

NATIONAL METROLOGY LABORATORY

QUALITY MANUAL

Name of Document: Quality Manual	Approved by: Director General BSB	Revision No.: 0
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AMMENDMENT DETAILS

SI. No	Affective pages	Amended by	Signature	Date	Approved by	Signature / Date
1.	Section 4.1 page no.5/6 Section 4.2 page no. 3/3 Section 4.3 page no. 1/2 Section 4.13 page no. 1/1 Section 5.3 page no. 1/1 Section 5.4 page no. 1/2 Section 5.5 page no. 2/2 Section 5.6 page no. 1/1 Section 5.9 page no.1/1 Section 5.10 page no 2/2	Technical Manager		19/07/ 2014	Director General	
2.	Section 4.1 page no.3/6 Annex-1	Technical Manager		19/07/ 2014	Director General	
3.	Annex-3 (page 1)	Technical Manager		09/02/ 2015	Director General	
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DISTRIBUTION DETAILS:

- 1. Director General / NML BSB Copy-1
- 2. Head NML / Technical Manager Copy-2
- 3. Quality Manager Copy-3
- 4. Calibration Mass lab Copy-4
- 5. Calibration Length lab Copy-5
- 6. General Copy-6
- 7. Master folder Copy- 7

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SCOPE AND FIELD OF APPLICATION

The National Metrology Laboratory (NML) is actively involved in the calibration of mechanical parameters like Mass, Volume and Length to start with. This Quality Manual addresses all those requirements which are detailed in ISO/IEC 17025: 2005 in general and to the Specific Criteria for Calibration Laboratories in Mechanical discipline.

This Quality Manual is applicable only to those activities of "NML" (National Metrology Laboratory) that are related to the calibration activities of the organization. The NML may add calibration of other parameters in the near future and accordingly changes will be incorporated when required.

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INTRODUCTION

With the booming businesses in trade and industries in the country, the need for quality infrastructure in the country was increasingly felt by the Royal Government of Bhutan to ensure that the goods and services produced in the country and imported from other countries are of good quality. Therefore Bhutan Standards Bureau was established after the enactment of the 'Bhutan Standards Act 2010', by the parliament in the year 2010 to ensure that customers get value for their money by enabling them to accessing desired quality of goods and services in the country.

While quality is desired, it is impossible to achieve quality of products and services without a good measurement system in place. Therefore the act also mandates Bhutan Standards Bureau to establish and operate Metrological Referral and Calibration Laboratories. The National Metrology Laboratory (NML) is incorporated as per the above mandates.

The Features of NML are:

- Calibration of measuring equipments /devices used for measuring physical parameters. It intends to serve the customers from laboratories, industries, government & non-government organizations, societies, private entities, and the individuals.
- Provide training to the scientific community on all aspects for implementing ISO/IEC 17025.

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QUALITY POLICY STATEMENT

SCOPE

The Quality Manual of the National Metrology Laboratory is its apex document and is prepared to satisfy the needs of the people in accordance with ISO/IEC 17025-2005 and also to serve as the main reference document. The NML implements its quality management system in all its activities, right from receipt/collection of calibration items till the reporting and submission of the result to the customer.

Objectives of the Management system of the NML are:

- Provide accurate and reliable calibration services to its customer.
- Achieve international recognition and reliability via implementing integrated management & technical system as per ISO/IEC 17025-2005 and by getting accreditation from a APLAC's MRA accreditation body.
- Use standard calibration methods and satisfy customer's requirement, and to work towards scientific excellence.
- Provide training to its staff in the field of calibration & Quality System related activities to ensure delivery of Good Professional Practices and to keep the staff updated with the latest information on the subject they work.

These objectives are being achieved by:

- Providing complete documentation as required by ISO-17025 -2005 and on all calibration protocols, procedures and activities carried out within the NML.
- Ensuring that its personnel are professionally competent and familiar with the quality system documentation, and implement the policies and procedures specific to their work.
- NML staffs are required to give a pledge/undertaking as per annex-1, meant to ensure their commitment.

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- Participating in appropriate inter-laboratory comparisons and/or in proficiency testing programs conducted by national and international organizations to monitor its working.
- Ensuring implementation of appropriate quality procedures at all stages of laboratory operations to comply with ISO/IEC 17025-2005.
- Management is committed to provide the required resources and required support to ensure that NML's standard of services are of global equivalence and are kept consistent, and to maintain accreditation of its laboratory.

AUTHORIZATION & RESPONSIBILITIES:

The Head or Technical Manager is authorized and made responsible for implementation of the Policies and Procedures of the management as detailed in this Quality Manual. Technical Manager is also authorized and made responsible to continually improve the management system, review/update all documents, including the Quality manual.

Quality Manager of NML is responsible for preparing the required documentation on the Quality Management System, and to guide the support staff. He / She is also responsible to ensure that the documentation on Quality management system is followed continuously to maintain the compliance of NML with ISO/IEC 17025-2005. Quality Manager is authorized to conduct and coordinate the internal audits and review the activities as per the defined policies and procedures. He / She shall organize management review meetings and shall report to Director General BSB.

It is also hereby notified that Quality Policy Statement and Quality Management System as defined in the Quality Manual and in supporting documents are mandatory to be followed by all with immediate effect. NML's Quality Manager is responsible to ensure compliance of, as stated above.

DIRECTOR GENERAL BHUTAN STANDARDS BUREAU

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1- Normative References:

ISO/IEC 17025-2005 is taken as the main reference document; care will be taken to incorporate all changes in this manual whenever any reference document is revised.

NABL 122, issue no: 04, Amendment No: 01, Specific Criteria for Calibration Laboratories in Mechanical Discipline.

2- Terms and Definitions:

All the relevant terms and definitions used in this manual are taken from the standard ISO/IEC17025/2005.

NML	National Metrology Laboratory
Laboratory	National Metrology Laboratory
ТМ	Technical manager
QM	Quality manager
BIPM	International Bureau of Weights and Measures
CIPM	International Committee of Weights and Measures
ILAC	International Laboratory Accreditation Cooperation
IEC	International Electro-technical Commission
ISO	International Organization for Standardization
BSB	Bhutan Standards Bureau
M&LSD	Metrology & Laboratory Services Division
MLA	Multi-Lateral Arrangement
MRA	Mutual Recognition Arrangement
NABL	National Accreditation Board for Testing and Calibration
	Laboratories
OIML	International Organization of Legal Metrology
QMS	Quality Management System
(UoM)	Uncertainty of Measurement

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4- MANAGEMENT REQUIREMENTS

4.1-Organisation:

Policy:

National Metrology Laboratory (NML) Bhutan is committed to operate its management system without any discrimination and to protect customer's confidential information and proprietary rights. NML is not involved in any activity that may erode confidence in its competence, impartiality, judgment and operational integrity.

