This is to authorize the implementation of this Quality Manual and other related documentation effective on the date specified herein.

The management of the Laboratory Quality Management System (LQMS) of the division shall be represented by the Quality Manager.

Updating of this Quality Manual is the responsibility of the Quality Manager, the Document and Information Controller and the Documentation Committee, as described in General Procedure GP 4.3-01 "*Creation, Review, Approval, Revision and Control of Documents.*"

ANNABELLE V. BRIONES, PhD
DIRECTOR, DOST-ITDI

QUALITY POLICY STATEMENT

The Standards and Testing Division of the Industrial Technology Development Institute (STD-ITDI), Department of Science and Technology (DOST) is committed to promptly and efficiently deliver quality testing and other technical services for the satisfaction of its customers.

Customers' satisfaction is guaranteed by:

a. Conducting tests with accuracy and reliability, conforming with the PNS ISO/IEC 17025:2017 standard and other relevant national and international standards;
b. Ensuring utmost impartiality in all laboratory operations and confidentiality of information obtained from customers and created from laboratory activities;
c. Incorporating risk-based thinking in the implementation of its Laboratory Quality Management System (LQMS); and
d. Promoting a safe and customer-oriented environment.

Continual improvement of its management system is achieved by:

a. Strengthening human, financial and physical resources;
b. Complying strictly with the established policies and procedures; and
c. Monitoring the effectiveness of its implementation.

ANNABELLE V. BRIONES, PhD
Institute Director

4.10.1 Continual Improvement

The STD continually improves the effectiveness of its LQMS through the use of the following:

- quality objectives (refer to QM 4.2 Section 4.2.2.1)
- quality policy (refer to QM 4.2 Section 4.2.2.2)
- analysis of data (refer to QM 4.7)
- corrective actions (refer to QM 4.11)
- preventive actions (refer to QM 4.12)
- audit results (refer to QM 4.14)
- management system review (refer to QM 4.15)

During management system review, specific improvements in the effectiveness of the LQMS are identified, discussed and documented.

Where quantitative targets are set in the LQMS such as in key performance indicators, quality objectives indicators and customer satisfaction feedback, data trends are analyzed and used as guide for continual improvement.

It is also a policy of the STD to review its test methods regularly and update, if necessary, to adhere to latest relevant technical information from the latest editions of standard methods or references, if available, and guidance documents and supplementary requirements from accreditation bodies. Technical staff will be assigned to review relevant information and this will be presented during a technical meeting in each laboratory where the main agenda is updating discussions.

4.12.1 Procedure

The STD implements risk management to identify needed improvements and potential sources of non-conformities, either technical or concerning the LQMS as contained in GP 4.12-01 "Risk Management." Action plans are developed, implemented and monitored in the conduct of identified improvement opportunities or required mitigation plans to reduce the likelihood of the occurrence of identified risks and to take advantage of the opportunities for improvement.

The procedure includes how actions are initiated and application of controls to ensure effectiveness. It also includes the integration of actions into the LQMS and that evaluations are done to check the effectiveness of the actions completed after the agreed time period.

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

4.13.1 Policy and Procedure

The STD maintains a procedure in the identification, collection, indexing, access, filing, storage, maintenance, retention and disposal of quality and technical records as contained in GP 4.13-01 "Control of Records." All records are treated confidential and secured accordingly.

The retention period of records is 6 years, unless superseded earlier, or their permanence is necessary for continuity of documentation.

Records are legible, stored and retained so that they are easily retrievable in facilities that provide a suitable environment to prevent damage and deterioration and loss.

4.13.2 Electronic Records

The protection and back up of records stored electronically follows GP 5.4-04 "Control of Data." The STD maintains this procedure as means of protection of data held in computers to prevent unauthorized access to or amendment of data on computers.

4.13.3 Technical Records

The STD maintains records of original observation in testing containing sufficient data to be repeated under conditions as close as possible to the original that includes at least the following:

- Sample identification and description;
- Identity of test method used;
- Date of test;
- Identity of standards or reference cultures used whenever applicable;
- Original test observation and calculations;
- Identity of person performing the test; and
- Identity of person checking test results.

4.13.4 Observations, Data and Calculations

The STD ensures that observations, data and/or results of calculations are recorded at the time they are made and are identifiable to the specific testing activity performed.

4.13.5 Corrections

Permanent blue ink is used to record the actual data and any mistake made is not erased, made illegible or deleted, but is crossed out and the correction entered alongside. The person making the correction affixes his/her signature/initials and writes the date of correction. Testing data are checked either by permanent blue or red ink.

4.15.1 Policy and Procedure

The STD's Top Management conducts a Management System Review of the LQMS once every year, at the last quarter of each year to ensure its continuing suitability, effectiveness and to introduce necessary changes or improvements.

