statement shall state which clauses of the specification are met or not met taken into account, the uncertainty of measurement.

7.5.1.3 When an adjustment is performed on a measurement item, the measure results before and after the adjustment shall be reported if available.

7.5.1.4 The laboratory shall not make any recommendation on the calibration intervals in any calibration certificate except where this has been agreed by the customer or when it is the regulatory requirements.

7.5.1.5 NIMT has the policy not to express opinions or interpretations on the certificate for whatever reasons.

7.5.1.6 In case of reference material, the contents of label can be found in the DQM of Chemical Metrology and Biometry Department.

7.5.1.7 **When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of risk associated with the decision rule employed, and apply the decision rule.**

7.5.1.8 **Details of Procedure for Preparing of the Certificate are described in QP-15.**

7.5.2 THE CERTIFICATES ISSUED FOR ACCREDITED PARAMETERS

7.5.2.1 All certificates issued by the laboratory that cover scopes of accreditations shall be prepared according to guidelines provided by the appropriate accreditation bodies.

7.5.2.2 Measurement results outside the scope of accreditation shall be reported on the same certificate but not more than one quarter of the whole content. However, these results shall be clearly marked.



7.5.3 AMENDMENT TO CERTIFICATE

7.5.3.1 NIMT has a policy to issue only a replacement certificate if the already issued report requires any correction. The replacement report shall be prepared in whole and the policies and procedures described in QP-15: Procedure for Preparing of the Certificate must be strictly followed.

7.5.4 COMPLEMENT TO CERTIFICATE

7.5.4.1 NIMT shall issue the complement to the certificate if the issued certificate requires addition. Such certificate shall contain material necessary to complete the original one. Such complement certificate shall meet all the requirements of the QM and this QP and the policies and procedures described in QP-15: Procedure for Preparing of the Certificate must be strictly followed.

7.5.5 REPRODUCTION OF CERTIFICATE (ONLY FOR NEEDED AND REASONABLE CASES)

7.5.5.1 NIMT shall reproduce the certificate if the issued certificate necessarily requires reproduction. Such certificate shall be issued in whole to replace the issued original one. Such reproduced certificate shall meet all the requirements of the QM and this QP and the policies and procedures described in QP-15: Procedure for Preparing of the Certificate must be strictly followed.

7.5.6 TRANSMISSION OF RESULTS

7.5.6.1 All certificates must be issued in full with the original copies.

7.5.6.2 NIMT's laboratories have policy not to send any measurement results by telephone, facsimiles or other electronic means **except for the case of amendment of the certificates for the lot production of the certified reference material.**

7.5.6.3 The certificates shall be handed to the customer upon the completion of the measurement.



7.6 ENSURING THE VALIDITY OF RESULTS

- 7.6.1 NIMT has the policy to assure the quality of the measurement results by implementation of an appropriate quality control measure.
- 7.6.2 The results shall be recorded in such a way that trends are detectable and where practicable, statistical techniques shall be applied to the reviewing of the results.
- 7.6.3 The quality control measure shall be planned and reviewed and may include, but not limited to the following:
- a) regular use of certified reference materials and/or internal quality control using secondary reference material ;
 - b) participate in inter laboratory comparison or Proficiency Testing scheme
 - c) replicate testing or calibrations using the same or different methods;
 - d) retesting or recalibration of retained items; and
 - e) correlation of results for different characteristics of an item.
- 7.6.4 The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:
- a) participation in proficiency testing; NOTE ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.
 - b) participation in inter-laboratory comparisons other than proficiency testing.
- 7.6.5 Quality control data will be analyzed and, where they are found to be outside pre-defined criteria, planned action will be taken to correct the problem and to prevent incorrect result from being reported.
- 7.6.6 Details of Procedure for Assuring the Quality of Results are described in QP-14.



7.7 CONTROL OF NONCONFORMING WORK

- 7.7.1 When any aspects of the measurement work, or the result of the work are found to be nonconforming to the laboratory's own procedures or the agreed requirements of the customer, NIMT shall implement procedures to ensure that:
- a) the responsibilities and authorities for the management of nonconforming work are designated and actions are defined and taken;
 - b) an evaluation of the significance of the nonconforming work is made;
 - c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work;
 - d) where necessary, the customer is notified and work is recalled;
 - e) the responsibility for authorizing the resumption of work is defined.
- 7.7.2 All nonconforming measurement work shall be promptly identified, halted (if necessary), segregated, and documented.
- 7.7.3 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operation with its own policies and procedures, the Procedure for Corrective Action (QP-07) shall be followed.
- 7.7.4 Details of Procedure for Control of Nonconforming Work are described in QP-06.



7.8 COMPLAINTS

7.8.1 POLICY

- 7.8.1.1 Customer satisfaction is paramount to the success of NIMT. It is each staff's responsibility to record a customer or any other party's complaint as soon as it is received so that it can be responded expeditiously.
- 7.8.1.2 NIMT has the policy to investigate and resolve all complaints received from customers or other relevant parties promptly and effectively.
- 7.8.1.3 Complaints may be raised by means of conversation, telephone, paper mail, electronic mail, facsimile or any other electronic media and all shall be accepted by NIMT.
- 7.8.1.4 Those negative feedbacks which have been evaluated in 8.9.6 shall be documented as customer complaints.