4.1.1 Legal Identity

BSB is an autonomous body and was incorporated by an act of Parliament in the year 2010, and has the mandate by the Act to establish the NML as the referral metrology lab for Bhutan. The legal status of NML is the same as of BSB.

4.1.2 Responsibility

The Head of NML is responsible for the activities that are being performed at NML, and is committed to provide quality services to its customers by adhering to specifications of international standard ISO/IEC 17025:2005 and other regulatory & accreditation bodies.

4.1.3 Metrology & Calibration Facility:

NML is operational since 2012, from the first floor of BSB office complex, Thimphu. This facility houses Mass, Volume and Linier measurements laboratory. It serves the purpose of providing the traceability in measurements to the industry and laboratories of Bhutan traceable to international standards.

4.1.4 Conflict of Interest:

National Metrology Laboratory is involved in providing traceability and calibration to domestic measurement system and by maintaining traceability to international System of Units. And as such there is no conflict of interests between any in its working.

4.1.5

a. There are adequate number of technical and non-technical staff who have necessary authority and resources needed to carry out the technical and non-technical activities pertaining to the laboratory. Adequate supervision of calibration by person competent in calibration and capable of assessment of

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calibration results is provided. These personnel are collectively responsible to maintain the management system and to identify any deviation from defined management system and calibration procedure and take such corrective and preventive actions as necessary.

- **b.** The laboratory's technical staff is free from any commercial, financial pressures and their remuneration is not linked to the number of calibrations they do. All employees of BSB are governed by government rules.
- c. Confidentiality:

The policy of NML is to protect confidentiality and proprietary rights of the information it may have regarding its customers. Any information/document that gets generated in the course of carrying out any calibration/testing activity is treated as confidential and not allowed to be seen by any other person who is not concerned with it. Further, the records of calibration are archived in the form of soft copies but only authorized persons can have access to such records. There is a system of keeping back-up copies of the records separately. When Calibration results are sent through electronic media the proper identity of customer is ensured. The laboratory has its Procedure on Maintaining Confidentiality and impartiality. (NML/P/4.1/01).

d. Competence, Impartiality, Judgment and Operational Integrity

- **Competence:** The new staff is recruited on the basis of required qualification, experience and where required by imparting training as per the need of the laboratory, to ensure their competence.
- Impartiality: The laboratory is committed to be fair and impartial to all its customers. It does not discriminate between the customers and follows the norm of first come first served. However when a calibration is required to be given a priority, the Director BSB may use his discretionary powers to by pass the norm of first come first serve.
- **Judgment:** NML has training system to update the competence level in its personnel so that their judgment capability is assured.
- **Operational Integrity:** To maintain integrity, its managerial and support staff are required to give a written declaration/pledge as their commitment in the prescribed format given at annex-1.

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e. Organizational structure

Fig 1: Organizational chart of BSB

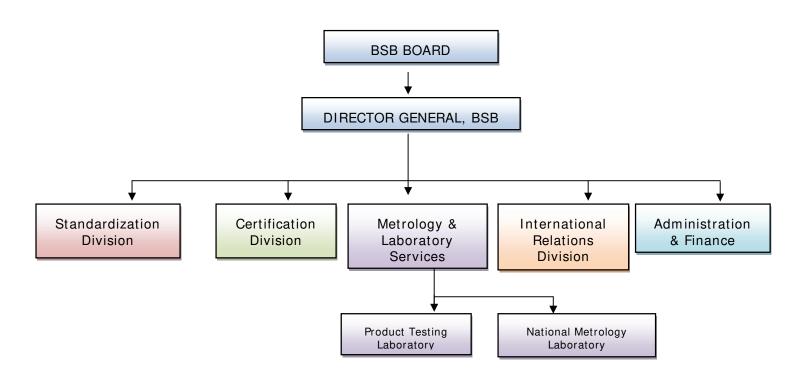
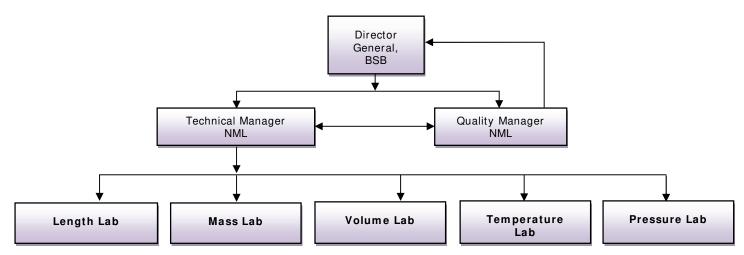


Fig 2: Functional Chart of NML Laboratory



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f. Responsibilities and Authorities:

NML maintain a job description manual. The responsibilities and the authorities of the technical and non-technical personnel have been defined and communicated to its staff. The qualification and experience for each position of the lab have been defined in Job Description Manual.

Responsibilities & Authorities of the key personnel are as follows:

Director General BSB/NML.

- To provide the infrastructural support.
- Conducts management reviews.
- Approves Quality Manual.
- Provide general supervision when required.

Head, NML/Technical manager

- Liaise with Accreditation bodies and regulatory authorities.
- Conduct unscheduled checks by recalibrating the already calibrated items.
- Management of laboratory facilities.
- Evaluation of Staff competency
- Liaise with customers and vendors.
- Responsible for calibration & Quality control norms.
- Responsible for preparation of technical & all other documents.
- Timely delivery of the calibrated items.
- Attention on matters relating to impartiality and confidentiality.
- In selection, appropriate calibration/test method.
- Provide supervision/advice (Guidance) to support staff.
- Training of technical staff.
- Responsible for the technical validity of calibration results.
- Technical Manager is responsible for document control.
- Responsible for ILC/PT Participation.

Deputy Technical Manager

He/she looks after all the jobs of technical manager in his absence in addition to his/her normal functions.

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Quality manager

- Responsible for monitoring the quality management system.
- Plans and conducts the internal audits.
- Plans and conducts the management reviews.
- Conducts unscheduled recalibration as a surprise check.
- Review procedures and work instructions.

Deputy Quality manager

He/she looks after all the jobs of quality manager in her/his absence in addition to his/hers normal functions.

- g. Organizational structure of NML has inbuilt built provision of adequate supervision of staff involved in calibration/testing.
- h. Head NML/ Technical manager shall be a technical person with several years of scientific/technical experience, and quality system, is empowered to provide the required resources to the lab for its needs.
- i. Head mass laboratory is designated as the quality manager to perform the functions of internal audits, and other jobs relating to quality assurance with access to Director BSB.
- j. As per an order of the management next in command is responsible for the job of his senior in his absence, except for authorized signatory.
- k. NML employees are required to give a pledge (annex -1). This ensures that each staff member is well aware about his work and its importance, besides their receiving trainings.