The Quality Manager has the responsibility to ensure that Management System Review takes into account the following agenda:

- Overall objectives of the LQMS;
- Suitability of policies and procedures;
- Reports from supervisory and managerial staff;
- The outcome of recent internal quality audits;
- Corrective and preventive actions;
- Assessments of external bodies;
- Results of interlaboratory comparisons or proficiency testing programs, including trend analysis of a number of participations;
- Changes in the volume and type of work;
- Customer satisfaction feedback measurement;
- Valid customer complaints;
- Quality activities, resources, and staff training;
- Recommendations for improvement; and
- Other relevant factors.

4.15.2 The conduct of Management System Review follows GP 4.15-01 "Management System Reviews." The Quality Manager ensures that the minutes of these reviews are documented and that finding and courses of action plans that arise are carried out within an appropriate and agreed timescale. Management system review records are retained and serve as basis for the Division's planning system.

4.3.1 Document Control Procedure

All internally-generated documents that form part of the Laboratory Quality Management System (LQMS) established in STD are controlled using GP 4.3-01 "Creation, Review, Approval, Revision, and Control of Documents."

Externally-sourced documents which are used as references of the various internally-generated documents of the Division are controlled using GP 4.3-03 "Control of Externally-sourced Documents."

4.3.2 Document Approval and Issue

4.3.2.1 The authorized personnel who prepares, reviews and approves documents are contained in GP 4.3-02 "Format and Coding System of Internally-generated Documents of the Laboratory Quality Management System."

4.3.2.2 LQMS documents issued to units, sections and laboratories of the Division are reviewed and approved prior to their use.

4.3.2.3 All internally-generated documents are uniquely identified that includes the document code, revision number, effectivity date, page number, total number of pages, policy/procedure author, and approving authority.

4.3.2.4 A master list identifying the current revision status of internally-generated documents is maintained to ensure that only current editions are in use.

4.3.2.5 The STD ensures that:

- documents are reviewed and approved for use by authorized personnel prior to issue;
- current or authorized editions of documents are available at all locations where operations essential to the functioning are performed;
- invalid or obsolete documents are removed from all points of issue, promptly withdrawn from circulation; and
- obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

4.3.2.6 LQMS documents are reviewed periodically and revisions are made when necessary to ensure continuing suitability and compliance with applicable requirements.

4.3.3 Document Changes

4.3.3.1 Changes or revisions in documents are reviewed, approved by the Documentation or Technical Review Committee, whichever is applicable.

4.3.3.2 Amendment of a document may be made by the Quality Manager or Head of a laboratory/section. Documents amended by hand shall be marked, signed, and dated and will be formally re-issued as soon as practicable.

4.3.3.3 Controlled LQMS documents are maintained in hard copies. Computers and software are used as tools and not as means for control. STD maintains computerized documents backup files for reference.

4.4.1 Policy and Procedure

The STD reviews test and/or other technical services requests or contracts to any customer and accepts only when the following conditions are met:

- requirements, including methods to be used are adequately defined, documented and understood;
- capability, time and resources are available to meet requirements; and
- appropriate test method is selected and capable of meeting customer's requirements.

The STD resolves first any difference in the request of tender and must ensure that each contract is acceptable to both the laboratory and the customer before any work commences.

The procedure relevant to the review of requests, tenders and contracts follow GP 4.4-01 "Validation and Assignment of Testing Jobs."

4.4.2 The STD maintains records of reviews including any significant changes and any pertinent discussions relating to customer requirements or the results of work during the execution of the contract.

4.4.3 The STD maintains a record of communications with the customer from request/quote through commencement of work. This includes informing the customer of any deviation from the contract. The same review process is repeated if a contract has to be amended after work has commenced and all affected staff are advised of the amendment.

4.5.1 Policy

The STD performs testing and other technical services within its capability and does not subcontract in part or in full any of such services. Accordingly, there is no procedure on subcontracting of services.

4.6.1 Policy and Procedures

The quality of test results also depends on the quality of input materials and services to equipment and facilities, thus, the STD purchases supplies, materials, and services only from reliable suppliers.

The STD ensures that supplies, materials, services and equipment acquired conform with the Division's requirements and in accordance with ITDI acceptable procurement process and procedures.

The suppliers are evaluated and selected for reliability through ITDI Work Instructions Manual WI-ADM-PPMS 05-03 "Supplier Performance Rating." The ITDI Purchasing Officer (Administrative Officer V) maintains a List of Accredited Supplier.

Purchasing of supplies and services follow ITDI Procedure Manual PM-ADM-PPMS 05-01 "Purchasing of Goods."

The STD maintains a database and procedure for purchase, receipt and storage of consumable materials relevant to the tests.

The STD also maintains a procedure for evaluation and monitoring of its supplies. The concerned laboratory uses purchased items only after they have been inspected or otherwise verified for adequate quality. The acceptance, storage and release of reagents and consumable materials relevant to testing follows GP 4.6-01 "Procurement of Equipment, Supplies and Services." Records of inspections and verifications of these items are maintained by the Property and Procurement Section of the ITDI Administrative Division.

The STD ensures that purchasing documents for items affecting quality of test results are reviewed for technical content. Purchasing documents are approved by the ITDI top management.

4.7.1 Policy and Procedure

The STD is willing to cooperate with customers or their representative in clarifying the customer's request and in monitoring the Division or the concerned laboratory's performance in relation to the work performed without detriment to the confidentiality of other customer's job.