7.8.2 RESPONSIBILITY

- 7.8.2.1 The Quality Manager is responsible for handling of complaints. **In Case the Quality Manager involved with the original activities in question, the Deputy Quality Manager will act as the Quality Manager for handling of complaints.**
- 7.8.2.2 The relevant Head of Department or Quality Manager **or Deputy Quality Manager** is responsible for taking any corrective actions required as a result from the investigation of the received complaint.

7.8.3 RECORDS

- 7.8.3.1 Records of complaints and their resolutions shall be maintained by the Quality Manager.
- 7.8.3.2 Details of Procedure for Handling of Complaints are described in QP-05.



7.9 DISTRIBUTION SERVICE OF RM

NIMT is considering to avoid deterioration of the reference material during distribution process. This is to ensure that the reference material is in the best quality. Record of all reference material sales or distributions will be updated and maintained at the Chemical Metrology and Biometry department.

The details of distribution processes of RM are described in the DQM of Chemical Metrology and Biometry department.



8. PRODUCTION REQUIREMENT

8.1 REFERENCE MATERIAL PRODUCTION PLANNING AND CONTROL

The laboratory which produces the reference material shall prepare an annual program of work and funding for reference material production.

Details of Procedure for Reference Material Production are described in QP-16.

Details for production planning and control to ensure the quality of each stage of reference material are described in DQM of Chemical Metrology and Biometry Department.

8.2 MATERIAL PROCESSING, HOMOGENEITY AND STABILITY ASSESSMENT AND CHARACTERIZATION

For reference material production, it is the responsibility of Head of Group to ensure its validity.

Preparation, homogeneity, and stability assessment are specific to each reference material certified. The details of preparation processes for assuring the quality of homogeneity and stability measurements and procedures are documented in the DQM of Chemical Metrology and Biometry Department.

The production and distribution of an RM should be carefully planned and reviewed to ensure that production processes are in accordance with requirements stated in ISO 17034 prior to undertaking and actual activity

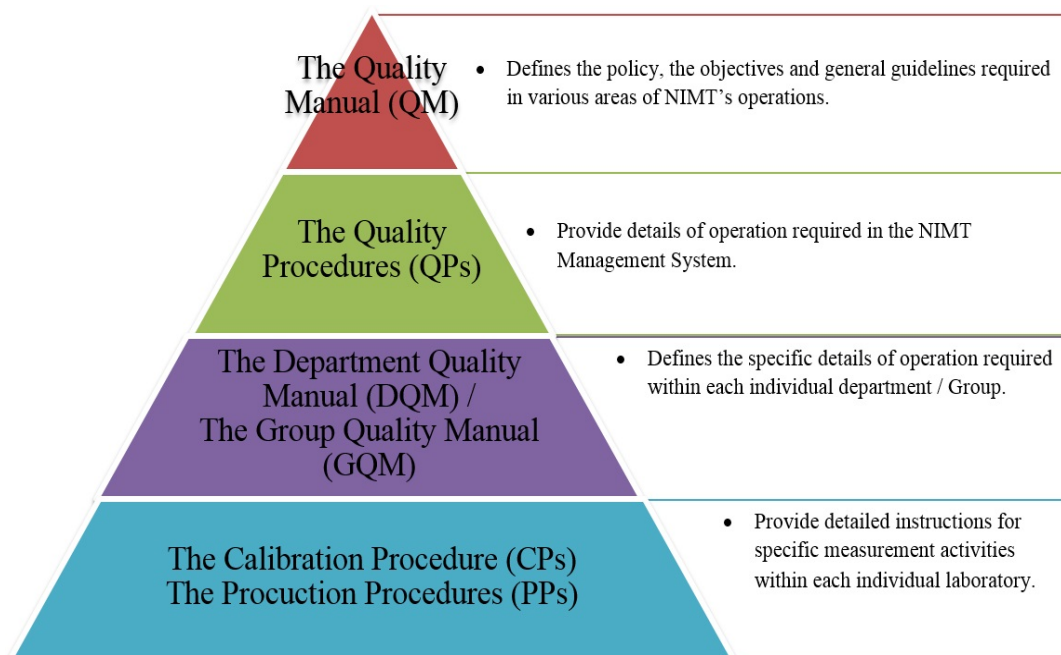
9. MANAGEMENT SYSTEM REQUIREMENTS

9.1 MANAGEMENT SYSTEM

9.1.1 MANAGEMENT SYSTEM DESCRIPTION

9.1.1.1 The management system of NIMT aims to ensure that all measurement services and documentation associated with the work performed within NIMT are carried out based on the requirements of the customers and according to the requirements of ISO/IEC 17025 and/or the relevant requirements of ISO 17034. The management system is established and documented in four levels to ensure the quality of measurement services and to guarantee that it shall be acknowledged and implemented at all levels of the laboratory organization.

