Edition 10

Revision 00

QUALITY PROCEDURES

QSWG

NIMT

1 February 2019

FOREWORD TO CURRENT EDITION

In this edition, the following changes have been applied to accommodate the requirements of ISO/IEC 17025:2017 and ISO 17034:2016:

1) In QP-02: The GQM has been added in the procedure.
2) In QP-05: The procedure for handling of complaints has been modified to be more transparent and comply with the new concept of ISO17025: 2017.
3) In QP-06: The procedure is improved to allow any staff to raise the nonconforming work with more examples of nonconforming work.
4) In QP-07: The handling of risks and opportunities determined during planning for corrective actions are defined.
5) In QP-08: The risk to impartiality is considered in the procedure for addressing the risk and opportunities.
6) In QP-10: The inputs of management review is updated to comply with the new concept of ISO17025: 2017
7) In QP-15: The information reported in analysis certificate of CRMs has been updated.

Other changes are for typographical errors and grammatical errors.

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QP-01: PROCEDURE FOR CONTROL OF GENERAL QUALITY DOCUMENTS

1 OVERVIEW

	Responsibilities	Activities	Related Documents
1.1	Quality system staff	Prepare a draft of document	– New / re-issued document – Master Document Register
		⇩	
1.2	QSWG	Review the document	– New / re-issued document
		⇩	
1.3	Director of NIMT	Approve the document	– New / re-issued document
		⇩	
1.4	Quality System Staff	Update Master Document Register, makes the document available to all staffs via the intranet and reviews the document periodically	– Master Document Register – Electronic document – Original document file – Document Review Record

2 PURPOSE

The purpose of this procedure is to establish and maintain a system to control all general quality documents that relate to the management system of NIMT.

3 SCOPE

This procedure applies to all general quality documents of NIMT which are under the responsibility of the Quality Manager.

4 DEFINITION

4.1 General quality documents

General quality documents are documents defined for the general administrative and management system including Quality Manual (QM), Quality Procedure (QP), Work Instruction (WI) and Forms.

5 PROCEDURE

5.1 The Quality system staff prepares a draft of new or re-issued general quality document (hereafter referred to as "document") as requested by the Quality Manager.

5.1.1 A document is uniquely identified by the title, the current edition and revision numbers, which are also referred to in the form Fr-DOC-01: Master Document Register, and the date of issue. All pages in all documents must contain page numbering with the total number of pages.

5.1.2 Forms required by documents are issued with individual form number, year of issue and revision identification.

5.1.3 Details of the QP consist of overview, purpose, scope, definition procedure, and related forms.

5.1.4 In case of a re-issued document, the designated personnel will receive an electronic file of original document from quality system staff. He/she shall have access to pertinent background information prior to instigating a change. For the QM, changes are made as the whole document while changes are made separately for each individual QP and the number of revision is changed accordingly. The altered or new text is marked in such a way to make the change observable.

In case of the immediate change in the QM / QP are needed. The Quality Manager can make the amendment by hand. The amendment shall be clearly marked, initialed and dated. The revised document shall be formally re-issued within two months.

5.2 The QSWG reviews the document and makes corrections, if necessary. Then the final document is submitted to the Director of NIMT for the approval.

5.3 The Director of NIMT approves the document. This document will be considered as the original document.

5.4 The Quality System Staff updates the Master Document Register and makes the document available to all staff via the intranet.

5.4.1 The Quality System Staff electronically protects the approved document in its electronic format (read and print only). The protected electronic document is placed in the intranet server by the server controller. At the same time, the information of document issue or change is also provided to all staff via the intranet.

When the document is printed, it will be considered as an uncontrolled copy. However, the external distribution of any documents, electronic or paper, shall be prohibited without permission.

5.4.2 The Quality System Staff keeps the original paper document and its corresponding electronic file. Obsolete original document is retained and clearly marked as cancelled or obsolete. Retention period of these documents is 10 years.

5.4.3 The electronic file of original document maintained in computerized system is duplicated for backing-up purpose prior to all changes. The computerized system is protected by the use of password to prevent unauthorized access.

5.4.4 The document may be given to external organizations and customers for information purposes only with the permission from the Quality Manager. Unless otherwise specified, such document will be uncontrolled copy.

5.4.5 The whole documents are re-issued for a new edition after a practical number of changes, but not more than 10 times.

5.4.6 The quality documents from external sources, such as regulations and standards, will be marked as controlled document. The Quality Section will control these documents by the use of the record fileFr-DOC-01: Master Document Register.

5.4.7 The QSWG shall review all documents (including the quality documents from external sources) to ensure continuing suitability and compliance with applicable requirements by a period not exceeding 12 months.

Results of the review are retained in the record file Fr-DOC-02: Document Review Record.

6 RELATED FORMS

6.1 Fr-DOC-01: Master Document Register

6.2 Fr-DOC-02: Document Review Record

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QP-02: PROCEDURE FOR CONTROL OF DEPARTMENTAL QUALITY DOCUMENTS

1 OVERVIEW

	Responsibilities	Activities	Related Documents
1.1	Designated personnel	Prepare a draft of document	– New / reissued document – Master Document Register
		⇩	
1.2	Head of Laboratory	Review the document	– CP, PP, WI, SOP and Forms
		⇩	
1.3	Head of Group	Approve the document	– CP, PP, WI, SOP and Forms
		⇩	
1.4	Head of Group	Review the document	– DQM / GQM – Document Forms and External source
		⇩	
1.5	Head of Department	Approve the document	– New / reissued document
		⇩	
1.6	Document Control Personnel	Updates Master Document Register, and makes the DQM/GQM available to the staff via the server	– Master Document Register – Electronic document – Original document file
		⇩	
1.7	Head of Group	Review the document periodically	– Master Document Register – Review Record

2 PURPOSE

The purpose of this procedure is to establish and maintain a system to control all departmental quality documents that relate to the management system of NIMT.

3 SCOPE

This procedure applies to all departmental quality documents which are under the responsibility of Head of Department.

4 DEFINITION

4.1 Departmental quality documents

Departmental quality documents are documents defined for specific details of operation within each Department including the Department Quality Manual (DQM), the Group Quality Manual (GQM), the Calibration Procedures (CP), the Production Procedure (PP), technical Work Instructions (WI), Standard Operating Procedure (SOP) and Forms.

5 PROCEDURE

5.1 The designated personnel prepares a draft of new or re-issued departmental quality document (hereafter referred to as document) as requested by the Head of Department.

5.1.1 The document is uniquely identified by the title, current edition and revision status by referring to the record file Fr-DOC-01: Master Document Register, date of issue, page numbering with the total number of pages.

Forms required by the document are issued with individual form number, year of issue and revision identification.

5.1.2 Each DQM / GQM consists of description of the department / group, premises and environmental condition, equipment, calibration and/or measurement procedures, handling of the service items and recording and filing system.

5.1.3 Each CP as minimum, consists of calibration description, equipment requirements, preliminary operations, calibration procedure in details, basic equations or measurement model(s) and description of measurement uncertainty budget.

5.1.4 Each PP as minimum, consists of RM description, material selection, accommodation and environment condition, equipment requirements, metrological traceability, material processing, certification measurement method, homogeneity and stability assessment, measurement uncertainty and material handling and storage.

5.1.5 In case of a re-issued document, the designated personnel shall have access to pertinent background information prior to instigating a change. Changes to each document are made as a whole document, and the number of revision is changed accordingly. The altered or new text is marked in such a way to make the change observable.

5.2 The Head of Group reviews the DQM / GQM and Head of Laboratory reviews the CP, PP, WI, SOP and Form.

5.3 The Head of Department approves the DQM / GQM and Head of Group approves the CP, PP, WI, SOP and Form. This document will be considered as the original document.

5.4 The Document Control Personnel updates the Master Document Register and makes the DQM / GQM available to all staff in the department on the appropriate departmental directory on NIMT server(s).

5.4.1 The Document Control Personnel protects the corresponding electronic file of the approved DQM / GQM to allow only reading and printing, and then places it in the departmental directory on NIMT server.

5.4.2 When the DQM / GQM is printed, it will be an uncontrolled copy (using the watermark).

5.4.3 In case of the DQM / GQM , the Document Control Personnel keeps the original document. Obsolete original DQM / GQM is retained and clearly marked as cancelled.

5.4.4 In case of the CP, PP,WI, SOP and Form the original document is given to the staff who performs the operation. Obsolete document (if any) is promptly removed from the point of use. It should be clearly marked as cancelled when it is retained for knowledge preservation purposes. The minimum retention period is 10 years.

5.4.5 The electronic file of the original document maintained in computerized system is duplicated for back-up purpose prior to any changes. The computerized system is protected by the use of password to prevent unauthorized access.

5.4.6 The document may be given with the permission from the Head of Department to external organizations and customers for information purposes. Unless otherwise specified, such document will be uncontrolled copy which is not successively updated.

5.4.7 The whole documents are re-issued for a new edition after a practical number of changes, but not more than 10 times.

5.5 The Head of Laboratory shall review CP, PP, WI, SOP and Form and Head of Group shall review DQM / GQM(including the quality documents from external sources) to ensure continuing suitability and compliance with applicable requirements by a period not exceeded 12 months.

Results of the review are retained in record file Fr-DOC-02: Document Review Record.

In case of the immediate changes in the DQM / GQM, CP, PP are needed, the Head of Group can make the amendment by hand. The amendment shall be clearly marked, initialed and dated. The revised document shall be formally re-issued within two months.

The quality documents from external sources, such as regulations, standards, and equipment's instruction/operation manuals (only the ones which need to control the versions), will be marked as controlled document. The Head of Group will control these documents by the use of the record file Fr-DOC-01: Master Document Register.