The STD ensures that it understands its customer's needs and that they are kept up to date on progress with their work. Upon formal request for witnessing of tests performed, the customers or the customers' representative are given reasonable access to relevant areas of the laboratory.

The STD should maintain communication with customers throughout the work informing them of any delays or major deviations in the performance of the tests. It should be willing to cooperate with them or their representative on advice and guidance regarding technical matters, and opinions and interpretations based on results and monitoring of laboratory's performance through 2nd party audits.

4.7.2 Customer Satisfaction Feedback

To improve the Laboratory Quality Management System, feedbacks on the Division's testing activities and customer service, both positive and negative are solicited from customers and analyzed following GP 4.7-01 "Customer Satisfaction Feedback Measurement."

4.8.1 Policy and Procedure

In the event of complaints from customers or other parties which may raise doubt to the laboratory's competence or compliance with relevant procedures, STD ensures that these are promptly investigated and resolved. Procedure for handling complaints is contained in GP 4.8-01 "Customer Complaints Resolution."

The concerned laboratory maintains records of all complaints, results of investigations and corrective actions.

When complaints will heavily affect the reputation and integrity of ITDI, the Institute Director signs all correspondence to the complaining customer or party.

In cases of complaints on technical operations, STD maintains records on non-conforming work and makes corrective actions. Other issues may be reported and discussed during Management System Reviews and/or seek assistance to the Division Chief for immediate resolution.

4.9.1 Policy and Procedure

The STD ensures that appropriate actions are implemented by authorized personnel whenever any aspect of tests or the results of this test do not conform to its own procedures or the agreed requirements of the customer.

The Quality Manager has the over-all responsibility and authority in the management of a non-conforming work and may designate personnel within the STD to manage it.

The following have outright authority and holds responsibility for the management of non-conforming work involving technical operations that includes stopping work, withholding the release of Test Report, as well as in resuming work:

Over-all Technical Manager, BL for work in the BL
Over-all Technical Manager, CHL for work in the CHL
Over-all Technical Manager, PPTL for work in the PPTL
Deputies as defined in QM 4.1 "Organization" Section 4.1.8 in case of absences of the concerned personnel.

The STD ensures that the significance of the non-conforming work is evaluated and corrective actions are taken immediately, together with any decision about the acceptability of the corrective action, as described in GP 4.9-01 "Control of Non-conforming Work." The STD notifies the customers and recalls the work and test report when previously released, together with the responsibility for amendment and the resumption of work.

4.9.2 Possible Recurrence

Where the evaluation indicates that the non-conforming work could recur or that there is doubt about the compliance of the STD operations with its own policies and procedures, the corrective action procedure in GP 4.11-01 "Corrective Action" is promptly followed.

5.1.1 Factors to Reliability of Test Results

The STD ensures technical competence for the type of tests its laboratories undertakes. It recognizes that many factors determine the correctness and reliability of the tests performed by a laboratory. These factors include contributions from: human factors, competent technical and support staff (QM 5.2), appropriate accommodation and environmental conditions (QM 5.3), validated and/or verified test methods (QM 5.4), equipment satisfying test requirements (QM 5.5), measurements traceable to national and international standards (QM 5.6), and documented sampling procedures and proper handling of test items (QM 5.7 and QM 5.8).

5.1.2 The extent of which the factors contribute to the total uncertainty of measurement differs considerably between types of tests. The STD takes into account these factors in doing testing, in the training and qualification of personnel, and in the selection of the equipment it uses.

5.10.1 Test Results

The results of each test as carried out by the STD are reported accurately, clearly, unambiguously, and objectively, and in accordance with any specific instructions in the test methods.

The results are normally reported in a Test Report and include all the information requested by the customer and all information required by the test method used.

In the case of internal customers, or as agreed with the customer, the results may be reported in a simplified way and may not require the formal Test Report. However, all data that should have been included in the Test Report are readily available and kept permanently on file.

5.10.2 Test Reports

Test Reports include the following information:

- a title (i.e. "Test Report");
- name and address of the laboratory;
- unique test report number below the title which is the same as the Technical Service Request (TSR);
- unique Test Report number on every page and at the bottom of each Test Report which is followed by the page number and total page number of the report;
- name and address of the customer;
- identification of test method used;
- sample code unique to each sample tested;
- sample description including conditions observed when sample was received;
- date of receipt of sample and date of performance of tests;
- test results, expressed with units of measurement, where appropriate;
- name, function, and/or position and signature of person(s) authorized to sign Test Report;
- a statement to the effect that the result relate only to the samples tested; and
- a statement that the Test Report shall not be reproduced except in full without the approval of the STD Chief and is/are of no value for advertising or sales promotions.

In addition, the following may be included in the Test Report:

- deviations, additions, or exclusions to the test method and other relevant information including environmental conditions existing during test (when applicable);
- a statement on the estimated uncertainty of measurement, where applicable and when requested by the customer; and

- tables, graphs, sketches and other supporting information which may be required by specific methods, customer, or group of customers or when necessary for the interpretation of the Test Report.