4.1.6 Head NML/ Technical manager works closely with the staff of laboratory besides taking weekly meeting to ensure effective communication in achieving effectiveness of management system.

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4.2 MANAGEMENT SYSTEM

NML, as a policy has established and maintains a management system suitable for its activities, which are in compliance to ISO/IEC 17025:2005. The objective of Quality system is to ensure that all its activities are carried out in a consistent manner.

4.2.1 Policies and objectives of the NML's management relating to the implementation of the relevant clauses of ISO/IEC 17025:2005 are defined and documented in the Quality manual and the procedures, to assure the quality of calibration results. And by means of distribution of its documents, qualification/training of its staff and periodical internal audit, NML Lab ensures that the system's documents are available to, understood by and implemented by appropriate personnel.

4.2.2- Management Policy:

NML is committed to provide consistent, accurate and reliable calibration by:

- Adopting good laboratory and professional practices
- Deploying qualified and trained technical staff
- Adopting national/international methodology as may be applicable in quality system and for technical norms
- Using only those instruments, which are fit for intended calibration
- Commitment to the compliance with ISO/IEC 17025:2005 and continued improvement of management system.

A signed "Quality Policy Statement" from the Director General of BSB/NML, is given at page VII& VIII of this Quality Manual.

4.2.3-Documented Management system:

NML has developed and documented a management system conforming to the requirements of ISO/IEC 17025:2005, for effective implementation and easy operations. The management system is documented at these levels of documents:

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Level I - Quality Manual

The policies of NML regarding the elements of ISO/IEC17025 are given in broad terms in the Quality Manual. The applicable procedures are identified in the Quality Manual. It also defines the responsibilities and authorities of its key personnel, & Director General of BSB/NML is the main authority to approve the Quality manual.

Level II - Working Procedures including Calibration Procedures /Methods

Working Procedures address how NML's policies and management system are being implemented for its compliance to ISO/IEC 17025:2005. Head NML/Technical Manager is responsible to approve working procedures and working instructions/forms/tags etc.

A list of Procedures in use, that comply with ISO/IEC 17025:2005, is given at annex 2, and the list of Procedure for calibration of instruments against NML's standards is given at annexe-3

Level III – Working Instructions (WI)

Working Instructions (WI) addresses in detail how technical work is to be done. The responsible person to approve WI is the Head NML/ Technical manager.

Level IV – Forms and Records

Where practicable, standardized forms/formats and registers are used. Records include technical and managerial records, e.g. Quality System Records, Log Books, Calibration Records, Equipment Manuals, Certificates of Reference standards and Personnel Records, etc.

Level I	Quality Manual
Level II	Working Procedures, including Calibration Procedures/Methods
Level III	Working Instructions.
Level IV	Forms/tags and Records.

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Management maintains the distribution records of the document holders including their receipts. All copies are numbered and controlled copies are stamped. The holders of the controlled copies of Quality Manual are listed below:

1	Director General copy -1
2	Head NML/Technical Manager Copy-2
3	Quality Manager Copy-3
4	Calibration Mass Lab - Copy-4
5	Calibration Length Lab - Copy-5
6	General – Copy-6
7	Master folder – Copy -7

- 4.2.4 Technical Manager has been made to understand the need to meet the customer's requirements and also the regulatory norms to be followed. To this effect, he/she has been given training in ISO/IEC 17025:2005 requirement.
- 4.2.5 The list of Procedures is given at annex-2 & 3.
- 4.2.6 The roles and responsibilities of the technical management have been described in Job Description manual and section 4.1.5 (f) of Quality manual.
- 4.2.7 To ensure the continuity in the operational integrity of the quality system, in the event of management of NML Lab undergoing a change, the staff of NML Lab would continue to follow the laid down policies and procedures and an undertaking from them (annex-1) has been taken to this effect.

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4.3 DOCUMENT CONTROL

Policy: NML is committed to provide valid and latest version of the documents to its personnel and ensure that they work with latest scientific and international norms.

4.3.1-General: There are procedures to control all internally and externally generated documents. Technical Manager of NML is responsible to maintain and implement the Procedure for document control (NML/P/4.3/01).

4.3.2-Document Approval and Issue:

4.3.2.1- All documents prepared are to be put in effective use; identify the persons who have prepared and approved it; the person approving the document is required to review before it is issued & giving the current revision status; issue number; and issue dates. Copies for use by authorized personnel are marked as "**Controlled Copy**" and uniquely numbered. External documents, e.g. Standard Calibration/Test Methods, specifications, drawings, and charts are stamped as "**Controlled Copy**" and the status indicated. A master list of current version of documents and its distribution are maintained in NML/F/4.3/01.

Technical Manager is responsible for distribution of the controlled copies of documents to the concerned person(s) and maintains the distribution record.

4.3.2.2- Authorized editions of appropriate documents are available to personnel as necessary.

Technical Manager ensures that documents are periodically reviewed & revised. Obsolete documents are promptly removed from use and users notified. One copy of all obsolete documents (**suitably marked as 'obsolete'**) is preserved for a minimum of three years for any future use or legal purposes. This procedure is explained in NML/P/4.3/02.

4.3.2.3- All management system documents, generated by the NML are identified with prepared by, issued & approved by, first release, date of issue, issue number, revision number, page number, nature of document. This procedure is explained in (NML/P/4.3/03).

4.3.3-Document Changes:

4.3.3.1- As a policy of NML, all documents are reviewed and revised, if required to ensure their continuing suitability. The policy is to review the documents after three years, but mandatorily before four years.

4.3.3.2- Changes in documents are identified in the amendment sheet giving the

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4.3.3.3- Hand written amendments are not permitted.

4.3.3.4 - Amendment if required is done as per amendment procedure. Laboratory staff uses hard copies of documents, which are duly authorized in their day to day work. The following stamps are used to identify the status of the documents.

Controlled copy	To identify controlled documents
Uncontrolled copy	To identify uncontrolled documents
Obsolete copy	To identify obsolete documents

Records: the records relating to document control are kept in NML/F/4.3/01

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4.4 - REVIEW OF REQUESTS, TENDERS AND CONTRACTS

Policy: The policy of NML is to take up review of a new works / assignments related to quality subject to its capability to undertake such new works, and through acceptance of the contractual requirements between NML& the Customer.

4.4.1- NML has established and maintains a procedure for review of requests (NML/P/4.4/01).

When reviewing the request of customer NML assures that: "It has the capability and resources to meet the requirements of the customer. And any differences between the request and tender/contract are resolved before starting work. Contract is made in such a way that it is acceptable to both the Laboratory and the customer."

4.4.2- The records of reviews of request and contract are maintained.

4.4.3- The Laboratory does not take up work where subcontracting is involved.

4.4.4- The customer is informed if there is any deviation in the contract.