6 RELATED FORMS

6.1 Fr-DOC-01: Master Document Register

6.2 Fr-DOC-02: Document Review Record

QP-03: PROCEDURE FOR REVIEW OF REQUESTS,TENDERS AND CONTRACTS

1 OVERVIEW

	Responsibilities	Activities	Related Documents
1.1	Customer / Staff of Corporation and Partnership Development Group	Fill in the online request for measurement services.	http://calservices.nimt.or.th
		⇩	
1.2	Staff of Corporation and Partnership Development Group	Review and make necessary corrections in the online database and send ORJ to the senior staff.	– Online customer's request job (ORJ)
		⇩	
1.3	Senior Staff of Corporation and Partnership Development Group	Review and make final approval and distribute the job to the relevant Head of Department.	– ORJ
		⇩	
1.4	Head of Department	Review the ORJ and distribute to the relevant Head of Group.	– ORJ
		⇩	
1.5	Head of Group	Review and assign the ORJ to the relevant laboratory staff.	– ORJ
		⇩	
1.6	Relevant Laboratory staff	Fill in necessary information (service fee and additional charge) and send to the Head of Group for review.	– Completed ORJ

		⇩	
1.7	Head of Group	Review the completed ORJ and if no changes, forwards to the Head of Department	– Completed ORJ becoming reviewed ORJ
		⇩	
1.8	Head of Department	Make final review and if there are no objections, approve the reviewed ORJ and send back to the staff of Corporation and Partnership Development Group	– Reviewed ORJ becoming the approved ORJ (equivalent to approved CIF)
		⇩	
1.9	Staff of Corporation and Partnership Development Group	Review the approved ORJ, print out the report from the job onto the CIF template, keep the hardcopy, key in the information from the CIF to the Forma system to issue the quotation and print out the quotation. Send the approved ORJ to the senior staff and concurrently submit the hard-copies of CIF and quotation to the senior staff for approval.	– Approved ORJ – CIF (paper version) – Quotation
		⇩	
1.10	Senior Staff of Corporation and Partnership Development Group	Review the approved CIF and the quotation to verify the agreement of all information and submit the online job for pending status (wait for customer's acceptance.)	– Pending ORJ for converting to the Online Work Order (OWO) – CIF – Quotation
		⇩	
1.11	Customer	Customer accepts or rejects the quotation.	– Quotation

2 PURPOSE

The purpose of this procedure is to ensure that the customer's requirements have been reviewed in a systematic and efficient manner before any work is accepted by NIMT.

3 SCOPE

The procedure applies to all customers' requirements for review of requests, tenders, and contracts by NIMT.

4 DEFINITION

4.1 Request - Any inquiry, requirement and request for quotations.

4.2 Contract - Agreed order or quotation with customer's signatory.

5 PROCEDURE

5.1 The customer fills in the online request for measurement services at http://calservices.nimt.or.th.

5.2 Staff of the Corporation and Partnership Development Group reviews and makes necessary corrections in the online database and sends the online customer's request job (ORJ) to the senior staff.

5.3 The senior staff of the Corporation and Partnership Development Group reviews and makes final approval of the ORJ then distribute the ORJ to the relevant Head of Department.

5.4 The Head of Department reviews the ORJ and forwards to the relevant Head of Group. Refer to quality procedures under the management system according to ISO 9001 for further details.

5.4.1 In case of the ORJ being distributed incorrectly, the ORJ shall be returned back to the senior staff of the Corporation and Partnership Development Group for re-distribution.

5.5 Head of Group reviews the job and assigned the ORJ to the relevant Laboratory staff.

5.5.1 In case of the ORJ being assigned incorrectly, the ORJ shall be returned back to the Head of Department for re-distribution and the process shall loops back to 5.4 and continue.

5.6 The relevant Laboratory staff fills in necessary information (service fee and additional charge) and sends back to the Head of Group.

5.6.1 In case of the ORJ being assigned incorrectly, the ORJ shall be retuned back to the Head of Group for re-assignment and the process shall loop back to 5.5 and continue.

5.7 The Head of Group reviews the completed ORJ and if no changes, forwards to the Head of Department.

5.7.1 Any changes and pertinent discussions with the customer shall be recorded in the note area of online customer's request job.

5.7.2 If any corrections are needed, the ORJ shall be sent back to the relevant Laboratory staff for correction and the process shall loop back to 5.6 and continue.

5.8 The Head of Department makes final review and if there are no objections, approves the ORJ and sends the approved ORJ back to the staff of Corporation and Partnership Development Group.

5.9 Staff of Corporation and Partnership Development Group reviews the approved job, print out the report from the job onto the CIF template, keeps the hardcopy, key in the information from the CIF to the Forma system to issue the quotation and print out the quotation. He/she then sends the approved ORJ to the senior staff and concurrently submit the hard-copies of CIF and quotation to the senior staff for approval.

5.10 The senior staff of Corporation and Partnership Development Group reviews the approved CIF and the quotation to verify the agreement of all information and submit the approved ORJ for pending status (wait for customer's acceptance.)

5.11 Customer accepts or rejects the quotation.

In some cases, the changes might affect the service cost and there is need for a new quotation to be issued. In these cases, the laboratory shall inform the Corporation and Partnership Development Group to issue the new quotation accordingly and step 5.6 to 5.8 shall be repeated.

Records of request and contract review shall be maintained by the electronic database but the record of contracts (accepted quotations) shall be maintained by the Corporation and Partnership Development Group.

If the customer requests any change of information at any point after the ORJ has been approved by the Head of Department and send to the Corporation and Partnership Development Group, the customer have to fill-in another Online Request Form and the Corporation and Partnership Development Group shall close the approved ORJ job.

If the customer requests any change of information at any point before the ORJ has been approved by the Head of Department and send to the Corporation and Partnership Development Group, use the flow-back loop to correct the information accordingly. The relevant staff must record all notes including date and time that the change is requested by the customer and who is corresponding with the customer.

NOTE: The steps 5.1 to 5.11 above apply for service items performed in-house for external customers only. For service items of the internal customers, the following steps from 5.9 to 5.16 shall be adopted.

5.12 The metrologist who intends to have the equipment calibrated internally must log in to the online system at http://calservices.nimt.or.th/cal2017/staff/login.php to fill in the Internal Calibration Service Request. Please note that the owner of the equipment must be the log-in person. The online request must have details of parameter(s) and range(s) requested as well as the laboratory who will provide the internal calibration service. Additionally, the period of calibration must be specified. The request should be done during the month of October to January before the intended calibration year.

5.13 The online request shall be sent to the relevant targeted Head of Department. Head of department reviews the online request and distributes the job to the relevant Head of Group.

5.14 Head of Group reviews the assignment and forward the job to relevant laboratory staff.

5.15 The relevant staff accepts the assignment and sends back to Head of Group.

5.16 Head of Group reviews and forwards the reviewed job to the Head of Department.

5.17 Head of Department approves the job and sends to the staff of the Corporation and Partnership Development group and the job will be pending until the scheduled calibration date.

5.18 When the equipment is ready for calibration, the owner informs the staff of the Corporation and Partnership Development Group to update the job status to the Work Order job.

5.19 Processing of Measurement Service Items according to QP-13.

6 RELATED FORMS

6.1 CIF: Customer Inquiry Form

6.2 Quotation

6.3 Online customer's request job (ORJ)

QP-04: PROCEDURE FOR PROVISION OF PRODUCTS, SERVICES AND SUPPLIES

1 OVERVIEW

	Responsibilities	Activities	Related Documents
1.1	Laboratory staff	Prepare requisition	– Purchase Requisition (PR) – Approved Vendor List (AVL)
		⇩	
1.2	Head of Group	Preliminarily review requisition	– Purchase Requisition (PR)
		⇩	
1.3	Head of Department	Review and verify the technical specification	– Purchase Requisition (PR)
		⇩	
1.4	Staff of Account, Financial accounting and supply Group	Inspect the procurement procedure	– Purchase Requisition (PR)
		⇩	
1.5	NIMT Director / authorized personnel	Approve the requisition	– Purchase Requisition (PR)
		⇩	
1.6	Staff of Procurement Section	Process the purchasing	– Purchase Order (PO)
		⇩	
1.7	Head of Group / the designated receiving committee	Inspect product before use and evaluate the supplier	– Equipment Inspection – Vendor Evaluation

		⇩	
1.8	Staff of Account, Financial accounting and supply Group	Update AVL	– Approve Vendor List (AVL)

2 PURPOSE

The purpose of this procedure is to ensure that all equipment, consumable materials and services are evaluated and have the ability and capacity to meet the specified requirements.

3 SCOPE

This procedure applies to all purchasing of all equipment, consumable materials, and services that are necessary to provide and maintain measurement services.

4 DEFINITION

4.1 Purchase Requisition

A **Purchase Requisition** is a document (including drawings and specifications) which clearly describes the scope of works or the requirements being purchase.

5 PROCEDURE

5.1 The laboratory staff selects the product or service provider that can provide the product and service according to the required specifications of the laboratory. The providers listed in the Approved Vendor List are preferred.

In case of external calibration utilized by laboratory, the laboratory staff 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.

The laboratory staff shall then clearly fill and concisely write in the Purchase Requisition Form or other attached documents with the technical requirements that may include detail such as:

1) select the purchasing method;
2) type, class, grade or other accurate and precise identifications;
3) description, quantity of the request for calibration services or supplies;
4) calibration or test certificates, delivery dates, packing and shipping instructions;

5) appropriate drawings, processes, and special instructions;
6) any requirements for approval and/or qualification of product;
7) the proper purchasing method according to NIMT's regulations (only in some special circumstance such as the goods are needed in a short time).

5.2 The Head of Group shall preliminarily review the Purchase Requisition to ensure accuracy and completeness of specified information.

5.3 The Head of Department is responsible for final review and verification of the technical specification stated in the Purchase Requisition.

5.4 The staff of the Account, Financial accounting and supply Group is responsible for previewing the Purchasing Requisition, and/or confirms the purchasing method and proposes a laboratory staff or a committee responsible for the inspection (the so-called "designated receiving committee) according to NIMT's regulations (refer to Quality Procedures under the management system according to ISO 9001). The staff shall then propose the Purchase Requisition to the NIMT director or the authorized personnel as govern by NIMT's regulation.

5.5 The NIMT director or the authorized personnel approves the Purchase Requisition if he/she sees appropriate.

5.6 The staff of the Account, Financial accounting and supply processes the purchasing according to the information and method stated in the Purchase Requisition.

5.7 The Head of Group is responsible for inspecting the received product or service to ensure its compliance with the original specification as stated in the Purchase Requisition when the product and service is delivered. The result of the inspection shall be recorded onto the form Fr-EQU-01: Equipment Inspection and forward its copy to the staff of the Account, Financial accounting and supply Group for the payment. The original of equipment inspection shall be kept in the laboratory.

In case of the receiving committee is designated, the inspection process shall follow NIMT's regulation accordingly.

In some circumstance, any items of services and supplies do not conform to specified requirements. In such case, the items shall be rejected and the Head of Group shall notify the staff of the Account, Financial accounting and supply Group.

In case of purchased reagents or consumable materials, they shall be stored in such a manner to prevent damage or deterioration for whole period of their useful lives.

The Head of Group shall then evaluate the supplier in technical parts according to the procedures defined in the management system according to ISO 9001 at least every 12 months.

5.8 The staff of the Account, Financial accounting and supply Group updates the Approved Vendor List based on the evaluation information provided by the laboratory.

The staff of the Account, Financial accounting and supply Group shall cooperate with NIMT laboratory staff to annually evaluate the whole Approved Vendor List.