Reference to sampling is not included since this is not conducted by the STD as expressed in QM 5.7.

5.10.3 Opinions and Interpretations

Opinions and interpretations are not included in the Test Report.

5.10.4 Results from Subcontractors

Subcontracting of test is not practiced by the STD as expressed in QM 4.5.

5.10.5 Electronic Transmission of Results

The electronic transmission of results is through email of scanned Test Reports only following GP 5.10-01.

Disclosure of test results by any means, e.g. by fax, phone calls, email message, text message, etc., prior to the official release is strictly prohibited.

5.10.6 Format of Test Report

The format of Test Reports follows GP 5.10-01.

5.10.7 Amendments to Test Reports

Amendments to Test Reports after issue are made in the form of a new Test Report that includes the statement "This amends Test Report with Report No. _____ which is rendered invalid". The new Test Report is assigned the same Report number but with the suffix "- R1, - R2, etc.", representing the revisions made, and contains a reference to original it replaces. This is a case where amendments are made because of errors in the test results and information regarding the sample or customer.

When the error is on the part of the customer, he/she pays reissuance fee. The amended Test Report must be retrieved. Amendments not allowed are the name of the customer, the sample submitted, and the sample description.

Breakdown of test results may only be done per sample if the Test Report contains many samples in one report, but breakdown of test results for one sample is not allowed. In the case where there is no error but the customer requests for breakdown of results in two or more reports after the issuance of a formal Test Report, new Test Reports are issued upon payment of corresponding fee. If the request was made during sample validation, no fee is required. The new Test Reports are assigned the same

Report number but with suffixes of "-1, -2, -3, etc.", depending on the number of breakdown of test results. The earlier issued Test Report may not be retrieved.

In case where the customer requests a partial report when the tests had not been completed by STD, the test results already finished are released through a Partial Test Report.

5.2.1 Competence and Authorization

The STD ensures the competence and authorizes relevant laboratory personnel involved in:

- Operation of specific equipment;
- Performing tests;
- Evaluating test results; and
- Signing of test reports

Furthermore, authority is also provided to competent personnel in giving opinions and interpretations. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience, and/or demonstrated skills, as required. Staff undergoing training must be under direct supervision of a qualified staff.

Through GP 5.2-01 "Recruitment, Training Program, Competence Evaluation, Training and Educational Needs Assessment, and Authorization of Personnel", the STD ensures that:

- Minimum qualification standards of personnel are satisfied;
- Additional qualification requirements set by STD are met;
- Training needs of the laboratory are identified and provided;
- Only authorized personnel are allowed to conduct sampling, testing, and preparation and issuance of test reports; and
- Job descriptions for managerial, technical, key and support personnel are maintained.

5.2.2 Goals on Education, Training and Skills

The STD believes that an educated, trained and skilled laboratory personnel is one key to quality test results. Therefore, all laboratory personnel are given equal opportunity to improve their education, training and skills. The STD has a policy and procedure for identifying training needs and formulating a training program for laboratory personnel, which is relevant to the present and anticipated tasks of the laboratory. Further, personnel who have attended training, seminars and workshops related to the technical operations will conduct an echo-seminar to the rest of the Division or section/laboratory staff, whichever is applicable. The qualifiers on which training, seminars and workshops need the conduct of echo-seminar and how it will be evaluated are detailed in GP 5.2-01.

The STD ensures that the effectiveness of the training attended by personnel is evaluated and training records are maintained.

5.2.3 New and Contract Employees

The STD uses personnel who are under contract in the conduct of tests provided such personnel are competent and authorized and that they work in accordance with the

LQMS. New employees, or staff who are still undergoing training, are adequately supervised. New staff undergoes in-house training following the specified induction program and evaluated for competence according to GP 5.2-01. A training program for laboratory personnel with identified training requirements also follows GP 5.2-01. The effectiveness of the training actions taken is evaluated as contained in the same procedure.

5.2.4 Job Description and Personnel Data File

Job descriptions of managerial, technical and key personnel are maintained as well as the personnel data file for all technical and support, including contracted personnel. The personnel data file contains the laboratory personnel's records of relevant authorities, competence, educational and professional qualifications, training, skills and experience. This information is readily available and includes the date on which authorization and/or competence is confirmed.

5.3.1 Facilities and Conditions

The STD provides facilities, including its testing, energy sources, lighting, air-conditioning, and ventilation which will aid the correct performance of tests and in-house intermediate checking.

The STD ensures that environmental conditions are appropriate for specific technical requirement as documented in each specific test methods or supplementary procedures and do not invalidate the test results or adversely affect the required quality of measurement. Due attention is paid to biological sterility, dust electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound, and vibration levels as appropriate to the technical activities concerned. The technical requirements for accommodation and environmental conditions that can affect the results of tests shall be documented when applicable.