9.1.1.2 Documentation of the management system is at minimum composed of:



9.1.1.3 This management system is provided for those activities affecting quality which can be achieved under controlled conditions in an appropriate environment and taking into account the needs for standards, test equipment and relevant skills



9.1.2 QUALITY POLICIES

- 9.1.2.1 NIMT Laboratory, by its management, has committed itself to good professional practice, impartiality and to the quality of its measurement services.
- 9.1.2.2 NIMT Laboratory's standard of service is, at minimum, to satisfy the requirements of ISO/IEC 17025 and/or the relevant requirements of ISO 17034 and expectations of its customers and relevant agencies.
- 9.1.2.3 The main purpose of the management system established by NIMT is to assure the accuracy and reliability of calibration/measurement results so that they will be reliable, interpretable, repeatable and defensible. In order to fulfill this principle goal, NIMT shall establish the metrological system and infrastructure that is internationally recognized by cooperation with other NMIs and BIPM under CIPM MRA.
- 9.1.2.4 All staff members concerned with measurement activities within NIMT shall familiarize themselves with the content of the quality documentation and implement the policies and procedures in their work at all times.
- 9.1.2.5 In accordance with this policy, NIMT's Top Management is committed to comply with the requirements of the ISO/IEC 17025 and/or the relevant requirements of ISO 17034 and obligations of accreditation bodies and to continually improve the effectiveness of the management system at all times.

9.1.3 QUALITY OBJECTIVES

- 9.1.3.1 NIMT's principal quality goal is to consistently meet or exceed customer needs and expectations and provide high value, continually improving services. NIMT's quality objectives support this goal. These quality objectives are as follows:
- NIMT develops and maintains Thailand's national standards and reference materials for all fields of measurement that are appropriate to current and anticipated needs of Thai industry and government.
 - To the extent permitted by resources, NIMT participates in comparison of its national standards with those of other National Metrology Institutes (NMIs), both as a mean of assuring the quality of its measurement services and to satisfy the requirement that the Thai standards are consistent with those of other NMIs, and with the SI, within stated uncertainty.
 - NIMT provides measurement services that are customer focused and, at a minimum, are:

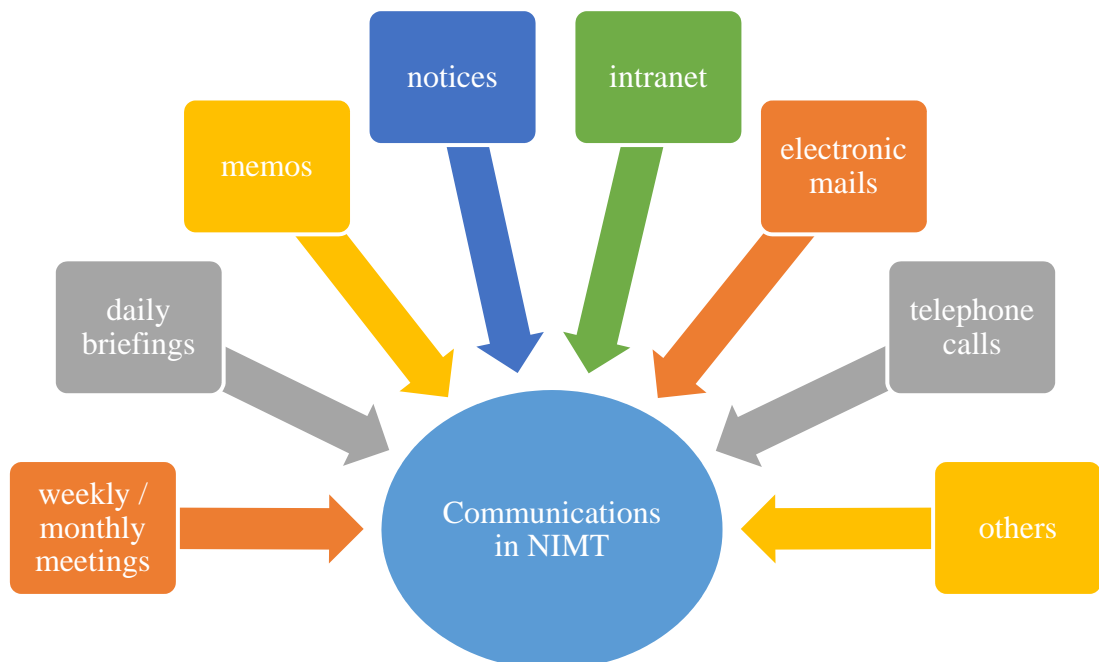
- marked by clear and open communication with customers to assure mutual understanding of customer needs and NIMT capabilities;
- technically consistent with customer needs; and
- timely and cost effective.

9.1.3.2 Detailed measurable quality objectives are updated and announced annually by the Top Management and annually documented in a separate document entitled “NIMT Quality Objectives for the Year YYYY” The original copy of the aforementioned document is kept in the Quality System Office. Moreover, the corresponding electronic copy of such document shall be available on the intranet.

9.1.4 QUALITY MANAGEMENT

9.1.4.1 The Top Management shall ensure that all staff understand and are aware of the relevance and importance of meeting customers’ expectation, NIMT’s requirements, statutory and regulatory requirements, their activities as well as their contribution to the achievement of the objectives of the management system.