6 RELATED FORMS

6.1 Purchase Requisition Form

6.2 Approved Vender List Form

6.3 Fr-EQU-01: Equipment Inspection

QP-05: PROCEDURE FOR HANDLING OF COMPLAINTS

1 OVERVIEW

	Responsibilities	Activities	Related Documents
1.1	NIMT Staff	Receive the complaint and fill-in the complaint form	– Complaint Note (Section 1)
		⇩	
1.2	Quality Manager / Deputy Quality Manager and Relevant Persons as defined in QP-06 or QP-07 by NC or CAR	- Evaluate the significance of the complaint and initiate NC report or issue CAR, based on detail of the nature of the complaint and proceed according to Procedure for NC or Procedure for CAR as necessary - Acknowledge the complaint the receipt of complaint	– Complaint Note (Section 2) – Complaint Log – Report of Nonconforming Work – Corrective Action Request
		⇩	
1.3	Assigned NIMT Staff	- Process the correction of the complaint according to justification of the Quality Manager / Deputy Quality Manager - Provide the progress report and the outcome to complainant	– Complaint Note (Section 3) – Complaint Log – Report of Nonconforming Work – Corrective Action Request
		⇩	
1.4	Quality Manager / Deputy Quality Manager	- Approve the completion of the complaint when the process for NC and/or CAR is/are completed as necessary - Give the formal notice of the end of complaints handling to complainant	– Complaint Note (Section 3) – Complaint Log

2 PURPOSE

The purpose of this procedure is for ensuring that any complaints received from customer or other parties are considered, justified and resolved promptly and effectively.

3 SCOPE

This procedure applies to all complaints received from customers or other parties, which can be verbally or in writing.

4 DEFINITION

4.1 Complaint

A **complaint** is any dissatisfactory issues raised by customers or other parties, relating to the activities or results of NIMT.

5 PROCEDURE

5.1 The NIMT staff receiving a complaint shall fill-in the detailed description of the complaint in the section 1 of the form Fr-COM-01: Complaint Note. When the section 1 is completed, the form shall be sent to the Quality Manager (either via e-mail if using the electronic format or by person if using the paper format)

5.2 To handle the complaints transparently, the Deputy Quality Manager will act as the Quality Manager in case the activities in question involved with the Quality Manager.

The Quality Manager / Deputy Quality Manager shall investigate the complaint and justify the significance of the complaint. The Quality Manager / Deputy Quality Manager shall determine the nature of the complaint and justify whether it leads to any nonconformity or noncompliance or not. There could be three circumstances:

5.2.1 If the complaint leads to a nonconforming work, the Quality Manager / Deputy Quality Manager shall enter the complaint in the form Fr-NCR-01: Report of Nonconforming Work and concurrently follows QP-06:Procedure for Control of Nonconforming Work

5.2.2 If the complaint leads to any other noncompliance (aspect related to quality system), the Quality Manager / Deputy Quality Manager shall issue CAR and concurrently follows QP-07:Procedure for Corrective Actions.

5.2.3 For any other cases, it implies that the complaint needs only an immediate correction and therefore the process can go directly to the last step.

The Quality Manager / Deputy Quality Manager shall then fill-in the detail of the investigation and the result of his/her justification into section 2 of the received form and keeps the form on record until the process reaches the last step which depends on whether NC or CAR is issued or not.

The process goes through QP-06:Procedure for Control of Nonconforming Work or QP-07:Procedure for Corrective Actions as necessary.

The Quality Manager / Deputy Quality Manager shall acknowledge the complainants the receipt of their complaint(s).

5.3 The assigned laboratory staff performs the necessary actions according to the investigation and the result of justification of the Quality Manager / Deputy Quality Manager.

Whenever possible, the progress reports and the approved outcome of the complaint handling shall be provided and communicated to the complainant.

5.4 The Quality Manager / Deputy Quality Manager reviews and approves the outcome and completes the handling of the complaint by filling in section 4. For the case of 5.2.1 or 5.2.2, the complaint is approved only when NC or CAR is completed. After all sections of the form Fr-COM-01: Complaint Note have been completed, the Quality Manager shall keep the appropriate record of the Complaint Note and give formal notice of the end of the complaint handling to the complainant.

6 RELATED FORMS

6.1 Fr-COM-01: Complaint Note (Electronic fill-able form)

6.2 Fr-COM-02: Complaint Log (Electronically maintained log file)

6.3 Fr-NCR-01: Report of Nonconforming Work(Electronic fill-able form)

6.4 Fr-CAR-01: Corrective Action Request (Electronic fill-able form)

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QP-06: PROCEDURE FOR CONTROL OF NONCONFORMING WORK

1 OVERVIEW

	Responsibilities	Activities	Related Documents
1.1	NIMT Staff	Raise a nonconformity	– Report of Nonconforming Work (Section 1) – Nonconforming Report Log
		⇩	
1.2	Head of Group	Evaluate the nonconformity and propose an optimized disposition.	– Report of Nonconforming Work (Section 2)
		⇩	
1.3	Head of Department /Quality Manager (In case CAR has been raised)	Approve the proposed disposition / Issue CAR	– Report of Nonconforming Work (Section 3)
		⇩	
1.4	Assigned NIMT Staff	Perform the necessary action	– Report of Nonconforming Work (Section 4)
		⇩	
1.5	Head of Department	Verify the effectiveness of the resolution to the nonconformity and maintain the record.	– Report of Nonconforming Work (Section 5)
		⇩	
1.6	Quality Manager	Acknowledge the verification of the effectiveness of the resolution.	– Report of Nonconforming Work(Section 6) – Nonconforming Report Log

2 PURPOSE

The purpose of this procedure is to provide a system for ensuring that nonconforming measurement work is promptly identified, documented and corrected in accordance with the laboratory policy and the requirements of the customer.

3 SCOPE

This procedure applies to all nonconformities detected in measurement work or problems with the management system or with the calibration activities.

4 DEFINITION

4.1 Nonconformity

Nonconformity is a deficiency in characteristics, documentation, or process implementation which renders the quality of a measurement work that required by the relevant specification, contract or regulation.

NOTE The examples of nonconformity are as follows:

- Significant mistakes of calibration certificate

- Overloading or mishandling of equipment

- Overdue status of equipment

- Unsatisfying result of quality control

- Customer complaints that cause the doubt about laboratory's compliance

- Record system failures

5 PROCEDURE

5.1 NIMT Staff who discovers that any aspect of a measurement work or the result of such work does not conform to the defined procedures or the agreed requirements of the customer can raise the nonconformity by filling-in the section 1 of the form Fr-NCR-01: Report of Nonconforming Work. The running number shall be in the format of NCR-DD-YYYY-###. The new report number shall be recorded on to the Nonconforming Report Log using the form Fr-NCR-02: Nonconforming Report Log. The filled form shall then be submitted to the relevant Head of Laboratory either by sending the saved file as an e-mail attachment or by submitting the paper form in person.

5.2 The Head of Group investigates the laboratory own measurement system, measurement standards, and measurement procedures used for the nonconforming work and justify the significance of the nonconformity by the following criteria :

5.2.1 Insignificant nonconformity has no direct effect on the accuracy, trueness and precision of the measurement and its reported uncertainty budget e.g. the discovery that the standard used in the measurement work drifted unexpectedly, but the uncertainty component due to the drift of the standard is a minor component in the uncertainty budget. In this case, the work shall be considered "accepted-as-is".

5.2.2 Significant nonconformity has direct effect on the accuracy, trueness and precision of the measurement and its reported uncertainty budget. In this case, the Head of Group shall decide whether or not to halt the calibration works being affected, to withhold the calibration certificates and to resume works. He / She shall then propose to the Head of Department. Disposition of the major nonconforming measurement work may be one of the following;

a) "rework" means the measurement or its report shall be reproduced for the nonconforming measurement item;
b) "reject" means the nonconforming measurement item is proved to be nonconforming by itself; the reproduction of the measurement cannot resolve the nonconformity and therefore, the item shall be rejected and returned to the customer.

For the case of significant nonconformity, the Head of Group shall inform the customer regarding the matter.

After the completion of the investigation, the Head of Group fill-in the result of the investigation and the detail of the proposed disposition in the section 2 of the received form and continue sending the form to the Head of Department.

5.3 The Head of Department shall evaluate the proposed report from the Head of Group. If the report indicates that the nonconforming work could recur or that there is doubt about the compliance of NIMT's operations with its own policies and procedures, the Head of Department shall notify the Quality Manager to issue CAR by filling-in necessary information into the section 3 of the received form before sending it to the Quality Manager and request the Quality Manager to send the form back with the complete information in the section 3. Meanwhile, QP-07:Procedure for Corrective Actions shall be followed. When the Head of the Department gets the form back from the Quality Manager, he/she shall then send the form to the assigned laboratory staff. However, if the CAR is not necessary, the Head of the Department can directly send the form to the assigned laboratory staff.

5.4 The NIMT laboratory staff performs necessary actions as assigned by the Head of Department and when the action is completed, he/she shall report the result of the taken action into the section 4 of the received form and returns the form to the Head of Department.

5.5 The Head of Department shall verify the effectiveness of the taken action by filling-in the section 5 of the received form and continues on sending the form to the Quality Manager for acknowledgement. In case of the CAR has been issued in step 5.3, the Head of Department shall ensure that the CAR is closed prior to the verification. In case of the effectiveness of taken action is not approved, the Head of Department shall decide whether or not to raise the new nonconformity to resolve as unapproved issue.

5.6 The Quality Manager acknowledges the control of the nonconforming work by completing in the section 6 of the received form. At the end, the Quality Manager has to send the completed form back to the Head of Department who will then save the form in the appropriate record file. The Nonconforming Report Log shall be updated.

6 RELATED FORMS

6.1 Fr-NCR-01: Report of Nonconforming Work (Electronic fill-able form)

6.2 Fr-NCR-02: Nonconforming Report Log (Electronic Log File)

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QP-07: PROCEDURE FOR CORRECTIVE ACTIONS

1 OVERVIEW

	Responsibilities	Activities	Related Documents
1.1	Quality Manager	Issue CAR	– NC Report, Internal Audit Report, External Audit Report, Management Review Report, Customer's complaint, etc. – Corrective Action Request (Section 1)
		⇩	
1.2	Head of Department*	Accept CAR	– Corrective Action Request (Section 2)
		⇩	
1.3	Head of Group	Investigate root cause(s), specify corrective action plan and assign the responsible staff with consensus by Head of Department	– Corrective Action Request (Section 3)
		⇩	
1.4	Assigned Staff	Implement the corrective action	– Corrective Action Request (Section 4)
		⇩	
1.5	Head of Department*	Approve the effectiveness of the corrective action	– Corrective Action Request (Section 5)
		⇩	
1.6	Auditors**	Preliminarily verify the effectiveness of the correction	– Corrective Action Request (Section 6)
		⇩	

1.7	Quality Manager	Monitor the corrective action process and close-out the CAR	– Corrective Action Request (Section 7) – CAR Status Log

* In some circumstances, the responsible person can be the Quality Manager.