5.3.2 Environmental Conditions

Environmental conditions are controlled and monitored as required by the relevant test method. In instrumentation rooms where monitoring of temperature and humidity readings are highly needed, as required by the instrument's metrological requirements or by national and international standards, records are maintained. In biological testing, monitoring of sterility is required. Tests are suspended or repeated when the environmental conditions jeopardize the test results. Technical Manager in each laboratory section is responsible in the suspension of all works whenever environmental conditions jeopardize the result of test following GP 4.9-01 "Control of Non-conforming Work."

5.3.3 Incompatible Activities

Neighboring areas in the laboratory are effectively separated. The STD conducts measures to prevent cross-contamination from incompatible activities.

5.3.4 Access

The Technical Manager in each laboratory section is responsible in controlling access to and use of test areas that might affect the quality of test results, as well as when it may compromise customer confidentiality. A restriction sign, i.e. "Restricted Area" or "Authorized Personnel Only," is posted in rooms with limited access.

5.3.5 Housekeeping

Each laboratory personnel ensure that housekeeping standards are maintained for the proper performance of laboratory activities. Maintenance procedures and appropriate supplementary procedures are available for housekeeping of specialized equipment and facilities as maintained by those authorized to operate them.

5.4.1 Test Methods

The STD maintains appropriate methods and procedures for all tests within its scope as reflected in QM 6.4 STD Testing Capabilities. These methods include storage and preparation of samples to be tested and for some methods an attempt to estimate the uncertainty of measurements as well as statistical techniques for analysis of test data.

Equipment manuals, operating instructions, reference data, and specifications relevant to test methods and in operating relevant equipment are maintained up-to-date in the laboratory, and are readily available to all relevant personnel.

The STD ensures that deviation from test work are documented, technically justified, authorized and accepted by the customer.

5.4.2 Selection of Methods

The STD uses test methods that are published in international and national standards or those taken from scientific texts or journals from reputable technical organizations such as, but not limited to:

- The Official Methods of Analysis (OMA) of the AOAC International;
- Standard Methods of the Examination of Water and Wastewater (SMEWW) by APHA, AWWA, and WEF;
- International Organization for Standardization (ISO);
- American Society of Testing and Materials (ASTM);
- U.S. Environmental Protection Agency (US EPA);
- U.S. Pharmacopeia (USP)/National Formulary (NF);
- Organization for Economic Cooperation and Development (OECD) Guidelines for Testing of Chemicals;
- World Health Organization – Pesticide Evaluation Scheme (PES);
- Bacteriological Analytical Manual (BAM) of the U.S. FDA;
- Philippine National Standards (PNS); and
- Other methods specified by the equipment or test manufacturer.

The Technical Manager of the laboratory/section ensures that methods meet the needs of the customer and are appropriate for the test undertaken. The procedure in the selection of test methods is detailed in GP 5.4-01 "Selection of Methods."

The STD selects appropriate methods when the customer does not specify so, but has to obtain the latter's agreement to the choice. Furthermore, the concerned STD personnel inform the customer if the method proposed is inappropriate and outdated.

5.4.3 Laboratory-developed Methods

The STD does not develop test methods.

5.4.4 Non-standard Methods

The use of non-standard method/STD in-house method is subject to agreement with the customer taking into account a clear specification of his/her requirements. These non-standard methods are validated before used for routine test.

5.4.5 Validation and Verification of Test Methods

All test methods included within the scope of accreditation are validated/verified for their intended use by the STD following GP 5.4-02 "Method Validation and Verification."

The results of such validation/verification are recorded together with the methods utilized and any other relevant information. The record states whether the method or procedure is fit for the intended use. The STD ensures that the range and accuracy of the values obtainable from validated/verified test methods are relevant to the customers' needs.

The STD uses one or a combination of the following techniques in the determination of the performance of the test method:

- Inter-laboratory comparisons or proficiency testing;
- Calibration using reference standards or reference materials;
- Comparison of results achieved with other standard/established methods;
- Systematic assessment of the factors influencing the test result; and
- Assessment of the uncertainty of the test results based on scientific understanding of the theoretical principles of the method and practical experiences.

5.4.6 Estimation of Uncertainty of Measurement

Where applicable, procedures in calculation of the uncertainty of measurement are attempted and used as the basis for expression of uncertainty in measurement. This procedure is detailed in GP 5.4-03 "Estimation of Uncertainty of Measurement."

Procedures for estimating the uncertainty of measurement in testing are available, except when the test methods preclude such rigorous calculations. In certain cases where it is not possible to undertake metrologically and statistically valid estimations of uncertainty of measurement, the laboratory attempts to identify all the components of uncertainty and make the best possible estimation, and ensure that the form of reporting does not give an exaggerated impression of accuracy. Reasonable estimation is based on knowledge of the performance of the method and on the measurement scope, and makes use of previous experience and validation/verification data.

The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

- requirement of the test method;
- requirement of the customer; or
- existence of narrow limits on which decisions on conformance to a specification are based.

In cases where a well-recognized test method specifies limits to the values of major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the STD has satisfied the estimation of the uncertainty of measurement by following the test method and reporting instructions.

5.4.7 Control of Data

Appropriate checks of data and calculations on test results are made by the concerned Technical Manager to ensure measurement integrity.