4.4.5- If it is necessary to make amendments after the calibration work has commenced, the same procedure for contract review is followed and the amendments are communicated to all affected personnel.

Records: All records relating to review of request, tender & contracts are kept in NML/F/4.4/01

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4.5- SUBCONTRACTING OF CALIBRATION: NML does no subcontract.

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4.6 - PURCHASING SERVICES AND SUPPLIES

NML Policy is to define the specification all those purchased items, which can affect the results, and accept only those supplies which meet the specifications.

4.6.1- NML Lab has established and maintains a procedure for purchasing, acceptance of purchased items and storage of instruments and spare parts, as per NML/P/4.6/01

4.6.2- The Laboratory ensures that purchased equipment, and supplies comply with the specified requirements of calibration standard/methods and are not used until they have been inspected, verified against specifications. Records of checking are maintained for critical supply

4.6.3- Purchasing documents contain details such as product name, quantity, specifications, as required in the calibration method, and supplier.

4.6.4- NML maintains the records of suppliers of critical consumables and services and evaluates their performance over a period of time. The approval status is reviewed on the basis of this evaluation.

Records: All records relating to Purchase Services and supplies are kept in NML/F/4.6/01

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4.7 - SERVICE TO THE CUSTOMER

Policy: NML is committed to extend its full cooperation to its customer or its representative, in providing the clarification or the assistance which may help solve his / her (customer's) calibration related problem.

4.7.1 The ultimate target of NML is customer satisfaction. It maintains contact with the customers in order to provide a timely and effective service.

- NML is open to extend cooperation to the customers, to witness the calibration, if it is requested but by ensuring confidentiality relating to other customers.
- NML is open to repeat the calibration, if requested, also in the presence of the customer.
- When requested, NML cooperates in packing of calibrated item.

4.7.2 The NML management is open to maintain cordial and professional relationships with its customers. It has a system of seeking suggestions/feedback through a feed- back form (Annex - 6) which is sent with the calibration report. The feedback is studied and appropriate action taken.

Records: Records of customer feed- back and action taken are kept in: NML/F/4.7/01.

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4.8 - COMPLAINTS

Policy: As a policy NML is open to receive complaints from its customer or other parties and to investigate to eradicate the root cause of complaint, if any. It gives a prompt feedback to customer/other parties and assures continued good service to restoring the confidence of the customers. Complaints/customer feedbacks are treated as a source for improvement and motivation.

The complaints are resolved as per procedure NML/P/4.8/01.

Records of complaints received, investigations carried out, corrective actions taken and time taken to resolve the complaints are maintained. If the investigation raises a doubt that certain aspect of quality system is not being followed properly, then that aspect of quality system is subjected to additional audit.

Technical manager is responsible to resolve the complaints and maintain the records to this effect.

Records: Records on complaints are kept in NML/F/4.8/01

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4.9 - CONTROL OF NONCONFORMING WORK

Policy: As a policy NML is committed to pin down any non–conforming work in calibration and in its management system. When a non-conforming work is identified, appropriate steps are taken for Control of Nonconforming Testing Work.

4.9.1 The Management has informed its staff that when they identify a nonconforming work being performed, they are to inform the Technical manager or Quality manager, based on their availability.

In the event a non-conforming work is identified, the significance of nonconforming work is evaluated and corrective action is taken as per procedure (NML/P/4.9/01). Where necessary, the customer is notified and work is recalled. Technical Manager is responsible for the proposed corrective action that is to be undertaken, and is authorized to restart work.

4.9.2 If found that the nonconformities still reoccur, and there is doubt about the compliance of NML operation with the established policies and procedures, corrective actions as described in 4.11, are taken.

Records: All records relating non-conforming work are kept in NML/F/4.9/01

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4.10 - IMPROVEMENTS

Policy: The policy of NML is to maintain a regime of continual improvement. This is achieved by regularly reviewing such sources of improvement as:

- Results of PT participation, QC Results;
- Findings of Internal Audit;
- Customer Complaints/feed back;
- Calibration data;
- Management Review;
- Analyst feedback (informal suggestions);
- Formal lab meetings;
- Instrument and personal logbooks;
- External audit findings;

Technical Manager is responsible for coordinating the improvement measures. He also maintains the records of the inputs for considering the opportunity for improvements, and the details of the decisions.

Records: All records relating to improvements are kept in NML/F/4.10/01

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4.11 - CORRECTIVE ACTION

4.11.1 General

Policy: NML is committed to undertake corrective action whenever any departure from policies and procedures in the Management System is noted or nonconformities in technical operation are identified. Technical manager is responsible to initiate the process of corrective action when a non conformance is found, in accordance to the Procedure of taking corrective action NML/P/4.11/01.

4.11.2 Cause analysis.

When an external or internal audit is done and a NC's is noted it also reveals the cause of NC. Corrective action is taken as the root-cause(s) of a non-conforming work is made known.

But when a complaint is received or the results of PT participation are not satisfactory, then the cause analysis is required to locate the root-cause of the problem and then take corrective action. There may be a situation, when NML staff themselves are doubtful about the results of a calibration, then also it requires cause analysis.

To determine the root cause in the above situations normally vertical audit is performed. The technical manager of NML is responsible to determine the root cause of the non conforming work.

4.11.3- Once the root cause of a non-conforming calibration/testing is identified appropriate corrective action is taken.

4.11.4- After implementation of the corrective action, results is monitored to ensure the effectiveness of corrective action. The technical manager of the laboratory is responsible for the required corrective action as per the corrective action procedure (NML/P/4.11/01).

4.11.5- An additional internal audit is conducted in the area(s) where nonconformities cast doubts on compliance with its policies and procedures.

Records: All records relating to corrective action are kept in NML/F/4.11/01

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4.12- PREVENTIVE ACTIONS

Policy: As per its Policy NML encourages and appreciates its employees to identify the potential sources of non-conformance and in suggesting appropriate action to prevent a possible non-conformance from happening.

4.12.1- Also preventive actions are identified through the following procedure:

- Observations made during internal-audit, management-reviews and inhouse management checks.
- Trend analysis of the results of calibration certificates for laboratory owned equipment.
- Observation made by customers and assessment bodies.

Any of the staff may suggest any potential source of nonconformance work. If any preventive action is required, action plans are developed. The potential action plan may get its inputs from review of operational data, test result data, proficiency test results, trend and risk analysis and work experience.

4.12.2- The action plan is developed and implemented according to the procedure (NML/P/4.12/01) to ensure effectiveness.

Records: All records relating to preventive action are kept in NML/F/4.12/01

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4.13 - CONTROL OF RECORDS

Policy: NML policy is to retain and maintain its work records in the form of hard copies, and where required these also preserved in form of CDs, as per its procedure NML/P/4.13/01.