** This step is followed only for cases of internal audits

2 PURPOSE

The purpose of this procedure is to provide a system for controlling condition within the laboratory, which are adverse to quality by:

1) finding the root cause(s) of the problem;
2) taking corrective action to eliminate the problem and taking necessary actions to prevent a recurrence of the problem.

3 SCOPE

This procedure applies to any problem found in the management system which includes but not limited to the following:

1) non–compliances found during auditing the management system;
2) complaints;
3) problems identified by management/laboratory staff including nonconforming works.

4 DEFINITION

CAR: Corrective Action Request

5 PROCEDURE

5.1 The Quality Manager issues CAR when it is determined that an adverse quality condition exists. The Quality Manager can do so by filling-in detailed information in the section 1 of the form Fr-CAR-01: Corrective Action Request. Please note that for the case of the CAR arising from the internal audit, the form shall be firstly filled by the internal auditor who raises the CAR. The Quality Manager shall submit the form either by e-mail or in person to the appropriate Head of Department. Additionally, the Quality Manager enters CAR in the log file Fr-CAR-02: Corrective Action Status Log in order to monitor the status of the CAR.

CAR issued according to the process of handling the Complaint or arising from the Non-conformity Report, Quality Manager can refer to the detail description in each Complaint No.-xx or NCR No.-xx in section 1 and attached the appropriated document without filling-in.

5.2 When the Head of the Department receives the CAR form, he/she shall then review the CAR. Additionally, the Head of Department and the Quality Manager shall verbally discuss about the tentative dateline for the completion of the corrective action and once the agreement has been reached, he/she shall accept the CAR by filling-in the section 2 of the received form. Nevertheless, if he/she does not agree with the issued CAR, he/she can initiate the discussion meeting with the Quality Manager to resolve the disagreement issue. In a very rare circumstance that the mutual agreement cannot be reached, the matter shall be passed to the relevant Deputy Director / Assistant Director for the final judgment. After the review, the Head of Department shall assign the Head of Group for taking the corrective action plan and Staff Assignment to Execute the plan.

5.3 The Head of Group shall investigate the root cause(s), specify the corrective action plan and assign the responsible staff to implement the corrective action. The selected corrective action shall be to a degree appropriate to the magnitude and the risk of the problem and it must include immediate correction to the problem as necessary.

In some cases, root cause cannot be explicitly determined and in such cases, the corrective actions should be to a degree appropriate to the magnitude and risk of the problem.

5.4 Once the corrective action has been implemented, the assigned staff shall report in details by filling in the section 4 of the received form and send it to the Head of Department for evaluation (approval/not approval) of effectiveness of the corrective action.

5.5 The Head of Department shall evaluate effectiveness of the corrective action and analyze the risk and opportunities that may arise by filling-in the section 5 of the received form and send it either to the appropriate internal auditor who raised the CAR for the CAR arising from the internal audit or to the Quality Manager for all other CARs.

5.6 In case of the CAR arising from the internal audit, the auditor shall preliminarily verify the effectiveness of the corrective action by filling-in the section 6 of the received form before submitting the CAR form to the Quality Manager.

5.7 The Quality Manager shall monitor the process of the corrective action by reviewing the CAR Status Log on a regular basis.

5.7.1 If a response to any CARs be overdue, a reminder shall be sent to the responsible Head of Department requesting a response. If no response is received within two weeks of the reminder date, the subject shall be passed to the relevant Deputy Director for further action.

5.7.2 When the process is completed, the Quality Manager shall verify the effectiveness of the corrective action and

a) if the action taken is verified to be effective and satisfactory, the Quality Manager shall close-out the CAR.
b) if the verification indicates that the action taken has not been effective in correcting the deficiency and/or preventing recurrence, this shall be recorded and this CAR shall be closed-out and the QM shall re-issue a new CAR for the continuing deficiency. The number of the new CAR shall be cross referenced to the old CAR and vice versa.

5.7.3 If the follow-up CAR indicates that the action taken is still unsatisfactory; the CAR should be followed to the relevant Deputy Director for further action.

5.7.4 Where the result of investigations casts doubts on the laboratory's compliance with the NIMT's policies and procedures, or on its compliance with the ISO/IEC 17025, the appropriate areas of activities in questions shall be audited in accordance with QP-09:Procedure for Internal Audits as soon as possible.

5.7.5 The Quality Manager shall update the Corrective Action Status Log and maintain the record of the Corrective Action.

The Quality Manager shall fill-in the details of the CAR close-out in the section 7 of the received form. Once the CAR form has been closed, the Quality Manager shall save the form and maintain it in an appropriate record file.

6 RELATED FORMS

6.1 Fr-CAR-01: Corrective Action Request (CAR) (Electronic fill-able form)

6.2 Fr-CAR-02: Corrective Action Status Log (Electronic log file)

QP-08: PROCEDURE FOR ADDRESSING THE RISKS AND OPPORTUNITIES

1 OVERVIEW

	Responsibilities	Activities	Related Documents
1.1	Any staff and/or Risk Management Committee	Identify and assess risk and identify improvement opportunities and propose action plan	– Preventive Action Request (Section 1) and/or – Risk Issues – Preventive Action Log
		⇩	
1.2	Head of Department and/or Risk Management Committee	Approve preventive action	– Preventive Action Request (Section 2) and/or – Annual Risk Management Plan
		⇩	
1.3	Relevant staff	Implement the preventive action	– Preventive Action Request (Section 3)
		⇩	
1.4	Head of Department and/or Risk Management Committee	Evaluate the effectiveness of the implemented action	– Preventive Action Request (Section 4) and/or - Annual Risk Management Report Preventive Action Log

2 PURPOSE

The purpose of this procedure is to provide a pro-active process to assess and evaluate probable incidents that could lead to catastrophic failure of any part of the system as well as to identify opportunities for improvement and taking preventive action. It is not intended to provide a reaction to the identification of problems and complaints

3 SCOPE

This procedure applies to any improvement opportunities which are identified by:

1) reviewing of the operational procedure and data;
2) risk analysis;
3) potential sources of nonconformities;
4) brainstorming.

4 DEFINITION

4.1 Risk

A **risk** is the possible factor that affects the policies, objectives, aims or management system of the organization's service activity such as lack of resources (e.g., financial budget, equipment, competent personnel), uncontrollable external policy or staff's impartiality (queueing, purchasing, consulting etc.), which could be avoid through the preventive actions.

4.2 Preventive Action

A preventive action is a proactive process to identify opportunity for improvement rather than a simple reaction to identified problems or complaints. Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analysis, report on evaluation and improvement of internal control and inter-laboratory comparison results.

5 PROCEDURE

5.1 Any member of NIMT's staff can assess risk and identify improvement opportunities and propose action plan by filling-in details of risk assessment and proposal of the preventive action plan in the section 1 of the form Fr-PAR-01: Preventive Action Request. The running number shall be in the format of PAR-DD-YYYY-### and the new running shall be registered into the Preventive Action Log using the form Fr-PAR-02: Preventive Action Log. After the section 1 is filled, the filled form shall be sent to the appropriate Head of Department.

Another path for the preventive action can go through the Risk Management and/ or Report on evaluation and improvement of internal control that is run by the assigned Risk Management Committee and/or Internal Auditor. Any member of Risk Management Committee and/or Head of Department who has found that there is a risk issue can raise the issue to the Risk Management Committee or Internal Auditor.

5.2 The Head of Department shall then review and decide whether to approve the proposed preventive action plan or not by filling in the information in the section 2 of the received form. If the Head of Department approves the proposed preventive action plan, he/she shall continue sending the form back to the responsible member of the staff who is assigned to hold the responsibility for implementing the approved preventive action plan.

The Risk Management Committee has regular meetings throughout the year to gather and assess all risk issues and prioritize all issues to make the Annual Risk Management Plan that will be proposed to the director.

5.3 The relevant member of the staff shall implement the approved preventive action plan. And when the implementation is completed, he/she shall report, in details, the result of the implementation in the section 3 of the received form and sends the form to the Head of Department.

All relevant staff as indicated in the approved Annual Risk Management Plan shall implement the actions according to the plan.

5.4 The Head of Department shall monitor and verify the effectiveness of the preventive action. He/she shall complete the section 4 of the received form and once the process is completed, he/she shall save the form in an appropriate record file and the Preventive Action Log shall be updated accordingly.

The Risk Management Committee has a function to monitor the effectiveness of the implemented actions and summarize the results into the Annual Risk Management Report.

*** In case of risks to its impartiality shall review by Risk Management Committee at least every 12 months.

6 RELATED FORMS

6.1 Fr-PAR-01: Preventive Action Request (Electronic fill-able form)

6.2 Fr-PAR-02: Preventive Action Log (Electronic log file)

6.3 Annual Risk Management Plan

6.4 Annual Risk Management Report

QP-09: PROCEDURE FOR INTERNAL AUDITS

1 OVERVIEW

	Responsibilities	Activities	Related Documents
1.1	Quality Manager	Prepare Audit Program and select Audit Teams	– Audit Program
		⇩	
1.2	Auditor	Contact laboratory staff and make appointment	
		⇩	
1.3	Auditee and Auditor	Perform internal audit	– Audit Check List
		⇩	
1.4	Auditor	Prepare official audit report and submit to the Quality Manager	– Audit Check List – Audit Report Summary – CARs – Audit Report Log
		⇩	
1.5	Quality Manager	Maintain the record and process CAR according to QP-07:Procedure for Corrective Actions	– Audit Check List – Audit Report Summary – CARs

2 PURPOSE

The purpose of this procedure is to establish methods and responsibilities for the execution of internal quality audits to surveillance the implementation and effectiveness of the management system.

3 SCOPE

This procedure applies to all internal quality audits performed by NIMT's laboratories.

4 DEFINITION

4.1 Auditor - A person who carries out an audit.

4.2 Auditee – A person who is audited.

4.3 Non-compliance - A deficiency in the management system whereby personnel are not following specified documented planned / arrangements and / or procedures.

5 PROCEDURE

5.1 The Quality Manager establishes and maintains an audit program to ensure that all aspects in the quality system including the activities of the Corporation and Partnership Development Group and Account, Financial accounting and supply Group which are related to the requirement of ISO/IEC 17025:2017 are subjected to audit at least every 12 months in advance. The audit program shall be prepared by using the form Fr-AUD-01: Audit Program.