Where computers or automated equipment are involved in data acquisition, processing, recording, reporting, storage or retrieval of test, the software used is documented and validated as adequate for use, except for commercial off-the-shelf software, which are considered validated.

Procedures to protect integrity and confidentiality of data entry, collection, storage, transmission and processing follow GP 5.4-04 "Control of Data."

The laboratory personnel maintains computers and automated equipment to ensure proper functioning through relevant Supplementary Procedures, Operational Procedures, and equipment manual. Procedures for preventive maintenance of laboratory equipment follow GP 5.5-02 "Preventive and Corrective Maintenance." The Technical Manager of the laboratory/section ensures that proper environmental and operating conditions are provided to maintain integrity of test data.

5.5.1 Performance of Tests

The STD has all the necessary equipment within its scope of testing services and the correct performance thereof, including preparation of samples or items, processing and data analysis. No equipment outside the permanent control of STD is used for its scope of testing services.

5.5.2 Capability

All equipment and their associated software in the STD are capable of achieving the accuracy required and comply with specifications relevant to the tests concerned.

The STD ensures that newly installed and just repaired equipment are checked and/or calibrated to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications, before being put to service. Checking procedures follow the equipment's operating manual.

5.5.3 Operation and Maintenance

The STD ensures that only competent and authorized personnel operate equipment as reflected in the respective authorizations. The STD also ensures that equipment Operational and Maintenance Procedures are up-to-date and readily available for use by the appropriate laboratory personnel.

5.5.4 Identification and Records

All equipment and its software used in the STD for testing are uniquely identified and their records of maintenance and calibration programs are maintained following GP 5.5-01 "Records of Equipment and Their Maintenance and Calibration." Records of the calibration program identify the calibration status of the equipment. Equipment records include at least the following:

- identity of the item of equipment and its software if available;
- manufacturer's name, type of identification, and serial number or other unique identification;
- checks that equipment complies with specification;
- current location;
- manufacturer's instructions, if available;
- dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
- maintenance plan, where appropriate, and maintenance carried out to date; and
- any damage, malfunction, modification or repair of the equipment

5.5.5 Safe Handling, Transport, Storage, Use and Planned Maintenance

The procedure in the safe handling, transport, storage, use and planned maintenance of each item of equipment is in accordance to what is provided in the operating manual. All STD equipment are maintained to ensure proper functioning and protected from deterioration.

Planned maintenance of equipment follows GP 5.5-02 "Preventive and Corrective Maintenance." In case of repairs, this same GP provides the procedures to be done.

5.5.6 Out-of-Service and Return to Service Equipment

Any item of equipment which has been subjected to overloading, mishandling, giving suspect results, or has shown to be defective or outside specified limits are taken out of service. The STD has a procedure in the examination of the possible effect of the equipment taken out of service to previous test results and institutes corrective actions in accordance with GP 4.9-01 "Control of Non-conforming Work."

All items of equipment in the STD are neither for lease nor to be lent outside the laboratory. All equipment sent outside the STD for purposes of repair and/or calibration are checked and shown to be satisfactory before equipment is returned to service.

5.5.7 Checks, Corrections, and Safeguards

In order to maintain confidence in the calibration status of the equipment, intermediate checks indicated in the test method are carried out by the laboratory personnel.

Test methods likewise include procedures on ensuring the incorporation of correction factors, whenever available.

The STD implements measures that safeguards test and intermediate checking of equipment, including software, from adjustments that may invalidate test results.

5.6.1 Specific Requirements in Testing

All test equipment that significantly affects the accuracy or validity of test results are calibrated before being put into service. Calibration program for all equipment follows GP 5.5-01 "Records of Equipment and Their Maintenance and Calibration."

The STD establishes a program for calibration of equipment used in testing. The program is designed to ensure that the calibration and measurements made by the laboratory are traceable to SI units or, if not possible, confidence of measurements is established to appropriate measurement standards such as:

- use of certified reference materials (CRM), standard reference materials (SRM), or secondary and in-house reference materials to give a reliable physical, biological, and chemical characterization of a material;
- participation in interlaboratory comparisons or proficiency testing; and
- use of specified test methods and/or consensus standards.

The STD avails of the services of the National Metrology Laboratory of ITDI-DOST and any other ISO/IEC 17025:2005 accredited calibration laboratory for the calibration of its testing equipment.

5.6.2 Reference Standards and Reference Materials

All reference standards, i.e. test weights, used in the STD are calibrated by an accredited supplier of calibration services. These reference standards are used for in-house intermediate checking purposes only.

All reference materials used in the STD are traceable to SI units or to CRMs, SRMs or reference cultures, whenever possible. STD maintains procedures for proper handling, storage and use of CRMs, SRMs and/or reference cultures in order to prevent contamination or deterioration and in order to protect their integrity.

5.6.3 Intermediate Checks

Checks are conducted as reflected in specific test methods to maintain confidence in the calibration status of reference and working standards, and reference materials.

5.6.4 Transport and Storage

The procedures in the safe handling, transport, storage, and use of reference standards and reference materials are in accordance with accompanying documentation during purchase or to appropriate scientific texts or journals from reputable technical organizations.