4.13.1.1- NML's procedure for Control of records (NML/P/4.13/01), covers identification, indexing, filing, storage, maintenance, location and disposal of all management and technical records, including all records of internal audits, management review, corrective and preventive action.

4.13.1.2- NML stores records in safe way to prevent distortion or damage or loss. Records are easily retrievable until final disposal.

4.13.1.3- All records of NML are held secure and in confidence for three years.

4.13.1.4- Electronic records/data (if any) are secured, using password protection and by giving accessibly only to authorized personnel.

4.13.2- Technical Record.

4.13.2.1- The laboratory retains all the raw data associated with calibration, original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of calibration certificates issued, calibration of equipment involved, for a defined period, as per the Procedure for maintenance of records (NML/P/4.13/01). The records include the identity of the personnel responsible for the sampling, performance of each calibration and checking of results.

Record of calibrations contains sufficient data, to reproduce the calibration done.

4.13.2.2- All data generated at the time of calibration like readings, observations and calculations etc. are recorded with details of sample identification and calibration procedure followed. The records are also traceable to specific tasks performed and the person involved.

4.13.2.3- Staff of Lab has been trained about those mistakes on the recorded data, when it needs a correction, is to be crossed out and correct value is to be entered alongside, with initials by the person making the correction.

Records: All records relating Control of records are kept in NML/F/4.13/01

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4.14 - INTERNAL AUDITS

Policy: Management of NML is committed to ensure that internal audit is carried out at least once in a year, by trained auditors, as per schedule to ensure compliance of the documented management system and procedures according to ISO 17025: 2005.

4.14.1- NML conducts an internal audit according to predetermined schedule, in which all the elements of management system are audited at least once in a year. Quality manager plans and organizes internal audits according to procedure (NML/P/4.14/01). The audit is carried out by trained auditor who is independent of activity to be audited.

4.14.2- If the findings of an internal audit cast doubt on the effectiveness of the operations or on the correctness or validity of the calibrations done at laboratory, NML takes timely corrective action, and notifies its customers in writing.

4.14.3- Records are maintained for the activity audited, audit findings and corrective actions taken.

4.14.4- After taking corrective actions their effectiveness is verified, during follow up audits and appropriate records are maintained.

Records: All records relating to internal audit are kept in NML/F/4.14/01

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4.15 - MANAGEMENT REVIEW

Policy: The Management of NML is committed to conduct management review at least once in a year, as per the Procedure for conducting management review (NML/P/4.15/01)

4.15.1- Quality Manager is responsible to organize the management review and record the minutes. Besides Quality Technical managers, their Deputies and Manager Administration are the members of the management review committee. Agenda covers following aspects:

- Minutes of previous management review.
- The suitability of policies and procedures.
- Feed back from managerial and supervisory personnel.
- The outcome of internal audits.
- Corrective and preventive action.
- Assessments by external bodies.
- The results of inter laboratory comparisons or proficiency tests.
- Changes in the volume and type of the work.
- Customer Feedback.
- Complaints.
- Quality control activities, resources and staff training.
- Any recommendation concerning improvement.
- Any issue of current interest.

4.15.2- Director General BSB/ NML ensures that findings are recorded and actions are taken on the basis of the review by management.

Records: All records relating to management review are kept in NML/F/4.15/01

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5 - TECHNICAL REQUIREMENTS

5.1-General:

5.1.1 NML is aware that correctness and reliability of calibrations performed depends on many factors and therefore is committed to ensure effectiveness of its human resources besides accommodation and environmental conditions, calibration methods, equipment, measurement traceability, and handling of calibration items.

5.1.2 It is the policy of NML to consider all those major factors which contribute towards the uncertainty of measurement and in estimating the uncertainty of individual steps of a calibration.

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5.2 - PERSONNEL

Policy: The policy of NML is to employ persons with relevant qualifications/ experience and to impart appropriate training to make sure that they are competent for the job they are assigned.

5.2.1 NML has identified and designated persons from amongst its staff to perform activities, like operation of equipment for carrying out calibration, evaluation of calibrated values/results, issue and signing of calibration reports, based on their competence. Staffs, who are under training, if used for performing calibrations, are supervised as appropriate by senior staff. Competence norms are: i) Qualification, ii) Training, & iii) Work Experience

5.2.2 As its policy NML has setup competence norms for its staff depending on activities they are to perform, on the basis of appropriate education, training, experience and demonstrated skills. NML has formulated its job requirement norms for its personnel on the basis of education, training and skills. The training policy covers:

i. Training is a must for newly inducted person who have no prior experience of working in a similar laboratory, and effectiveness of training is continually evaluated by trainer.

ii. For those who need to learn operation of laboratory's equipment & have no such experience from their previous work.

iii. Continual training to keep the staff updated with latest scientific technique and on Quality system.

5.2.3 - Personnel working in NML are regular staff as per government rules.

5.2.4 - NML maintains Job Description Manual for all, technical and non-technical personnel. These cover responsibilities with respect to performing calibration, issuing calibration certificates / and authorized signatories. It has defined qualification, training and required experience, for each of its job.

5.2.5 - Only identified persons operate calibration equipments, perform calibrations, issue calibration Certificates, gives opinions & interpretations. NML maintains the records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information is readily available and includes the date on which authorization and/or competence is confirmed.

Records: All records relating to Personnel & training are kept in NML/F/5.2/01

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5.3 - ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

Policy: As per its Policy Management of NML is committed to provide required environmental conditions and accommodation to conduct calibration activities, and suspend calibration activity where maintaining environmental conditions goes beyond control. This policy is implemented as per NML Procedure for control of environmental conditions (NML/P/5.3/01).

5.3.1 NML has made arrangements to provide required environmental conditions for smooth and comfortable performance of calibration activity and to safeguard the integrity of calibration items during collection and storage. And also to ensure that it does not invalidate the calibration results or adversely affect the required quality of measurement.

5.3.2 NML monitors, controls and records the environmental conditions as may be required by the relevant specifications for calibration methods. Calibrations are stopped when environmental conditions may jeopardize the results. The environmental conditions are monitored and records are maintained.

5.3.3 NML has provided effective physical separation between adjacent areas. The layout plan of the laboratory is in Annex-7

5.3.4 The entry to calibration area is restricted to unauthorized personnel.

5.3.5 Adequate housekeeping is maintained as per procedure applicable to the concerned laboratories. A first-aid box is maintained.

Records: All records relating environment control are kept in NML/F/5.3/01

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5.4 - CALIBRATION METHODS AND METHOD VALIDATION

Policy: The policy of the NML is to follow calibration procedures as specified in international, regional or national standard.

5.4.1 NML uses appropriate calibration procedure/methods for its all calibrations and within its scope. Documented instructions have been provided to its staff on the operation of all relevant equipment including handling, and transportation of the calibration items. All instructions and reference data are kept up-to-date and readily available to the personnel performing the calibration. Deviations from calibration procedure/method are not permitted.