The Quality Manager then selects teams of internal auditors from the available metrologists within the list of qualified metrologists who attend the Internal Auditor Training Course and the ISO/IEC 17025:2017 Training Course organized by NIMT or the equivalent training courses organized by other organizations. The Internal Auditors shall be nominated and authorized by Top Management at least 2 weeks prior to conduct the internal audit activities.

5.2 Once the auditor teams have been found and the tentative schedule has been made up in accordance with the Audit Program. Each team of auditors arranges proper schedule within reasonable time frame with the auditee.

5.3 The auditee is then audited according to the appointment with the auditor. The auditor performs the audition by the followings:

5.3.1 The auditor shall seek evidence of compliance with the requirements of procedures, instructions, method, etc. Such evidence shall be sought against a prepared checklist taken from laboratory procedures and other documented requirements.

5.3.2 Compliance checks shall be sought by sampling records and observation of activity. The results of the sampling and observation shall be recorded on the form Fr-AUD-02: Audit Check List.

5.3.3 The auditor shall classify audit findings as follows:

a) Compliance: no non-compliances detected,
b) Noncompliance: where there is a breakdown in the system caused by non-adherence to procedures and planned arrangements,
c) Observation: where the basic intent has been met but the procedure or practice could be improved to provide better assurance of compliance.

Upon the completion of the audit, the auditor shall allow the audittee to skim through the information noted in the Audit Check List. The audittee and auditor shall verbally discuss on all non-compliance issues and if an agreement cannot be reached on any issue, the Quality Manager and Head of Department shall be invited to resolve the matter.

5.4 The auditor shall complete the audit report by filling in the form Fr-AUD-03: Audit Report Summary using the information noted in the Audit Check List and shall determine whether each non-compliance has a potential for recurrence or whether it casts doubt on the effectiveness of the operation or on the correctness of the measurements' results. If that is the case, the auditor must preliminary fill-in the non-compliance information in the form Fr-CAR-01: Corrective Action Request, otherwise there will be no need to issue CAR. The report number shall be in the form AUD-DD-YYYY-### and the new number shall be registered into the Audit Report Log using the form Fr-AUD-04: Audit Report Log. The auditor then submits the formal audit report which includes the completed Audit Check List, Audit Report Summary, and Corrective Action Request Forms to the Quality Manager within one calendar month.

Distribution of the audit report shall be as determined by the Quality Manager but only the brief summary of the report will always be presented at management review meeting.

5.5 The Quality Manager keeps the record of the internal audit including all related documents and process the raised CAR according to QP-07:Procedure for Corrective Actions.

When the follow-up audit indicates that the actions taken have been implemented and are effective, the Quality Manager shall close out the CAR.

A copy of the closed out CAR is filed with the initial audit report.

6 RELATED FORMS

6.1 Fr-AUD-01: Audit Program (Electronic fill-able form)

6.2 Fr-AUD-02: Audit Check List (Electronic fill-able form)

6.3 Fr-AUD-03: Audit Report Summary (Electronic fill-able form)

6.4 Fr-AUD-04: Audit Report Log (Electronic Log File)

6.5 Fr-CAR-01: Corrective Action Request (CAR) (Electronic fill-able form)

QP-10: PROCEDURE FOR MANAGEMENT REVIEW

1 OVERVIEW

	Responsibilities	Activities	Related Documents
1.1	Quality Manager	Collect information and prepare the schedule and the agenda and initiate the meeting	– Management Review Agenda
		⇩	
1.2	Top Management NIMT Technical Management Team Any relevant personnel	Participate in the management review meeting	– Minutes of the previous meeting. – Other meeting documents – Meeting video or audio records. – Meeting Notes
		⇩	
1.3	Top Management	Establish or adjust the quality management policies as necessary and order the Technical Management Team and relevant personnel to implement the new policies	– NIMT Notes – NIMT Directives – NIMT Regulations
		⇩	
1.4	Quality Manager	Prepare the minute of the meeting, initiate all resolutions arising from the meeting and keep all records	– Minutes of the meeting. – All documents arising from the meeting

2 PURPOSE

The purpose of this procedure is to provide the method of periodic review of the management system by NIMT Top Management to ensure its continuing suitability and effectiveness.

3 SCOPE

This procedure applies to the management review meeting of the management system performed by NIMT's Top Management and Technical Management Team.

4 DEFINITION

N/A

5 PROCEDURE

5.1 The Quality Manager shall initiate a management review meeting, based on any of the following criteria;

1) a predetermined schedule every twelve-months (annual review);
2) excessive customer complaints;
3) serious quality issues or statistical trends requiring a review of the management system.

The Quality Manager shall initiate the meeting by filling in the form Fr-MGR-01: Management Review Invitation and sending the invitation to NIMT's Top Management, NIMT's Technical Management Team, and any relevant personnel.

5.2 The Top Management and all invited personnel shall then participate in the meeting.

The meeting shall be used as a tool to review and evaluate the entire management system, to reconfirm its adequacy and conformity to the current requirements of the laboratory.

Each annual review meeting shall address the following matters;

1) status of actions from previous management reviews; (Quality Manager)
2) changes in both internal and external issues that are relevant to the laboratory; (Head of Department /Group/Laboratory)
3) fulfilment of objectives; (Quality Manager)
4) the suitability of policies and procedures; (Quality Manager)
5) reports from managerial and supervisory; personnel which included matters arising from monthly meeting; (Head of Department /Group/Laboratory)
6) the outcome of recent internal audits; (Quality Manager)
7) corrective actions; (Quality Manager)
8) results of risk identification; (Quality Manager)
9) assessment by external bodies; (Quality Manager)

10) the results of inter-laboratory comparison or proficiency test; (Head of Department)
1) changes in the volume and type of work or in the range of laboratory activities; (Head of Department)
2) customer's and personnel's feedback; (Quality Manager)
3) complaints; (Quality Manager)
4) effectiveness of any improvements implementation; (Quality Manager)(Head of Department)
5) adequacy of resources;
6) outcomes of the assurance of the results' validity;
7) other relevant matters such as quality control activities, resources and staff trainings and where required, technical issues relating to the competence of the subcontractor and distributor of the reference materials; (Head of Department and concerned personnel)

Before the meeting actually commence, the Quality Manager can nominate a staff to take responsibility for collecting data for the meeting for him/her. The assigned staff is responsible to pass all collected information to the Quality Manager when the meeting is completed.

5.3 The Top Management shall then consider whether to issue any additional quality management policies or to adjust the current quality management policies or not. If there are any additions or changes, the Top Management shall direct all involved personnel to implement the new or adjusted policies.

5.4 The Quality Manager shall record minutes of all discussion items, resolutions and actions related to at least;.
a) the effectiveness of the management system and its processes;
b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;
c) provision of required resources; and
d) any need for change.

5.5 The Quality Manager shall issue copies of the minutes to concerned personnel as appropriate, where action is required. Minutes of reviews and their results of the action taken shall be retained by the Quality Manager for the period of at least 10 years.

Implementation of resolutions

1) Some resolutions may result in a change to work practices and/or procedures. In such cases all relevant manuals and procedures shall be reviewed and reissued in accordance with QP-01:Procedure for Control of General Quality Documents.
2) The Quality Manager is responsible for initiating corrective action for any problems identified during the management review meeting according toQP-07:Procedure for Corrective Actions.
3) When management identifies a problem but cannot determine the precise root cause, the Quality Manager shall arrange an unscheduled internal quality audit in accordance with QP-09:Procedure for Internal Audits.

The concerned committee and staff shall be assigned to account for those findings within the timescale defined by the Management Committee. The Quality Manager is responsible for ensuring that those actions are carried out efficiently within the defined timescale.

6 RELATED FORMS

6.1 Fr-MGR-01: Management Review Invitation (Electronic fill-able form)

QP-11: PROCEDURE FOR STAFF'S TRAINING AND AUTHORIZATION

1 OVERVIEW (FOR TRAINING EVALUATION)

	Responsibilities	Activities	Related Documents
1.1	Head of Laboratory	Determine training needs	– Training Needs (1 Lab : 1 Sheet)
		⇩	
1.2	Head of Group	Prepare a training program	– Training Program (1 Group : 1 Sheet)
		⇩	
1.3	Head of Department	Approve the training program	– Training Program
		⇩	
1.4	NIMT staff	Participate in training according to the approved program	– Training Report
		⇩	
1.5	Head of Group	Evaluate the training result	– Training Evaluation
		⇩	
1.6	Designated staff	Update and maintain record	– Training record – Training evidence i.e., training report and certificate

2 OVERVIEW (FOR STAFF AUTHORIZATION)

2.1	Head of Group	Evaluate the training result and report to Head of Department	– Staff Authorization
		⇩	
2.2	Head of Department	Authorize the staff and review	– Staff Authorization
		⇩	
2.3	Designated staff	Update and maintain record	– Staff Authorization

3 PURPOSE

The purpose of this procedure is to define a system for identifying, implementing and recording of staff training program within the laboratory and a system for authorizing specific personnel to perform particular tasks in each measurement system.

4 SCOPE

This procedure applies to all staff of NIMT who plays significant roles in the quality of measurement works.

5 DEFINITION

N/A

6 PROCEDURE

6.1 The Head of Laboratory shall determine the training needs, using the form Fr-PER-01: Training Need, to support the established goals by the following criterion:

1) position, responsibility and job engagement;
2) change and development of the technology that relate to metrology;
3) qualification, education, experience and expertise;
4) personnel staff training records.

The Head of Group shall prepare an effective training program using the form Fr-PER-02: Training Program, which is relevant to the present and anticipated tasks of the laboratory.

6.2 Head of Department approves the Training Program.

6.3 The laboratory staff participates in the training following the plan laid down in the approved Training Program.

6.3.1 In–house training: This type of training is conducted within NIMT including On-the–Job Training (OJT). For the case of OJT, it must be under supervision of the Head of Group for appropriate duration.

6.3.2 Outside training: This type of training is conducted by the reliable organization, which is related to the training topics. If the training is significant to the anticipated task of the laboratory, the trainee shall produce a detailed training report upon completion.

The outside training report shall include:

a) training course;
b) name of the institute or instructor;
c) training content;
d) training interval
e) advantage and contribution;
f) suggestion

Note: The laboratory member who manages, performs and verifies activities affecting quality must be trained to the level that they understand all requirements of the Management System.

6.4 Head of Group evaluates the staff's training.

When a new staff member is employed, he/she will be subjected to 4 months (or longer in some special circumstances) probation period. When the probation period ends, the new staff member shall be evaluated by the Head of Group (if applicable), the Head of Department, Deputy Director / Assistant Director and the Director, respectively, with the coordination by the Administration and Human Resource Development Group to consider whether he/she will be permanently employed by NIMT. Moreover, for the new staff member with the intended position of "Metrologist", he/she shall start working with the position "Metrologist Trainee" for at least a year before he/she will be re-evaluated by the Head of Group, the Head of Department, Deputy Director / Assistant Director, Director to determine whether he/she will be promoted to "Metrologist" position or not. All Metrologist Trainees shall be supervised by Head of Group when performing any measurement works.