9.1.4.2 The Top Management has the responsibility for ensuring that communication processes in NIMT are established in order to improve the effectiveness of its management system. The communication means established within NIMT are shown below:



9.1.4.3 The Top Management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

9.1.5 ADMINISTRATIVE PROCEDURES

9.1.5.1 General Information

- a) Measurement works shall be conducted only in the laboratory premises. In a case that the measurement work needs to be performed outside the laboratory premise, the Director is responsible for an approval of such case.
- b) Equipment submitted for measurement services should satisfy the following conditions :
 - the equipment must be in cleaned condition;
 - the equipment must be in good working order;
 - the equipment must bear some unique permanent marking such as serial number;
 - NIMT shall not issue a certificate of calibration/analysis for equipment without unique identification marking;
 - the equipment must be accompanied by comprehensive operations and service manuals written in Thai or English;
 - the equipment must be accompanied by any accessories required for its calibration.
- c) NIMT will not undertake any maintenance or servicing of submitted equipment. When an equipment is found to be faulty, or to have developed a fault during measurement service, the item will be rejected and the customer will be informed. Service fees may be charged to the customer for the work that has been performed by NIMT.
- d) Unless otherwise specified in the contract, NIMT shall not be liable for any fault or damage to the submitted equipment while it is in the custody of NIMT Laboratory.

9.1.5.2 NIMT certifies its results for calibrated instruments. NIMT shall not certify any calibrated instrument's performance relative to specifications, its suitability for an intended customer application, or its future performance.

9.1.5.3 Calibration/ Analysis Certificates or Measurement Reports

- a) Calibration/analysis certificates or measurement reports will be issued to the customer upon completion of the measurement works.
- b) The results given in the certificate only relate to the values measured under the conditions at the time of the measurement. The uncertainties of measurements are quoted at approximately 95% confidence intervals ($k = 2$).
- c) The k value may vary from two. This may be the case when the measurement applies the effective degree of freedom that is less than 30 to account for the quality

- d) of the estimation of the components of uncertainty. If this is the case, it shall be clearly shown in the calibration/analysis certificates or measurement reports.
- e) Calibration/Analysis certificates or measurement reports bearing accreditation logo or CIPM-MRA logo will be issued to the customer only for the measurement results that performed under the scope of accreditations or supported by CMCs published in the KCDB, respectively.
- f) The measurement results that are performed outside the scope of accreditation may be reported together with the results that are performed under the scope of accreditation on the same certificate. However, these results shall be explicitly identified.

9.1.5.4 QM

- a) The QM is the document that defines the policies and objectives of NIMT Laboratory. The QM is issued by the Quality Manager under the authorization from the Director of NIMT who is the Top Management of NIMT.
- b) The Quality Manager is responsible for compilation of the QM. The content of the QM shall satisfy, at minimum, the requirements of the ISO/IEC 17025 and ISO 17034.

The QM shall be revised and updated at least every 12 months. Interim amendments of the QM may be issued by the Quality Manager as necessary.

- c) All NIMT staff involved in activities that are related to measurement services within NIMT shall have ready access to a copy of QM via secure intranet and relevant information that are applicable to their responsibilities. The master copy of the QM shall be controlled by the Quality Manager.

9.1.5.5 QPs

The QPs contain the procedures that prescribe how specific tasks are to be performed. These procedures are listed as the followings;

- a) QP-01: Procedure for Control of General Quality Documents;
- b) QP-02: Procedure for Control of Departmental Quality Documents;
- c) QP-03: Procedure for Review of Request, Tenders and Contracts;
- d) QP-04: Procedure for Provision of Products, Services and Supplies;
- e) QP-05: Procedure for Handling of Complaints;
- f) QP-06: Procedure for Control of Nonconforming Work;
- g) QP-07: Procedure for Corrective Actions;
- h) QP-08: Procedure for Addressing the Risks and Opportunities;
- i) QP-09: Procedure for Internal Audits;
- j) QP-10: Procedure for Management Review;
- k) QP-11: Procedure for Staff's Training and Authorization;
- l) QP-12: Procedure for Maintaining Measurement Traceability;
- m) QP-13: Procedure for Processing of Measurement Service Items;
- n) QP-14: Procedure for Assuring the Quality of Results;
- o) QP-15: Procedure for Preparing the Certificate.
- p) QP-16: Procedure for Reference Material Production.
- q) QP-17: Procedure for Selecting, Maintaining the Competence of External Provider.



9.2 CONTROL OF MANAGEMENT SYSTEM DOCUMENTS

9.2.1 GENERAL

9.2.1.1 All quality documents (including policy statements, QM, QPs, DQMs, GQMs, PPs, CPs, SOPs, other needed procedures, specifications, text books, software, drawing, etc.) which may be internally generated or from external sources, are systematically controlled and maintained in order to ensure that the pertinent issue is available at all locations of use.

9.2.1.2 The control system is based on the review, approval, issue and maintenance of documentation.

9.1.1.1 The quality documents which are available to all staff at all locations on the secure network servers are controlled document with effective security and backup systems in place.

9.2.2 DOCUMENT APPROVAL AND ISSUE

9.2.2.1 All quality documents are reviewed and approved by authorized personnel prior to issue. It is periodically reviewed and revised (if necessary) to ensure continuing the suitability and compliance with the applicable requirements.