5.7.1 Policy and Procedure

The STD does not conduct sampling when requested by customers.

Samples or items received are already considered fit for testing as verified by the authorized laboratory/section's validator, during validation and acceptance, as outlined in GP 4.4-01 "Validation and Assignment of Testing Jobs."

5.8.1 Procedure

The STD receives, handles, protects, stores, retains and/or disposes test samples in accordance with GP 5.8-01 "Handling of Test Samples." The procedure includes provisions necessary to protect the integrity of the test samples and interests of STD and the customer.

5.8.2 System of Identification

A system of identification of test samples is described in GP 4.4-01 "Validation and Assignment of Testing Jobs" where they are uniquely identified to ensure that samples cannot be confused physically or when referred to in records and other documents. Such identification is retained throughout the life of a sample in the laboratory.

5.8.3 Receipt of Samples

Test samples are received following GP 4.4-01. Abnormalities or departures from normal or specified conditions are recorded. The STD validator consults the customer for further instructions, and/or records discussions before proceeding whenever:

- there is a doubt as to the suitability of the sample;
- sample item does not conform to the description provided; or
- required test is not specified in sufficient detail.

The STD performs necessary preparation of the test samples in case the customer fails to perform the requirements stated above.

5.8.4 Protection and Security

The STD protects and secures test samples in its custody or during storage, handling and preparation, to protect them from loss, deterioration, or damage as specified in GP 5.8-01 "Handling of Test Samples."

Handling instructions, as contained in specific test methods, operational procedures or in appropriate scientific texts or journals from reputable technical organizations, are strictly followed. Specified environmental conditions during storage or conditioning are maintained, monitored and recorded.

The STD stores and secures properly test samples that have to be retained, e.g. for retests.

5.9.1 Quality Control Procedure

The STD monitors validity of tests undertaken, using appropriate quality control procedures which may include the following, depending on appropriateness to the type and volume of work:

- use of CRM, SRM, reference cultures and/or internal quality control samples using secondary and in-house reference materials;
- use of reagent or control blanks and recovery in chemical testing;
- use of dilution blank and positive or negative control in biological testing;
- participation in interlaboratory comparison or proficiency testing programs;
- intralaboratory/inter-analyst comparison;
- replicate tests using the same or different test methods;
- retesting of retained samples; and
- correlation of results for different characteristics of an item.

Results are recorded in such a way that trends are detectable and statistical techniques are applied whenever practicable. Trend analyses of interlaboratory comparisons or proficiency testing participations are maintained.

5.9.2 Quality Control Data

Gathered quality control data are analyzed and when found to be outside predefined criteria, policies and procedures outlined in QM 4.9 "Control of Non-conforming Work", QM 4.11 "Corrective Action", GP 4.9-01 "Control of Nonconforming Work", GP 4.11-01 "Corrective Action" are taken to correct the problem and to prevent inaccurate test results from being reported. Test methods contain the specific acceptance criteria.

Service Name:

Laboratory Testing and Other Technical Services

Description:

Provision of the biological, chemical, physical, mechanical, and performance testing and formula of conversion (FOC) services to MSMEs, processors, industries, researchers, academe, and interested parties in the country

Requirements:

Schedule of submission of samples for testing
Valid samples for testing
Accomplished Technical Service Request (GP 4.4-01-F03)

Fees:

Refer to STD Schedule of Fees for Testing and Other Services which can be downloaded from the website of ITDI. The STD's Facebook Page may also be visited for list of testing services and sample requirements.

Procedures:

Maximum estimated time indicated is based on a single sample submitted by the customer.

Details	Maximum Estimated Time	Person(s) Responsible
1. Customer contacts STD to reserve schedule for submission of samples; STD can be contacted through telephone (02) 837-2071 local 2188, 2189, or 2198, or email address std@itdi.dost.gov.ph. Reserving of schedule for submission of samples can be done through telephone.	10 mins	• STD technical staff
2. The STD staff answers all inquiries from customers through telephone, email message, or personally at the STD Receiving and Releasing Unit (RRU) office.		• RRU and selected STD technical staff for telephone and on-site inquiries • Office of the Chief staff for email message inquiries

Details	Maximum Estimated Time	Person(s) Responsible
3. The STD staff sets a schedule of the submission of samples by the customer. Schedule will depend on the number of samples already scheduled for the week. The STD staff records the agreed schedule of submission and instructs customer on how to take care of their samples during transport to the laboratory. Submission of samples is until 4:00 PM only, except for samples for microbiological tests and selected chemical tests (e.g. pH in water) which are only until 12:00 PM.	5 mins	• STD technical staff
4. If sterile sampling bottle for microbiological test is needed, customer claims it from STD at least one day before submission of sample.	10 mins	
5. The STD staff instructs customer on how to properly collect samples, e.g. water samples. Guidelines on the collection of samples are provided to customers.		
6. At the entrance of the STD building, guard on duty warmly welcomes customers. Customer (person submitting a sample) registers at the guard post.	5 mins	• Guard on Duty
7. Customer proceeds to the RRU office upon instruction of the guard on duty. The RRU staff identifies test requirements of customer. Customers are asked to accomplish GP 4.4-01-F01 "Customer Information Sheet." The RRU staff requests for validator from concerned laboratory through paging system or through local phone call. Customer is asked to proceed to the Validation Room. If test requirement of customer is not within the testing capability of the STD laboratories, customer is referred to other laboratories, with provision of complete contact details of the laboratory/ies identified.		• RRU Staff