6.4.1 In–house training or outside training which is significant to the anticipated tasks of the laboratory shall be evaluated by the Head of Group and then report the evaluation result to Head of Department.

6.4.2 The evaluation shall be taken into account the objective evidences of training.

6.4.3 These may include the demonstrations of experiences and skills by oral and/or practical tests.

6.5 The Head of Department authorizes the staff member (if applicable) by using either the form Fr-PER-03: Staff Authorization or the Authorization List appropriate for each laboratory or department.

6.6 The designated staff member is responsible to update the record file Fr-PER-04: Training Evaluation,Fr-PER-05: Training Record and keep the training evidence, i.e., training certificate, training report etc. and records of authorizations, competence, educational and professional qualifications, training skills and experience of all Laboratory staff in the laboratory.

7 RELATED FORMS

7.1 Fr-PER-01: Training Needs (Electronic fill-able form)

7.2 Fr-PER-02: Training Program (Electronic fill-able form)

7.3 Fr-PER-03: Staff Evaluation (Electronic fill-able form)

7.4 Fr-PER-04: Training Evaluation (Electronically maintained record)

7.5 Fr-PER-05: Training Record (Electronically maintained record)

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QP-12: PROCEDURE FOR MAINTAINING MEASUREMENT TRACEABILITY

1 OVERVIEW

	Responsibilities	Activities	Related Documents
1.1	Head of Laboratory	Survey calibration statuses of equipment and standards and prepare Calibration Program	– Equipment Record – Calibration Program
		⇩	
1.2	Head of Group	Review the Calibration Program	– Calibration Program
		⇩	
1.3	Head of Department	Approve the Calibration Program	– Calibration Program
		⇩	
1.4	Laboratory staff	Send the equipment and standards for calibrations	– Calibration Program – Calibration Requirement
		⇩	
1.5	Calibration Provider (Internal or External)	Perform calibration and issue certificate	– CP – Calibration Certificate (NIMT or external)
		⇩	
1.6	Laboratory staff	Check the functional operation and calibration certificate and update equipment record	– Calibration Certificate (NIMT or external) – Equipment Record – Calibration Program

2 PURPOSE

The purpose of this procedure is to provide guidelines for the operation to maintain measurement traceability to the International System of Units (SI).

3 SCOPE

This procedure is applicable to all measuring instruments and measurement standards having significant effect on the accuracy and validity of the results of measurements. Their measurement traceability to SI units shall be achieved through an established calibration hierarchy composing of internal calibrations and/or external calibrations.

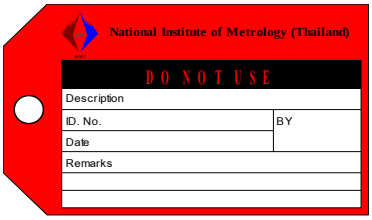
4 DEFINITION

4.1 Internal Calibration: Calibration performed by one of NIMT's laboratories.

4.2 External Calibration: Calibration elsewhere.

5 PROCEDURE

5.1 Head of Laboratory shall survey calibration statuses of all equipment and standards affecting measurement traceability periodically. The equipment or standards that are overdue for calibration or have not been calibrated shall be attached with a "Do Not Use" tag or segregated to prevent from their inadvertent use.



Head of Laboratory shall also prepare the Calibration Program by using the form Fr-EQU-04: Calibration Program to practically ensure that their measurements are metrologically traceable to SI units.

5.1.1 If external calibration services are necessary, the laboratory shall use the services from the BIPM, or another national metrology institute (NMI) or designated institute (DI) having relevant CMCs published in the KCDB, or the laboratories that have been accredited to the ISO/IEC 17025 or equivalent.

5.1.2 In the preparation of the Calibration Program, variable or floating calibration intervals are used. Calibration intervals are initially based on the manufacturer's recommendation or experiences from similar types of equipment. Subsequent calibration interval determinations are based on the history of at least three previous calibrations.

New measuring equipment shall normally put on 12 months interval unless standard recommended practices dictate otherwise.

Several techniques to determine appropriate calibration intervals for various types of equipment can be found in "ILAC-G24/OIML D 10 Edition 2007 (E): Guidelines for the determination of calibration intervals of measuring instruments".

5.2 The Head of Group shall review the Calibration Program to ensure the suitability of the calibration interval and calibration providers.

5.3 The Head of Department performs the final review and approves the Calibration Program.

5.4 Laboratory staff is responsible to prepare the details of calibration requirement and send the equipment or standards for calibration to keep up with the Calibration Program.

5.4.1 In case of internal calibration, he/she shall require the staff of Corporation and Partnership Development Group to issue a work order for the calibration laboratory. The equipment or standards shall be sent to the calibration laboratory within agreed timescale.

5.4.2 In case of external calibration, the services shall be procured in accordance with QP-04:Procedure for Provision of Products, Services and Supplies

The calibration provider, regardless of internal or external, will perform the calibration and issue the Calibration Certificate or Measurement Result.

5.5 Laboratory staff shall check the functional operation and verify the result of calibration before putting the equipment or standards into service. If the verification result is found to be out of acceptable criteria which are usually listed in either DQM or GQM or CP, he/she shall examine the effect of the defect on previous calibration and, if necessary, follow QP-06:Procedure for Control of Nonconforming Work.

Where calibrations give rise to a set of calibration factors, laboratory staff shall update all copies of calibration data including those in computer software. The Head of Group is responsible for checking these updates.

Laboratory staff shall then indicate the next calibration due date on the calibration label and update the record onto the form Fr-EQU-03: Equipment Record and the Calibration Program.

6 RELATED FORMS

6.1 Fr-EQU-04: Calibration Program (Electronic fill-able form)

6.2 Fr-EQU-03: Equipment Record (Electronically maintained record file)

QP-13: PROCEDURE FOR PROCESSING OF MEASUREMENT SERVICE ITEMS

1 OVERVIEW

	Responsibilities	Activities	Related Documents
1.1	Senior Staff of Corporation and Partnership Development Group	If the customer accepts the quotation, confirm the associated pending jobs.	– Confirmed ORJ
		⇩	
1.2	Staff of Corporation and Partnership Development Group	Accept the service item from the customer and perform initial inspection*, store and transport to the laboratory** Print out two copies of work order report from the job and asks the customer to sign one copy and give the copy without the customer's signature to the customer. Copy the signed work order, print out the service tag and attach to the service item and give the original signed work order to the Laboratory staff together with the service item with the service tag.	– Online Work Order (OWO)
		⇩	
1.3	Laboratory staff	Inspect and store the service item and then staff goes into the online job to check the agreement of all informations, makes corrections if necessary.	– OWO
		⇩	

1.4	Laboratory staff	After the measurement is completed, add relevant information into the OWO. Upload calibration record file to the database and send the finished job to the Head of Group.	– OWO – Calibration record, certificate and associated files
		⇩	
1.5	Head of Group	Verify the correctness of the measurement results and other relevant data on the certificates and sends back to the responsible Laboratory staff.	– OWO – Calibration record, certificate and associated files
		⇩	
1.6	Laboratory staff	Print out certificate. Additionally, prepare the calibration label and then send the online verified OWO and submit all paper documents to the Head of Department.	– OWO – Printed certificate – Calibration label
		⇩	
1.7	Head of Department	Approve to close the online work-order job (the OWO will be sent directly to the CPDG) in the online system, then signs the printed out certificate and return all documents to the responsible staff.	– OWO – Printed verified work-order report – Printed certificate – Calibration label
		⇩	
1.8	Laboratory staff	The Laboratory staff scans the approved certificate and saves into the appropriate location, then brings all signed documents and the service items to the staff of Corporation and Partnership Development Group.	– Approved Certificate – Calibration label

⇩

1.9	Staff of Corporation and Partnership Development Group	Close the approved online work-order job in the online system and stores the service item in the storage area.	– OWO – Calibration label – Approved Certificate

***Some specific service items may require additional initial inspection by Laboratory staff** when accepted at the Corporation and Partnership Development Group. In such cases, description on how to handle those specific items shall be provided in sufficient details in either appropriate DQM / GQM or appropriate CP.

**In some cases, the service item might need to be transported directly to the laboratory by the customer accompanied by the Laboratory staff.

2 PURPOSE

The purpose of this procedure is to establish the methods and responsibilities for processing of service items.

3 SCOPE

This procedure applies to all service items listed in the pricelist announced at http://www.nimt.or.th including their accessories received by NIMT.

4 DEFINITION

4.1 Service Item

An item of equipment or reference material that is submitted by the customer (regardless of internal or external) for measurement.

4.2 Work Order

The Work Order is a form that shows details of service items and natures of service required which are referred to the relevant quotation. It is a required internal order that uses for identify each service items and significant accessories.

5 PROCEDURE

5.1 If the customer accepts the quotation, Senior Staff of Corporation and Partnership Development Group confirms the associated pending jobs.

5.2 The staff of Corporation and Partnership Development Group accepts the service item from the customer and perform initial inspection*, store and transport to the laboratory**Print out two copies of work order report from the job and asks the customer to sign one copy and give the copy without the customer's signature to the customer. The staff then copy the signed work order, print out the service tag and attach to the service item and gives the original signed work order to the Laboratory staff together with the service item with the service tag.

The staff of Corporation and Partnership Development Group shall notify the relevant laboratory staff regarding the arrival of the service item, and after he/she has been confirmed by the laboratory staff that the laboratory is ready for service, he/she shall then transport the service item to the appropriate laboratory.

5.3 The Laboratory staff inspects, stores the service item and then staff goes into the OWO to check the agreement of all informations, makes corrections if necessary. After the measurement is completed, the Laboratory staff adds relevant information into the OWO. Upload calibration record file to the database and send the finished job to the Head of Group.

After the laboratory staff receive the item:

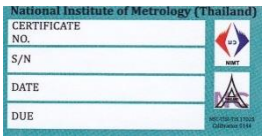
5.3.1 The laboratory staff checks to ensure the agreement between the OWO and the service item and to ensure the item is suitable for service. The laboratory staff shall then keep the service item in the "Incoming" area waiting for service to be performed.

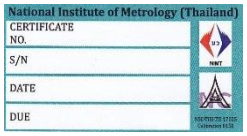
5.3.2 When the laboratory is ready for service, the laboratory staff checks the service item against the Work Order to reaffirm the service required before the service is undertaken. All disagreement issues must be resolved prior to starting the measurements.