9.2.2.2 The approval of general quality documents (including the QM, the QPs, general WIs and forms) is under the authority of the Director of NIMT. The Quality Manager or the designated personnel is responsible for reviewing, updating and controlling a master list of such documents.

Details of Procedure for Control of General Quality Documents are described in QP-01.

9.2.2.3 The approval of departmental quality documents (including the CPs, technical WIs, SOPs, other needed procedures and forms used in each department) is under the authority of the Head of Group. The approval of the DQM / GQM is under the authority of the Head of Department. The Head of Group or the designated personnel are responsible for preparing, updating and controlling a master list of such documents.

Details of Procedures for Control of Departmental Quality Documents are described in QP-02.

9.2.2.4 All quality documents generated by NIMT are uniquely identified with the current revision status, date of issue and/or revision identification, page numbering, the total number of pages and the issuing authorities.



9.2.2.5 All quality documents from external sources are marked as controlled document in order to ensure continuing suitability. The master list of general management system documents (such as regulations, standards, etc.) and technical documents (such as standards, specifications, instruction manuals, etc.) are controlled by the Quality Manager and the Head of Group respectively (refer to QP-01 and QP-02).

9.2.2.6 Invalid or obsolete documents are promptly removed from all points of use. The obsolete documents retained for either legal or knowledge preservation will be clearly marked as cancelled or obsolete.

9.2.3 DOCUMENT CHANGES

9.2.3.1 All quality documents shall not be altered without an approval of the authorized personnel.

9.2.3.2 Changes to documents shall be reviewed and approved by the same functions that performed the original review and approval. The designated personnel shall have access to pertinent background information prior to instigating any change.

9.2.3.3 Changes to the all quality documents are identified as described in QP-01 and QP-02.

9.2.3.4 Changes in documents that are maintained in the computerized system are protected by the use of password. The procedures for the control and back-up of the documents that are maintained in computerized system are described in QP-01 and QP-02.



9.3 CONTROL OF RECORDS

9.3.1 GENERAL

9.3.1.1 Records generated and maintained by NIMT constitute the objective evidence necessary to demonstrate:

- a) The conformity of the laboratory management system to the requirements stated in the QM, QPs, DQMs, GQMs, PPs and CPs.
- b) The conformity of the measurement work (contract) to the customer's requirements.

9.3.2 QUALITY RECORDS

9.3.2.1 The quality records are records associated with the management of the quality system and are not directly related to any measurement work. This type of records includes:

- a) record of documents related to document controls (master document registrar, etc);
- b) record of customers' feedbacks;
- c) record of customers' complaints;
- d) record of processed reports of nonconforming work;
- e) record of processed corrective action requests;
- f) record of processed preventive action requests;
- g) record of results of audits both internal and external;
- h) record of reports of management reviews; and
- i) etc.

9.3.2.2 Records can be in either paper or electronic form.

9.3.2.3 All records shall be legible and shall be properly filed and maintained to prevent deterioration and loss. Such records shall be identified with their respective subject title and where appropriate, the form/ record number should be included. They shall be held secure and in confidence to the customers. For all electronic records, the computers that contain such records shall have secured passwords that kept confidential only to authorized and relevant personnel. Moreover, all records in electronic form shall be backed-up at the appropriate interval.

9.3.2.4 All original copies of the above mentioned records except for the ones relating to controlling of the departmental documents and departmental purchasing of supplies and services are maintained in the Quality Manager's office. For these records, the Quality Manager assigns a NIMT staff to hold responsibility to establish and maintain his/her own system for identification, collection, indexing, access, filing, storage, maintenance and disposal.

9.3.2.5 However, each individual department can also keep additional copies or documents of similar records for the purpose of cross-referencing. Each department keeps and maintains its own records relating to controlling of departmental documents and purchasing of supplies and services. In this case, the Head of Department shall assign his/her supervised staff to establish and maintain the system for identification, collection, indexing, access, filing, storage, maintenance and disposal.

9.3.3 TECHNICAL RECORDS

9.3.3.1 The technical records are records that contain sufficient information to support the objective evidence necessary to verify conformity to the technical requirements of the customers. These records include:

- a) records associated with each measurement work performed by individual laboratory (raw data and their analysis);
- b) records associated with evaluation of uncertainty budget;
- c) records associated with data and their analysis that are used in quality control;
- d) environmental records;
- e) equipment records;
- f) records of calibration certificates of measurement standards and reference material used;
- g) records of method validations;
- h) record of software validations;
- i) record of reference material production;
- j) etc.

9.3.3.2 Technical records are maintained to ensure complete traceability of all details relevant to measurements performed by each laboratory. All information relating specifically to the measurement items, such as sample information, measurement results, copies of measurement reports, calibration procedure used and deviation from standard procedures shall be recorded and held on the laboratory record keeping and filing system.

9.3.3.3 Measurement results are generally recorded in measurement recorded files that are dedicated to recording of results from the item being measured. All of the following details must be available from record system:

- a) a measurement item description and identification;
- b) conditions of items in case when abnormally is observed;
- c) all relevant measurement results, observations and calculations;
- d) environmental conditions ;
- e) date of measurement; and
- f) name of person who performed the measurement work that generated such data.