5.4.2 - Selection of Calibration Methods:

NML has developed its calibration procedures that are based on the Standards form of BSB and other International Standard Writing Institutions. The Procedure for Calibration of Mass, Length etc is compiled in NML/F/5.4/01.

Specific requirement from customer if any is also honored, subject to reporting of this fact in calibration report, and records kept. Such a situation may arise to serve the cause of Instrument manufacturers, if any.

Laboratory is open to opt for the calibration method based on other international standard if there is a request of Customer.

The laboratory informs the customer when the method proposed by the customer is considered to be in appropriate or out of date.

5.4.3 Laboratory-Developed Methods: NML does not develop/use its own methods.

5.4.4 Non-standard Methods: NML does not use any non-standard methods.

5.4.5 Validation of Methods: NML does not have a program of developing its own calibration procedures; it uses only those calibration procedures which have been developed by standard writing institutions, like BSB, ISO, ASTM, and OIML & BIS.

5.4.6 Estimation of uncertainty of measurements: NML is committed to provide uncertainty of measurement for all calibrations done by it. The details on estimation of measurement uncertainty are covered in each Procedure for Calibration.

5.4.6.2 NML is not a testing lab.

5.4.6.3 As a policy NML takes into consideration all recommended inputs which are there in the national/international standards.

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5.4.7-Control of Data:

5.4.7.1 NML has a provision for check and recheck of calculations and transfers data in a systematic manner before reporting.

5.4.7.2 Since the computers and automated equipment are not used to control the data, therefore this clause is not applicable to NML.

Records: All records relating to raw data and calibration are kept in NML/F/5.4/02

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5.5 - EQUIPMENT

5.5.1- NML is equipped with all necessary instruments and equipment to correctly carry out calibration of the items under its scope and according to the national/international standard(s). NML does not use any equipment outside its permanent control.

5.5.2- NML ensures by verifying that the Calibration standards and its Software (if any) used for calibration are capable of achieving the required accuracy and comply with requirements of specification relevant to calibration. Verification records are preserved. NML calibrates all those equipments, which can influence the results of calibration. (NML/P/5.5/01)

5.5.3 Only authorized and trained staff is allowed to operate the equipment/instruments at NML. There are log books for key equipment, and the user is required to register his identity and fill the log-book for the work he or she does. Also there are operating instructions along with each Machine/equipment for use by staff.

5.5.4 – Standards and equipments are identified by a unique number with a sticker pasted on them, which also display the next due date of calibration. Software related to particular equipment is identified wherever practicable.

5.5.5- Lab maintains a centralized log-book to record about its reference standards and software (if any) and containing the following information:

- Name of the instrument, model and identification of software used;
- Manufacturer's name, identification of the instrument, serial number;
- Specifications;
- Location;
- Manufacturers instructions;
- Calibration status and due date, if applicable;
- Maintenance plan and maintenance carried out date;
- Damage, malfunction, modification or repair to the equipment details;

5.5.6 To ensure proper functioning and prevent any possible damage, NML maintains "Manual for safe handling of its Standards" equipments. Instructions for safe handling, transport, storage, of standard are available at work place.

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5.5.7 NML identifies its overloaded/mishandled equipment that are suspected for wrong results by segregating, and pasting the sticker stating: "OUT OF SERVICE / NOT IN USE/ NOT CALIBRATED", as may be the case. NML examines the effect of the defect on previous calibrations and institutes the control of non-conforming works if necessary as per NML/P/4.9/01

5.5.8 Standards/equipments that can affect the results of calibration are serviced and calibrated & labeled with date of calibration and next due date of calibration. The calibration interval is decided by the NML unless it is a requirement of regulators.

5.5.9 Reference standards like balance are not permitted to go beyond NML's control. If for whatever reasons equipment goes beyond the control of NML, the NML checks the function and the calibration status of the equipment and the equipment is put to service only if it shows satisfactory.

5.5.10 Procedure **(NML/P/5.5/01)** is followed to carry out intermediate checks, so as to maintain confidence in calibration status of the equipment.

5.5.11- NML system has an in-built provision in its calibration procedures to incorporate the corrections for the calibration it does, whenever required.

5.5.12 The calibration lab room no-1, & no-2, are housing weighing balance and linier calibration standards respectively and these are kept locked. And its computer is coded with pass-word to prevent unwanted access & also to keep these safeguarded.

Records: All records relating to equipments are kept in NML/F/5.5/01

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5.6 - MEASUREMENT TRACEABILITY

- **Policy:** The policy of NML is to maintain the traceability of its Standards and other supporting measuring instruments to SI Units, either through National Metrology Labs of other countries or through accredited laboratories from ILAC/APLAC region's accredited laboratories.
- **5.6.1 General:** NML has a procedure for calibration of its standards & supporting devices/equipments as per its Procedure for calibration (NML/P/5.5/01).

5.6.2. Specific Requirements

5.6.2.1 Calibration

BSB-NML is committed to maintain traceability to SI Units through unbroken chain of comparison or through comparisons by linking to relevant primary standards. NML maintains traceability by calibrating its standards from a reputed Regional or National Metrology Institute that can demonstrate high competence, measurement capability and traceability.

5.6.2.1.2 Since it is possible to measure in SI UNITS for scope being covered by NML, this clause is not applicable to NML.

5.6.3 Reference standards and reference materials

5.6.3.1 NML has a program and procedure for calibration of its Standards NML/P/5.5/01.

5.6.3.2 Since NML is not a testing lab it does not use reference materials.

5.6.3.3 Reference standard are regularly used for intermediate checks.

5.6.3.4 Standards held by NML are not transported, except the weight box. NML has procedure for to transport, storage and use of reference standard, NML/P/5.6/01.

Records: All traceability relating records are kept in NML/F/5.6/01

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5.7 - SAMPLING

The NML's work does not involve any sampling. It only does the calibration of the items it receives from customers.

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5.8 - HANDLING OF CALIBRATION ITEMS

Policy: Management is committed to preserve and protect the devises/ instruments received for Calibration and maintain their integrity throughout, till these remains in the custody of NML.

5.8.1 Calibration item are handled as per "The Procedure for handling of the calibration items", which aims at protecting the integrity of calibration items during transportation, receipt, handling, storage, and also to prevent loss/damage. (NML/P/5.8/01).

5.8.2 On receipt of calibration (item)/equipment; it is verified with its description from the calibration request received and is assigned a unique identification (code number) number, which is retained until the calibration instrument is handed over to the customer.

5.8.3 Upon the receipt of the calibration item/instruments for its calibration it is checked for its specifications, abnormalities, condition on its receipt and the details are recorded. If there exists any doubt in the suitability of the item to be calibrated or if the item does not conform to the description provided on the calibration requests, the customer is consulted for further instructions before the start of calibration. The details of discussions are recorded.