5.3.3 After everything is checked and confirmed, the laboratory staff shall perform the requested measurements in accordance with the customer's requirements using the appropriate and valid method. The laboratory staff shall ensure that the service tag remains with the service item or its case throughout the service process.

5.3.4 After all measurements have been completed, the laboratory staff shall place the service item in the appropriate area labeled "Outgoing". All accessories and documents relevant to the service item are once again checked for correctness by the laboratory staff.

5.3.5 The laboratory staff shall affix a "Calibration" label to the service item or its container. When it is impractical to do so, some other suitable measures may be used to reflect calibration status. The laboratory staff shall specify only the certification number, the calibration date, S/N (as needed), and/or the identification of the person who performs the measurement work, and must not specify the next calibration date for the customer.





5.3.6 "Calibration void if seal is broken" labels are applied to equipment whose conformity can be altered by adjustments. If these stickers are broken calibration is voided.

5.3.7 The laboratory staff shall prepare the certificate by following QP-15:Procedure for Preparing of the Certificate

5.3.8 If there is any service item that is found failure or developed faults during service, the customer shall be informed immediately for further instructions and the discussion with the customer shall be recorded in the note section of OWO.

5.3.9 Any changes to the service from the original agreement that will not affect the price of the service must be discussed with the customer before commencing or continuing any work and such change and acceptance of customer (date and time of acceptance, corresponding method and person) must be recorded into the note section of the OWO.

5.3.10 If there are changes or deviations to the original agreement that will affect the price of the service, the OWO must be sent back to the senior staff of the Corporation and Partnership Development Group who will reissue the new quotation and get the acceptance from the customer before the price in OWO will be adjusted accordingly and the OWO will be sent back to the Laboratory staff to continue the process.

5.4 Head of Group verifies the correctness of the measurement results and other relevant data on the certificates and sends back to the responsible Laboratory staff with comments and suggested corrections to prepare for the certification approval.

The Head of Group must ensure that:

g) the customer approved procedure, if applicable, or the laboratory approved procedure is used;
h) environmental conditions are recorded;
i) correction factors are applied, when applicable;
j) the work order and applicable data sheets are completed correctly;
k) raw data and their analysis together with any relevant information are collected together and covered either by the Fr-CAL-01: Calibration Record Form or any document created by individual laboratory containing the minimum information as required on the form Fr-CAL-01.

NOTE: Cleaning of measuring equipment may be accomplished prior to performing the measurement service. However, a measurement must be accomplished prior to cleaning if the cleaning activity could invalidate the "As Found" data. This is not applicable to items such as gauge blocks and weights that require cleaning prior to measurement and use.

5.5 The Laboratory staff makes necessary corrections, prints out the certificate. Additionally, prepare the calibration label and then send the verified OWO and submit all paper documents to the Head of Department.

5.6 The Head of Department approves to close the OWO in the online system (the OWO will be sent directly to the staff of Corporation and Partnership Development Group), then signs the printed out work-order and certificate and return all documents to the responsible staff.

5.6.1 If the Head of Department finds any errors that need corrections, the OWO must be sent back together with comments and suggestions in the note area to the Head of Group and the process shall be looped back to 5.4 and continue from there.

5.7 The Laboratory staff scans the approved certificate and saves into the appropriate location, then brings all signed documents and the service items to the staff of Corporation and Partnership Development Group.

5.8 The staff of the Corporation and Partnership Development Group is notified and the service item is picked-up. Nevertheless, some service items may be kept at the laboratory. After the service item is picked-up from the laboratory, the staff of Corporation and Partnership Development Group must do the followings:

5.8.1 The staff of Corporation and Partnership Development Group closes the approved OWO in the online system and stores the service item in the storage area.

5.8.2 The staff of Corporation and Partnership Development Group identifies each service item and significant accessories by a service tag bearing the same identification number as the Cal ID.

5.8.3 The service item shall be placed in the "storage" area waiting to be returned to the customer. The storage area in the Corporation and Partnership Development Group must be environmentally controlled to conserve the service item.

5.8.4 Some service items might need special care during transportation or might need to be transported only by technical experts. In such case, the responsible laboratory staff must give notice to the Corporation and Partnership Development Group and must either transport the item by themselves or accompany the transportation.

5.8.5 The staff of Corporation and Partnership Development Group inform customer to pick up the service item.

5.8.6 Where no further action is taken to the service item, it shall be returned under the customer's responsibility.

5.8.7 The laboratory reserves the right to take appropriate actions to any service item where there is no response from the customer after 3 months following the notification.

6 RELATED FORMS

6.1 Online Work Order (OWO)

6.2 Paper Work Order (PWO)

6.3 Fr-CAL-01: Calibration Record Form

6.4 Online customer's request job (ORJ)

QP-14: PROCEDURE FOR ASSURING THE QUALITY OF RESULTS

1 OVERVIEW

	Responsibilities	Activities	Related Documents
1.1	Head of Group	Select, monitor, record and determine of quality control measures	– Quality Control Related Documents
		⇩	
1.2	Laboratory staff	Implement the pre-defined quality control measures	– Quality Control Related Documents
		⇩	
1.3	Head of Group	Monitor the implementation of the quality control measures	– Quality Control Related Documents

2 PURPOSE

The purpose of this procedure is to provide a system for monitoring the validity of measurement results undertaken by NIMT.

3 SCOPE

This procedure applies to all measurements within the scope of the quality management system implementation.

4 DEFINITION

N/A

5 PROCEDURE

5.1 The Head of Group establishes an effective system to assure the quality of measurement results by selecting one or more of the following monitoring techniques:

5.1.1 The Head of Group review and monitor the calibration records regularly to ensure that the trends are detected and reminded actions are taken on a timely basis.

5.1.2 The Head of Group determine, according to the type and volume of the work undertaken, the frequency and method to be applied for the quality control check of the results of calibrations. The quality control checks may include, but not limited to, the following:

Example of method applied for assuring the quality of results:

Method	Application
a) Certified reference materials and/or secondary reference materials	a) analytical instruments for chemicals, materials, etc.
b) Inter-laboratory comparison or proficiency testing program	b) primary standards, reference standards, etc.
c) Replicate calibration	c) any standards and measuring instruments, etc.
d) Recalibration of retained items	d) any standards and measuring instruments
e) Correlation of results for different characteristics of an item	e) volume, flow, hardness, density etc.
f) Use of check standards	f) any comparison measurements

5.1.3 The check may be performed regularly at least one time per year under the discretion of the Head of Group.

5.1.4 The methods selected shall be documented and reviewed for adequacy by the Head of Group.

5.1.5 The resulting data shall be recorded in such a way that trends are detectable and, where applicable, statistical techniques shall be applied to the reviewing of the results. The results of the quality control check shall be recorded in the calibration record file of the calibration item or related record.

5.2 The responsible staff shall implement all the quality control measures as assigned by the Head of Group and shall statistically analyze all gather data such as:

5.2.1 using the previous and subsequent calibration results of the standards and plot against time to observe their long-term and trends by using control chart techniques;

5.2.2 determining a criteria of control chart that will be identified in DQM or CP;

5.3 The Head of Group surveillances the implementation of the quality control measures to ensure that they are effective and economical. He/she shall used the data resulting from the implementation of quality control measures for:

5.3.1 taking the projected values into account when performing calibrations;

5.3.2 using other statistical techniques to justify the adjustment the calibration intervals to increase the confidence in calibration results or to compromise the cost;

5.3.3 improving measurement capability by decreasing the total combined standard uncertainty;

In case of the quality control data are found to be outside pre-defined criteria, the Head of Group take necessary actions to correct the problem and to prevent incorrect results from being reported.

Records related to all quality control measures applied and their results shall be retained in the laboratory for the life of all equipments and standards involved.

6 RELATED FORMS

N/A

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QP-15: PROCEDURE FOR PREPARING OF THE CERTIFICATE

1 OVERVIEW

	Responsibilities	Activities	Related Documents
1.1	Laboratory staff	After the measurement is completed, the Laboratory staff adds relevant information into the online work-order job. Upload calibration record file to the database and send the finished job to the Head of Group.	– OWO – Calibration record, certificate and associated files
		⇩	
1.2	Head of Group	Head of Group verifies the correctness of the measurement results and other relevant data on the certificates and sends back to the responsible Laboratory staff.	– OWO – Calibration record, certificate and associated files
		⇩	
1.3	Laboratory staff	The Laboratory staff prints out the certificate. Additionally, prepare the calibration label and then send the online verified work order and submit all paper documents to the Head of Department.	– OWO – Printed certificate – Calibration label
		⇩	
1.4	Head of Department	The Head of Department approves to close the online work-order job in the online system, then signs the printed out certificate and return all documents to the responsible staff.	– OWO – Printed certificate – Calibration label
		⇩	

1.5	Laboratory staff	The Laboratory staff scans the approved certificate and saves into the appropriate location, then brings all documents and the service items to the staff of Corporation and Partnership Development Group.	– OWO – Calibration label – Approved Certificate
		⇩	
1.6	Staff of Corporation and Partnership Development Group	The staff of Corporation and Partnership Development Group closes the approved online work-order job in the online system and stores the service item in the storage area.	– OWO – Calibration label – Approved Certificate
		⇩	
1.7	Staff of Corporation and Partnership Development Group	Transmit the certificate and related documents to the customer	– Approved certificate

2 PURPOSE

The purpose of this procedure is to provide a system for issuing all certificates of service items.

3 SCOPE

This procedure applies to all certificates to be issued by NIMT.

4 DEFINITION

4.1 Certificate

A **certificate** is the measurement report of calibration/ analysis and certified reference material to be issued by NIMT.

5 PROCEDURE

5.1 Certificate Preparation

The laboratory staff who performed calibration or analysis and certified reference material will prepare the measurement results which shall be reported in a certificate.

5.1.1 The information reported in calibration or analysis certificates include at least the following information, unless NIMT has valid reasons for not doing so

l) a title "Certificate of Calibration" or "Certificate of Analysis";
m) name of the laboratory, name and address of NIMT ;
n) unique identification of the report shall be identified by using DL-XXXX-YY for customer and DL-YY-XXXX for internal customer.

Where D denotes the code of the department or the code of the acoustics and the vibration group ;

L denotes the code of the laboratory or the code of the group for the chemical metrology and biometry department (according to the organization chart);

XXXX denotes the running number of the certificate ;

YY denotes the year in which the certificate is issued ;

o) page n of N ;
p) name and address of the customer ;
q) description, condition and unique identification of measurement items ;
r) the date of receipt of customer measurement items where this is critical to the validity and application of the results;
s) identification of measurement method;
t) the relevant environmental conditions ;
u) any deviation from standard conditions ;
v) measurement results (as-found) obtained before any adjustments and as left data ;
w) the date on which the calibration was completed and the location where the calibration took place, either on-site (customer facility) or NIMT
x) a statement of the estimated uncertainty and/or compliance with an identified standard specification ;

y) evidence that the measurements are traceable ;
z) a signature of the person who performed the measurement ;
aa) a signature of approved signatories ;
bb) a statement that the certificate shall not be reproduced partially without any written permission from NIMT :
cc) a clear identification of the end of the certificate.