- 9.3.3.4 If no computerized data acquisition is implemented, measurement results must be recorded at the time they are made and must be recorded permanently in ink, in a tidy and legible manner. Any alteration to recorded calibration results must be made by placing a single line through the original result so that it remains clearly visible and recording the correct value beside the incorrect value. Any such alterations must be signed and dated.
- 9.3.3.5 Paper records related to measurement services to customers such as measurement data worksheets, raw data and any relevant information are collected in file separated by job number and stored in a safe place, such as a locked metallic cabinet, which only authorized staff can access. For paper records related to other issues, the responsible staff establishes and maintain his/her own filing system which allow any specific record to be retrieved quickly when needed.
- 9.3.3.6 For electronic records, the responsible staff establishes his/her own file indexing system to effectively organize, manage and protect the electronic records under his/her responsibility. Moreover, if the record has to be maintained, accessed and retrieved by multiple persons, the responsible staff who establishes the recording system shall communicate and explain to his/her peers regarding the detailed procedure to maintain the record so that the system remain harmonized and in place. All electronic records and data that are stored on the computer shall be periodically copied onto electronics or magnetic media such as external hard drives and then stored in the places, which only the authorized staff can enter. The computer that is used to store records or any relevant data shall be placed in the room, which only authorized staff can enter and be protected by using password before accessing this computer.
- 9.3.3.7 Unless otherwise specified by relevant orders or legislative requirements, the record retention period is 10 years.

9.3.4 JOB RELATED RECORDS

- 9.3.4.1 The Job related records are records which constitutes part of objective evidence necessary to verify conformity to the personnel requirements. These records include:
- employment contracts of NIMT staff;
 - training records including training plans and training evaluation;
 - staff evaluations (task/job assignments);
 - staff educational backgrounds and work experiences; and
 - job descriptions.



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- 9.3.4.2 Job related records except for employment contracts and original job description shall be maintained by the Head of Group under the direction of the Head of Departments. They shall be identified under the appropriate indexing system.
- 9.3.4.3 Employment contracts and original job descriptions of all NIMT staff are maintained by the Human Resource Section.
- 9.3.4.4 The quality manager maintains copies of job descriptions in his office for the sake of convenience in retrieval.

9.4 IMPROVEMENT

9.4.1 POLICY

9.4.1.1 NIMT improves the effectiveness of the quality management system and technical capabilities through the use of:

- a) quality policies and quality objectives;
- b) internal and external audit results;
- c) analysis of data;
- d) corrective actions;
- e) preventive actions;
- f) management review;
- g) proficiency testing results;
- h) risk assessment; and
- i) customers' feedbacks.

9.4.2 METHOD AND PROCEDURE

9.4.2.1 The improvement in NIMT is implemented by using the small-step ongoing process to ensure continuous improvement.

9.4.2.2 Continual improvement is a procedure that identifies and addresses improvements in the system and also potential sources of nonconformance.

9.4.2.3 NIMT staff is encouraged to identify the problems, possible improvements and suggestions to the management system or to measurement capability.

9.4.2.4 Suggestions can be made at anytime but are most likely to be made during monthly executive meetings, internal audits and the annual management review. They can then be included within the audit report, minutes of monthly executive meetings, management review report, and/or a Quality Improvement Note (Fr-QIN-01).

9.4.2.5 Head of Department has to select the possible responses to the above suggestions.

9.4.2.6 Relevant staff is responsible for implementing the selected response.

9.4.2.7 Head of Department has to ensure the effectiveness of implementation by monitoring and verifying the results of implementation.

9.4.2.8 All improvements and effectiveness of their implementations shall be reported and reviewed in the next monthly executive meeting and management review meeting.



9.4.2.9 The feedback, both positive and negative, from the customers shall be sought by the Cooperation and Partnership Development Group and analyzed to improve the management system during the management review. However, the negative feedback shall be immediately analyzed according to QP-05 by the responsible department.

9.5 CORRECTIVE ACTION

9.5.1 POLICY

9.5.1.1 Corrective action procedures are established and implemented for ensuring that nonconforming work or any departure from the policies and procedures in the management system or technical operations are identified and corrected in a timely manner.

9.5.1.2 NIMT shall investigate the root cause(s) of the problem found and determine the proper corrective action.

9.5.1.3 Details of Procedure for Corrective Actions are described in QP-07.

9.5.2 MONITORING OF CORRECTIVE ACTIONS

9.5.2.1 The Quality Manager is responsible for monitoring the results to ensure the corrective actions taken have been effective.

9.5.3 ADDITIONAL AUDITS

9.5.3.1 Where the result of investigations casts doubts on the laboratory's compliance with NIMT's own policies and procedures or on its compliance with the ISO/IEC 17025 and/or ISO 17034, the appropriate areas of activities in question shall be audited in accordance with 8.7 as soon as possible.

9.6 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

9.6.1.1 NIMT shall consider the risks and opportunities either concerning the management issue or the technical issue that address to:

- a) give assurance that the management system can achieves its intended result;
- b) enhance desirable effects;
- c) prevent, or reduce, undesired effects;
- d) achieve improvement;
- e) eliminates or minimizes a risk to impartiality.