5.8.4 Where required, calibration items are kept under monitored/observed conditions of environment to ensure their integrity. All items received for calibration are identified by tagging for their specifications and owner. The items to be calibrated are stored in a secured place to prevent their damage or loss & labeled as "INCOMING ITEMS" and when the instruments have been calibrated they are stored at other secured place and labeled as "OUTGOING ITEMS". Procedure for handling of the calibration items, (NML/P/5.8/01), covers all aspects.

Records: All records relating handling to calibration item are kept in NML/F/5.8/01

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5.9 - ASSURING THE QUALITY OF CALIBRATION RESULTS

Policy: NML has the policy to implement its quality assurance program, to ensure the Quality of its calibration results, generated in the lab.

5.9.1 The Quality control procedure (NML/P/5.9/01) is being used to implement its Quality assurance programs in a planned manner and include following, whenever possible:

- Participation in inter-laboratory comparison.
- Participation in proficiency-testing programs.
- Re-calibration on select basis of the already calibrated item.
- Replicate the calibrations using the same method.
- Correlation of results for different characteristics.

5.9.2 As a policy the results (data) of the above stated activities are analyzed to determine and apply the corrective measures where they are found to be outside pre-defined criteria.

Records: All records relating Assuring the Quality of calibration results are kept in NML/F/5.9/01

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5.10 - REPORTING THE RESULTS

5.10.1- The calibration results generated by the NML are reported accurately, clearly, unambiguously. The objectivity is to provide complete information to the user of the certificate of calibration.

Calibration certificates are issued in hard copies and/ also could be transferred using electronic data transfer system subject to the requirement of customer. The content of the calibration certificate take into account the clauses 5.10.2, 5.10.3, 5.10.4.

5.10.2- Contents of Calibration reports:

Each test report gives the following information:

- 1. A title (Calibration Report).
- 2. The name and address of NML.
- 3. Calibration certificates are given unique identity and numbered pages, as 1/n to n/n, to clear the end of calibration certificate.
- 4. The name and address of the customer.
- 5. Calibration standard used.
- 6. Identification of Instrument.
- 7. Date of calibration.
- 8. Calibration results along with, where appropriate, units of measurement.
- 9. Name(s) and signature(s) of person(s) who undertake the technical responsibility of calibration certificate.
- 10. The environmental condition in which the calibration was done.
- 11. The values of the uncertainty of measurements.
- 12. Traceability details of Calibration Standard.
- 13. Additional information when a specified calibration methods or clauses of the specification are not followed.

A statement is given in each calibration certificate, that when required NML "Calibration certificate shall be reproduced only in full."

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Above are the salient features of the "NML Procedure for making and issuing calibration certificates" NML/P/5.10/01.

5.10.3- Test Reports: Not applicable.

5.10.4 Calibration Certificates

5.10.4.1 NML calibration certificates do report the following information.

- a) Environmental conditions at which its instrument was calibrated.
- b) Uncertainty of measurement.
- c) Provide details of traceability, of the devices used to calibrate customers equipments.

5.10.4.2 While reporting the calibration results NML's policy is to follow the applicable IS or ISO or OIML or other international standards & report uncertainty of the measurement.

5.10.4.3 NML does not undertake those jobs which require repairs.

5.10.4.4 As a policy NML does not recommend any calibration interval unless customer requests for it. But if regulations or the calibration standard specify the calibration interval, NML may accordingly recommend as per its specification.

5.10.5- Opinions and Interpretations

NML does not give any opinion or interpretations.

5.10.6 Results from Subcontractors: NML does no subcontract any of its work.

5.10.7 Electronic Transmission of Results

NML may transmit calibration results by telephone, fax or by e-mail on request of customer, and in doing so it follows the procedure on confidentiality.

5.10.8 The format of calibration certificate contains all relevant as recommended by international standard ISO/IEC 17025:2005. The format of calibration certificate is given at Annex – 5.

5.10.9- Amendment to calibrations certificates

Whenever there is amendment to be made to the calibration certificates after the issue, NML issues a new calibration certificate with a unique certificate number which contains the reference to the original that it replaces.

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PLEDGE

1. I am aware about the relevance and importance of the work I do. I commit that I shall work in accordance with the procedures given by the laboratory management.

2. I commit to follow the rules of the country and regulatory authority that may be applicable for the NML.

3. The information which I am likely to know or is provided to me by the customers of the NML shall be treated as confidential and shall be kept by me in the laboratory which is as per procedure.

4. I also commit that I shall not share or give any information, to any person who is not concerned with the work which I may know or I am likely to know during the course of the my work or the job assigned to me. I also commit not to try to know about the information that may not be required for the work I perform.

5. I, commit that I shall not undertake any activity where financial and commercial interests are involved and shall not involve in any activity that may jeopardize my competence, impartiality, integrity and independence of decision-making.

6. I commit to update myself with the changes in the Quality Management system of NML and work accordingly.

7. I, declare that I have read the Quality Policy Statement of the BSB/ NML and commit to abide by it.

Name of the laboratory member	Initials	Position	Signature	Date
Mr. Prakash Sharma		Technical Manager		
Mr. Wangda Jamtsho		Quality Manager.		
Mrs. Tashi Pelden		Head, Lab.		
Ms. Rinchen Zangmo		Technician Volume lab.		
Ms. Choden		Technician Mass lab.		
Ms. Yeshey Choden		Technician Length lab.		
Ms. Nidup Zangmo		Technician Pressure lab.		
Mrs. Kinzang Wangmo		Technician Pressure lab.		
Mr. Ganesh Bahadur Mongar		Technician Temperature		
		lab.		

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ANNEX -2

LIST of NML PROCEDURES

Number	Name of Procedure	Procedure code
1	Procedure for maintaining confidently & impartiality	NML/P/4.1/01
2 Procedure for document control		NML/P/4.3/01
3	Procedure to review, amendment and distribution, withdrawal and archiving of invalid documents	NML/P/4.3/02
4	NML procedure for controlling externally generated documents	NML/P/4.3/03
5	Procedure for Review of requests, Tenders and Contracts	NML/P/4.4/01
6	Procedure for Purchase Services and Supplies	NML/P/4.6/01
7	Procedure for handling of complaints	NML/P/4.8/01
8	Procedure control of non conforming calibration work	NML/P/4.9/01
9	Procedure of taking corrective action	NML/P/4.11/01
10	Procedure of taking preventive action	NML/P/4.12/01
11	Procedure of maintaining records	NML/P/4.13/01
12	Procedure for conducting internal audit	NML/P/4.14 /01
13	Procedure for conducting management review	NML/P/4.15/01
14	Procedure for training NML Employees	NML/P/5.2/01
15	Procedure for maintaining environmental conditions	NML/P/5.3/01
16	Procedure for calibration of Equipments	NML/P/5.5/01
17	Procedure for achieving traceability	NML/P/5.6/01
18	Procedure for handling of calibration items	NML/P/5.8/01
19	Procedure for making and issuing calibration certificates.	NML/P/5.10/01