5.1.2 The information reported in analysis certificates for certified reference material shall include at least the following information, unless NIMT has valid reasons for not doing so

dd) a title "Certificate of Analysis" ;
ee) name and address of NIMT ;
ff) name of reference material ;
gg) reference material code and batch number ;
hh) description of the reference material ;
ii) intended use ;
jj) instructions for the correct use of the reference material ;
kk) instructions for appropriate conditions of storage ;
ll) page n of N ;
mm) identification of measurement method;
nn) the relevant environmental conditions ;
oo) a statement of the certified values and estimated uncertainty ;
pp) metrological traceability of the certified values ;
qq) period of validity;
rr) Information on commutability of the material (where appropriate);
ss) a signature of the person who performed the Certification;
tt) a signature and function of approved signatories ;
uu) document version;
vv) a clear identification of the end of the certificate.

5.1.3 The certificate shall be report in various formats due to the type of certificate issued as described below;

ww) Certificate issued under scope of accreditation shall follow the requirement of the accreditation body's regulation. Measurement results outside the scope

xx) of accreditation shall be reported on the same certificate and these results shall be clearly marked.

yy) The certificates that cover scope for CMC registration shall be issued as the certificates with the CIPM MRA symbol.

zz) Certificates that are not conformed to the above shall be issued with NIMT certificate format.

More details of each type of certificate and its' technical report for the specific measure and shall be demonstrated as a protocol in each DQM / GQM or CPs as appropriate.

5.2 The Head of Group shall systematically check all certificates prior to submission to the Head of Department.

5.3 The Head of Department shall review and approve the certificate.

5.4 The laboratory staff shall maintain the record of measurement and the laboratory staff scans the approved certificate and saves into the appropriate location. He/she shall return the approved certificate together with the service item and any additional labels to the staff of the Corporation and Partnership Development Group.

5.5 The staff of the Corporation and Partnership Development Group shall give the certificate to the customer or the agent assigned by the customer only in person and the customer or the agent must acknowledge the receipt of the certificate. However, if the customer is from oversea and cannot receive the certificate in person, the certificate shall be sent via EMS service only where the shipment can be tracked all the way to the recipient.

Amendment to Certificate

If a certificate that was already issued requires any correction, it is necessary to issue a new certificate in whole to replace the originally issued certificate. The replacement certificate shall include the statement: "This certificate replaces the certificate number DL-XXXX-YY". Such replacement certificate shall meet all the requirements of the QM and this QP. It shall be uniquely identified. The identification shall be such that the original identification

number still remain the same but be followed by AA, AB, …., up to AZ consecutively for each amendment made such as DL-XXXXAA-YY for the first amendment.

The amendment contents shall be clearly remarked.

Whenever the amendment to the certificate that might significantly affect the measurement result is issued, the responsible staff must follow the procedure in QP-06:Procedure for Control of Nonconforming Work.

Complement to Certificate

If a certificate that was already issued requires addition, the complement to that certificate shall be prepared to contain material necessary to complete the original one. The complement to the certificate shall include the statement: "This certificate contains additional material complementary to the certificate number DL-XXXX-YY". Such complement certificate shall meet all the requirements of the QM and this QP. It shall be uniquely identified. The identification shall be such that the original identification number still remain the same but be followed by CA, CB, …., up to CZ consecutively for each complement made such as DL-XXXXCA-YY for the first complement.

The additional contents shall be clearly remarked.

Reproduction of Certificate (Only for needed / reasonable cases)

The reproduction of certificate that was already issued shall be performed only with an approval from the Director to the official request from the customer. It is necessary to issue a new certificate in whole to replace the originally issued certificate. The reproduced certificate shall include the statement: "This certificate replaces the certificate number DL-XXXX-YY". Such reproduced certificate shall meet all the requirements of the QM and this QP. It shall be uniquely identified. The identification shall be such that the original identification number still remain the same but be followed by RA, RB, …., up to RZ consecutively for each reproduction made such as DL-XXXXRA-YY for the first reproduction. The actual date of certificate reproduction shall be reported as an issued date in the certificate with the remark of issued date previously reported in the replaced certificate. Related Forms

There are no related forms. However, the templates for the calibration certificates are available.

QP-16: PROCEDURE FOR REFERENCE MATERIAL PRODUCTION

1 OVERVIEW

	Responsibilities	Activities	Related Documents
1.1	The Head of Laboratory / Project Leader	Prepare the production plan and production control	– Production Plan – Production Control
		⇩	
1.2	Head of Group	Check the production plan and approve the production control	– Production Plan – Production Control
		⇩	
1.3	Head of Department	Approve the production plan	– Production Plan
		⇩	
1.4	Staff of Laboratory	Perform the production process including the assessment of homogeneity and stability, package, label and certificate	– Production Procedure – Production Plan – Production Control – Certification report – Label, Package
		⇩	
1.5	Head of Group	Certify the record and check the certificate, package and label	– Preparation and Measurement Record – Certificate report – Label, Package
		⇩	

1.6	Head of Department	Approve the certificate	– Preparation and Measurement Record – Certificate – Label, Package – Certification report

2 PURPOSE

The purpose of this procedure is to provide guidelines for reference material production.

3 SCOPE

This procedure is applicable to all reference materials produced by NIMT.

4 DEFINITION

4.1 Production Procedure is a document defining the specific details of all production requirements in accordance with ISO 17034.

4.2 Production Planning is a document that describes the production for a new reference material in detail.

4.3 Production control is a document that the NIMT uses to verify that the production plan has been implemented.

5 PROCEDURE

5.1 The Head of Laboratory / Project Leader shall prepare a production plan using the form Fr-PRO-01 and be responsible for preparing a production control using the form Fr-PRO-02.

The detail of production plan contains;

- Name of RM
- Customer request, target group or NIMT policies
- Total expenses
- Name of authorized person

- Method for preparation and material selection
- Requirement of subcontractor, if applicable.
- Requirement of package and storage conditions
- Methods for assessment of homogeneity and stability
- Methods for certification measurement
- Distribution management

5.2 The Head of Group shall review the Production Plan (Fr-Pro-01) and monitor that the staff have implemented the production plan by using a Production Control (Fr-PRO-02).

In case the work is carried out by subcontractor, the Head of Group shall evaluate the competence of subcontractor according to requirement specification as follows;

- Where uses subcontractors to undertake part of the reference material characterization, including homogeneity and stability testing, or characterization; the subcontractors to perform the concerned part must either comply to or be accredited to ISO/IEC 17025. In cases where accreditation is not practical, evidence of subcontractors successfully participating in a relevant proficiency testing scheme and producing acceptable results on well-characterized materials of similar or equivalent nature to that of candidate reference material may also be considered appropriate[6.2.4].

- For non-testing/calibration activities, including material processing, handling, storage or distribution of reference material, the subcontractors to carry out these activities must be accredited to the quality management system to ISO 9001.

5.3 The Head of Department approves the production planning.

5.4 The laboratory staff are responsible for performing the production work including assessing the homogeneity and stability of the RM, choosing RM packaging, preparing label and certificate and certification report (for new RM).

The Head of Group must ensure that:

- The approved procedure and the production planning are used.
- Raw data and their analysis together with any relevant information are collected.
- The method of stability and homogeneity assessment shall be performed in accordance to the recommendations of ISO Guide 35.
- All measurements performed in the scope of reference material production comply with the requirements of ISO/IEC 17025.

5.5 The Head of Group shall check the record of production and measurement/calibration results, the certificate, packaging and RM label.

5.6 The Head of Department shall approve the certificate and Certification Report.

6 RELATED FORMS

6.1 Fr-PRO-01: Production Plan Form

6.2 Fr-PRO-02: Production Control Form

QP-17: PROCEDURE FOR SELECTING AND MAINTAINING THE COMPETENCE OF EXTERNAL PROVIDER

1 OVERVIEW

	Responsibilities	Activities	Related Documents
1.1	The Head of Laboratory / Project Leader	Determine specification of task, select subcontractor and prepare a subcontractor record.	- Production Plan - Subcontractor Record
		⇩	
1.2	Head of Group	Check competence of subcontractor.	- Production Plan
		⇩	
1.3	Head of Department	Approve a subcontractor record	- Subcontractor Record -
		⇩	
1.4	Head of Group	Prepare and update a subcontractor list	- Subcontractor List

2 PURPOSE

The purpose of this procedure is to ensure that all tasks from subcontractor comply with the requirements of NIMT.

3 SCOPE

This procedure is applicable to task to be performed by subcontractor.

4 DEFINITION

4.1 N/A

5 PROCEDURE

5.1 The Head of Laboratory / Project Leader shall specify the works carried out by subcontractor in the production plan form FR-PRO-01. The technical expertise on measurements and material handling are the key performances for subcontractor selection process, which follows the department criteria on subcontracting approval.

5.2 The Head of Group shall evaluate the competence of subcontractor according to requirement specification of either department that shall be identified in individual DQM including;

5.2.1 Where uses subcontractors to undertake part of the reference material characterization, including homogeneity and stability testing, or characterization; the subcontractors to perform the concerned part must either comply to or be accredited to ISO/IEC 17025. In cases where accreditation is not practical, evidence of subcontractors successfully participating in a relevant proficiency testing scheme and producing acceptable results on well-characterized materials of similar or equivalent nature to that of candidate reference material may also be considered appropriate[6.2.4].

5.2.2 For non-testing/calibration activities, including material processing, handling, storage or distribution of reference material, the subcontractors to carry out these activities must be accredited to the quality management system to ISO 9001.

In addition, The Head of Laboratory shall regularly review a Subcontractor Record.

5.3 The Head of Department shall approve the competence of subcontractor in the Form Fr-SUB-02: Subcontractor Record.

5.4 The Head of Group is responsible to prepare and update the list of subcontractor by using form Fr-SUB-01: Subcontractor List. The Head of Group is responsible for ensuring products and services from subcontractors its compliance with the scope of work as stated in subcontractor record. The result of the inspection shall be recorded onto the form Fr-EQU-01: Equipment Inspection.

6 RELATED FORMS

6.1 Fr-SUB-01: Subcontractor List Form

6.2 Fr-SUB-02: Subcontractor Record Form

6.3 Fr-EQU-01: Equipment Inspection Form

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NIMT Quality Procedures

Edition: 10 Revision: 00

Total Number of Pages (including all sections and covers): 86 pages.

Back Cover Page

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