9.6.1.2 Actions taken to address risks and opportunities shall be proportionate to the potential impact of the validity of laboratory actions and the quality of laboratory results.

9.6.1.3 NIMT shall plan:

9.6.1.3.1) actions to address these risks and opportunities.

9.6.1.3.2) how to:

- a) integrate and implement the actions into its management system process.
- b) evaluate the effectiveness of these actions.

9.6.1.4 Effective action plans shall be developed, implemented and monitored.

9.6.1.5 The Head of Department and/or Risk Management Committee is responsible for evaluating preventive actions and determines if the preventive action is effective. Then further preventive action shall be applied as necessary while the opportunities for improvement will also be endeavored.

9.6.1.6 Records of preventive actions to address risks and opportunities shall be maintained as a quality record and shall be reviewed by NIMT Management during the management reviews of the management system.

9.6.1.7 Details of Procedure for Addressing the Risks and Opportunities are described in QP-08.



9.7 INTERNAL AUDIT

9.7.1 GENERAL

9.7.1.1 NIMT shall carry out internal audits at a predetermined interval in order to ensure that its operations continue to comply with the requirements of the laboratory's policies and procedures and to guarantee that there is no breach to any applicable requirements of the ISO/IEC 17025 and/or ISO 17034.

9.7.1.2 The internal audits must cover every aspect of the requirements of the management system of NIMT including the measurement.

9.7.1.3 Details of Procedure for Internal Audits are described in QP-09.

9.7.2 AUDIT INTERVAL

9.7.2.1 The internal audits are carried out on annual (every twelve months) basis or when a potential deficiency in the Management System has been encountered through means other than an audit.

9.7.3 RESPONSIBILITY

9.7.3.1 The Quality Manager is responsible for the planning, organization and conduction of internal audits. The Quality Manager may appoint any laboratory staff who is qualified as an audit officer(s). It is the policy of NIMT that laboratory staff are not permitted to audit their own activities. Additionally, He / she shall ensure that all corrective actions required by the audit results have been completed within agreed time scale.

9.7.4 AUDIT PERFORMANCE

9.7.4.1 Audit shall be performed in accordance with approved procedures.

9.7.4.2 Auditors shall have access to previous audit results to aid audit preparation.

9.7.4.3 All aspects, both management and technical, of the quality system including the activities of the Cooperation and Partnership Development Group and the Procurement Section shall be audited within the defined audit intervals.

9.7.4.4 Objective evidence shall be examined carefully to determine if the system elements are effectively implemented.

9.7.4.5 The area of activity audited, the audit findings, corrective actions and follow – up audit activities that arise from them shall be recorded.



9.7.5 AUDIT RESPONSE

9.7.5.1 When the audit findings cast doubt on the effectiveness of the operation or on the correctness or validity of the laboratory's measurement results, the Head of Department shall take timely corrective action according to the Procedure for Corrective Action (QP-07) and shall notify customers in writing if investigations show that the laboratory results may have been affected.



9.8 MANAGEMENT REVIEW

9.8.1 GENERAL

9.8.1.1 NIMT management system utilizes the monthly executive meeting and the management review meeting that is organized at least annually to ensure their continuing suitability and effectiveness and to introduce necessary changes or improvements.

9.8.1.2 When changes to the management system are planned and implemented, NIMT management shall ensure the integrity of the management system by monitoring or verifying the effectiveness of all changes.

9.8.1.3 Details of Procedure for Management Review are described in QP -10.

9.8.2 RESPONSIBILITY

9.8.2.1 The Quality Manager is responsible for organizing management review meetings according to the defined schedule.

9.8.2.2 The management review meeting shall be chaired by the Director or the Deputy Director.

9.8.2.3 Participants of the meeting consist of NIMT management team, Quality Manager and support functions concerned. List of NIMT management team was described in Section 5.1.4 and QP-10.

9.8.3 REVIEW FINDINGS AND RESPONSES

9.8.3.1 Findings from management reviews and the actions that arise from them shall be recorded.

9.8.3.2 The Quality Manager is responsible for ensuring that those actions are carried out within an appropriate timescale.



9.9 SERVICE TO THE CUSTOMER

- 9.9.1.1 NIMT reserves the right to prohibit customers from reviewing information, data and/or measurement activities being performed for other customers.
- 9.9.1.2 Access to the relevant areas of NIMT Laboratory by the customer or the customer's representative for the witnessing of work performed for the customer shall be defined and controlled.
- 9.9.1.3 Any feedbacks obtained from customers shall be used and analyzed to improve the management system, measurement activities and customer services by relevant personnel.
- 9.9.1.4 NIMT will seek feedbacks from customers. The feedbacks could be obtained in a form of:
- a) paper survey;
 - b) e-mail survey;
 - c) facsimile survey; or
 - d) telephone survey.
- 9.9.1.5 At least once a year, the Quality Manager shall solicit customer feedbacks both positive and negative as part of the continuous improvement process. Feedbacks shall be documented and evaluated. Negative feedbacks shall be documented as customer complaints.