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ANNEX - 3

CALI BRATI ON PROCEDURE

Number	Title of Procedure	Number
1	NML Procedure for Calibration of Length devices	NML/P/5.4.1/01
2	NML Procedure for Calibration of weights	NML/P/5.4.1/02
3	NML Procedure for calibration of Weighing Balances	NML/P/5.4.1/03
4	NML Procedure for Calibration of Micrometers	NML/P/5.4.1/04
5	NML Procedure for calibration of Vernier Calipers	NML/P/5.4.1/05
6	NML Procedure for calibration of Pressure Gauges	NML/P/5.4.1/06
7	NML Procedure for calibration of Volumetric measures	NML/P/5.4.1/07
8	NML Procedure for calibration of RTD & Digital Thermometer	NML/P/5.4.1/08
9	NML Procedure for calibration of Thermal Uniformity & Stability	NML/P/5.4.1/09

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Prepared by: Q	uality Manager	Page Number: 1 / 1		L

ANNEX - 4

LIST of NML MANUALS

Number	Name of manual	Code number
1.	QUALITY MANUAL	NML/QM
2.	JOB DESCRIPTION MANUAL	NML/M/01
3.	COMPETENCE MANUAL	NML/M/02

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Prepared by:	Quality Manager	Page Number: 1 / 1		L



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BHUTAN STANDARDS BUREAU

National Metrology Laboratory

Bijug Lam, Thimphu 11001



Certificate No. C-0964

Phone no.: +975 2 325104/328298 Fax. +975 2 323712 www.bsb.gov.bt

CALIBRATION CERTIFICATE

			Annex-5
Certificate No.:	Calibration Date:	Page:	01
Issue Date:	Date of receipt of calibration Item:	Total page:	02

Name and Address of the	Description of Calibration Item:
<u>customer:</u>	Name of the calibration item:
	Condition of the calibration item:
	Identification of the calibration item:
	Given by Manufacturer/Owner/Calibration Lab. :

Environment conditions during the calibration: Temperature:

Relative Humidity:

Calibration Procedure:

Standard Equipment used for calibration:

Name:	
Sr.no:	
Model:	
Make:	
Calibrated by:	
Certificate No.:	
Validity of Calibration:	

Notes:	Calibrated By:
 The result relates only to the items calibrated The certificate shall not be reproduced except in full without written permission from BSB 	Checked and Approved By:



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BHUTAN STANDARDS BUREAU

National Metrology Laboratory

Bijug Lam, Thimphu 11001



Certificate No. C-0964

Phone no.: +975 2 325104/328298 Fax. +975 2 323712 www.bsb.gov.bt

CALIBRATION CERTIFICATE

Certificate No.:	Calibration Date:	Page:	02
Issue Date:	Date of receipt of calibration Item:	Total page:	02

CALIBRATION RESULTS*:

• The Pattern of reporting the calibration results would be as required.

Notes:	Calibrated By:
 The result relates only to the items calibrated The certificate shall not be reproduced except in full without written permission from BSB 	Checked and Approved By:

Feed Back Form

Dear Customer,

Thank you for making use of the services of **MLSD BSB**, the National Metrology Laboratory. In line with the requirements of ISO/IEC 17025 on which our quality system is based, we would appreciate, if you could please complete this feedback form in order for us to improve, and to enhance our service to you and fulfill your requirements.

pany:						
e:	Contact Number:					
1 - Very satisfied, 2 - Satisfi	ed, 3 - Average, 4 - Dissatisfied, 5 - Very dissatisf		2	3		5
		1	2	3	4	
Was the work carried out	on time?					
Have we completed the v	vork to your requirement?					
Are we meeting your star	ndard of quality?					
How would you rate valu	e for money?					
			Yes		No	
Is the certificate issued cl	ear and easy to use?					
If NO please provide deta	1					
Did the services provided	add value to your business?					
· ·	· · · · · · · · · · · · · · · · · · ·					
Did the services provided Was the BSB Metrology L	· · · · · · · · · · · · · · · · · · ·					
Was the BSB Metrology L	· · · · · · · · · · · · · · · · · · ·					
Was the BSB Metrology L Would you use the service	Init easy to contact?					

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If YES please provide detail		
Would you like the BSB Metrology Unit to visit you to discuss any of these matters in detail?		

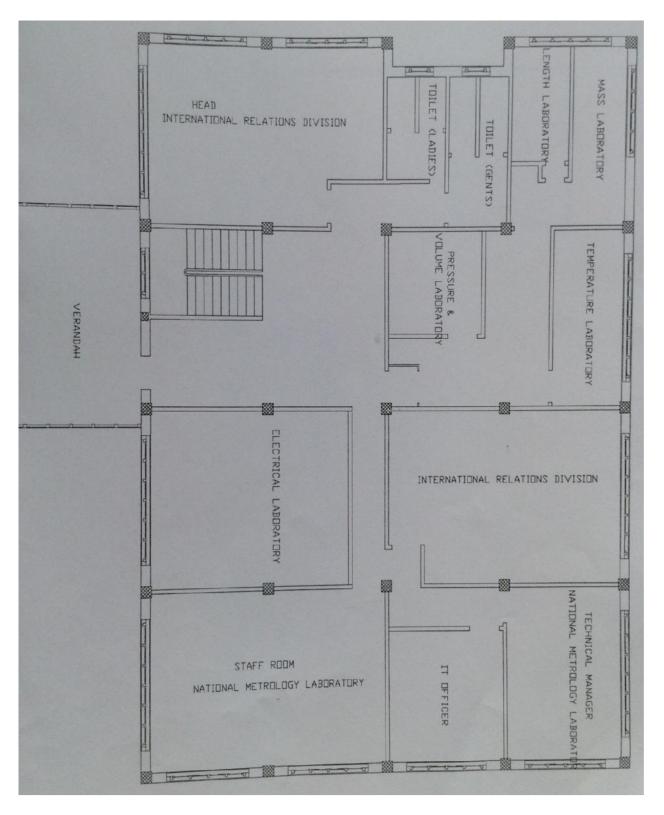
Please fax this form back to us at your earliest convenience at +975 2 323712. Alternatively, you can e-mail us at <u>stdunit@sqcd.gov.bt</u> or give us a call on +975 2 325104/326905/328298. Your cooperation and input will be highly appreciated.

Yours sincerely,

BSB Management

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LABORATORY LAYOUT PLAN



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