10. ANNEX

10.1 CROSS REFERENCE

10.1.1 CROSS-REFERENCES TO ISO/IEC 17025 REQUIREMENTS, ISO 17034 AND QP ARE LISTED IN THE TABLE.

ISO/IEC 17025:2017		ISO 17034:2016		QM		QP	
2	Normative references	2	Normative references	2	Definitions	N/A	N/A
3	Terms and definitions	3	Terms and definitions	2	Definitions	N/A	N/A
1	Scope	1	Scope	3.2	Scope	N/A	N/A
4	General requirements	4	General requirements	4	General Requirement	N/A	N/A
4.1	Impartiality	4.2	Impartiality	4.1	Impartiality	N/A	N/A
4.2	Confidentiality	4.3	Confidentiality	4.2	Confidentiality	N/A	N/A
5	Structural requirements	5	Structural requirements	5	Structural requirements	N/A	N/A
6	Resource requirements	6	Resource requirements	6	Resource requirements	N/A	N/A
6.1	General	N/A	N/A	N/A	N/A	N/A	N/A
6.2	Personnel	6.1	Personnel	6.1	Personnel	QP-11	Procedure for staff's training
6.3	Facilities and environmental conditions	6.4	Facilities and environmental conditions	6.2	Facilities and environmental conditions	N/A	N/A
N/A	N/A	6.2	Subcontracting	6.3	Externally provided products and services	QP-17	Procedure for selecting and maintaining the competence of external provider
6.6	Externally provided products and services	6.3	Provision of equipment, services and supplies	6.4	Provision of products, services and supplies	QP-04	Procedure for Provision of products, services and supplies
6.4	Equipment	7.7	Measuring equipment	6.5	Equipment	N/A	N/A
6.5	Metrological traceability	7.9	Metrological traceability of certified value	6.6	Metrological traceability	QP-12	Procedure for maintaining measurement
7	Process requirements	7	Technical and production	7	Process requirements	N/A	N/A
7.1	Review of requests, tenders and contracts	4.1	Contractual matters	7.1	Review of requests, tenders and contracts	QP-03	Procedure for reviews of requests, tenders and contracts
7.3	Sampling	N/A	N/A	7.2	Sampling	N/A	N/A
7.4	Handling of test or calibration items	7.4	Material handling and storage	7.3	Handling of measurement services	QP-13	Procedure for processing of measurement service items
7.2	Selection, verification and validation of methods	7.6	Measurement procedures	7.4	Methods and measurement procedures	QP-13	Procedure for processing of measurement service
7.6	Evaluation of measurement uncertainty	7.8	Data integrity and evaluation			N/A	N/A
		7.13	Assignment of property values and their uncertainties			N/A	N/A
7.8	Reporting of results	7.14	Reference material documents and labels	7.5	Reporting the results	QP-15	Procedure for preparing of the certificate
7.7	Ensuring the validity of results	N/A	N/A	7.6	Ensuring the validity of results	QP-14	Procedure for assuring the quality of results
7.10	Nonconforming work	7.17	Management of nonconforming work	7.7	Control of nonconforming work	QP-06	Procedure for control of nonconforming work



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ISO/IEC 17025:2017		ISO 17034:2016		QM		QP	
7.9	complaints	7.18	Complaints	7.8	complaints	QP-05	Procedure for handling of complaints
N/A	N/A	7.15	Distribution service	7.9	Distribution service of RM	N/A	N/A
N/A	N/A	7.1	General requirements	8	Production requirement	QP-16	Procedure for reference material production
N/A	N/A	7.2	Production Planning	8.1	Reference material production planning and control	QP-16	Procedure for reference material production
N/A	N/A	7.3	Production control	8.1	Reference material production planning and control	QP-16	Procedure for reference material production
N/A	N/A	7.5	Material processing	8.2	Material processing, homogeneity and stability assessment and characterization	N/A	N/A
		7.1	Assessment of homogeneity				
		7.11	Assessment and monitoring of stability				
		7.12	Characterization				
8	Management system requirements	8	Management system requirements	9	Management system requirements	N/A	N/A
8.1	Options	8.1	Options	N/A	N/A	N/A	N/A
N/A	N/A	8.2	Quality policy	9.1	Management system	N/A	N/A
8.2	Management system documentation	8.3	General management system documentation	9.1	Management system	N/A	N/A
8.3	Control of management system documents	8.4	control of management system documents	9.2	control of management system documents	QP-01	Procedure for the control of general quality documents
						QP-02	Procedure for control of departmental quality documents
7.5	Technical records	8.5	Control of records	9.3	Control of records	N/A	N/A
7.11	Control of data and information management						
8.4	Control of records						
8.6	Improvement	8.10	Improvement	9.4	Improvement	N/A	N/A
8.7	Corrective actions	8.9	Corrective actions	9.5	Corrective action	QP-07	Procedure for corrective action
8.5	Actions to address risks and opportunities	8.8	Actions to address risks and opportunities	9.6	Actions to address risks and opportunities	QP-08	Procedure for addressing the risks and opportunities
8.8	Internal audits	8.7	Internal audit	9.7	Internal audit	QP-09	Procedure for internal audits
8.9	Management reviews	8.6	Management review	9.8	Management review	QP-10	Procedure for management review
N/A	N/A	8.11	Feedback from customers	9.9	Service to the customer	N/A	N/A



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