Details	Maximum Estimated Time	Person(s) Responsible
8. At the Validation Room, laboratory validator warmly welcomes customers. The validator reviews the test requirement of customer. Customers are accommodated on a first-come-first-served basis.	10 mins	• Customer • STD Section/Laboratory Validators
9. The validator checks if the sample to be submitted is valid. The customer and the validator agree on tests to be conducted appropriate to the desired needs and within the technical competence of the concerned STD laboratory.	40 mins	• STD Section/Laboratory Validators
10. The STD uses the Unified Laboratory Information Management System (ULIMS) for a faster and more efficient sample validation. The validator registers customer at the ULIMS. For the case of FOC services, TACIS is used.		
11. Customer provides the validator with the needed information like company identification and sample description which are entered in the ULIMS and reflected in the Technical Service Request (TSR, GP 4.4-01-F03). Validator and customer review the content of the TSR for correct entry. Customer is given time to read the Terms and Conditions, which are included at the back page of the TSR. Customer and the validator sign the TSR as an agreement on the testing services availed and to be conducted.		
12. The validator discusses to the customer the date of release of the Test Report and instructs customer that TSR must be presented to claim the Test Report. In case the person who submitted the samples can't claim the report, customer must authorize a representative by using the back page of the TSR. The STD staff contacts customer in case when an extension of the due date is requested due to unavoidable circumstances. Customer identifies preferred mode of release of Test Report.		

Details	Maximum Estimated Time	Person(s) Responsible
13. The validator issues Order of Payment online using the ULIMS.		• STD Section/Laboratory Validators
14. The validator attaches sample tag to the sample(s) submitted for identification.		
15. Customer accomplishes Customer Satisfaction Feedback Form - Sample Submission (GP 4.7-01-F01) and when done, he/she drops the accomplished form in the Customer Feedback Box.	5 mins	• Customer
16. Upon completion of the TSR, customer pays total cost of fees to the ITDI Cashier and claims Official Receipt (OR) of payment. Customer is given his/her copy of the TSR and the other copies are left to the ITDI Cashier's office which will facilitate returning the other copies of TSR to the STD. Cashier's office updates ULIMS for the payment done.	10 mins	• ITDI Cashier, Administrative Division
17. On the scheduled date of release of Test Report, customer presents copy of the TSR. For authorized representatives, "Authority to Claim Test Report" must be presented together with a valid identification card (ID). The RRU staff checks the validity of the TSR copy presented and the identity of the person claiming the Test Report.	10 mins	• RRU Staff
18. Customer signs the Receiving Copy of the Test Report indicating that he/she received the report.		
19. The RRU staff releases the Test Report to the customer. Customer accomplishes the Customer Satisfaction Feedback Form - Releasing of Test Reports (GP 4.7-01-F02). Complaints Form is also available if customers have complaints regarding the technical services of STD.	5 mins	• RRU Staff • Customer

Details	Maximum Estimated Time	Person(s) Responsible
20. If customer requests for interpretation or explanations on the Test Report presented to him/her, the STD staff (Section/Laboratory Heads or deputized staff) attends to the request and presents some references.	10 mins	• STD Technical Staff • STD Quality Manager/Division Chief
21. If the chosen mode of release of the customer is email transmittal, the RRU staff scans the Test Report and other supporting documents requested by the customer then send all the electronic files to the email address provided by the customer as reflected in the TSR.	5 mins	• RRU Staff
22. If the chosen mode of release of the customer is through courier services, the assigned STD staff sends the Test Report contained in a sealed envelope through an identified courier service provider.	15 mins	• STD Technical Staff

Republic of the Philippines
Department of Science and Technology
INDUSTRIAL TECHNOLOGY DEVELOPMENT INSTITUTE

Standards and Testing Division

QUALITY MANUAL

Copy No. 1

Revision 2 : 2013 August 28

Copy for: Division Chief

The Standards and Testing Division of the Industrial Technology Development Institute - Department of Science and Technology (STD ITDI-DOST) has recognized the need to establish a Laboratory Quality Management System (LQMS) which is in accordance with the Philippine National Standard (PNS) ISO/IEC 17025:2005, "*General Requirements for the Competence of Testing and Calibration Laboratories*". This establishment of the QMS is in view of the standardization of the globalization of trade.

With the benefits of laboratory accreditation aiming at having competent laboratories in the Philippines which can compete globally, STD of ITDI-DOST established, continually implements, and maintains this LQMS. This is in pursuance of laboratory accreditation with the Philippine Accreditation Bureau (PAB). Together with this laboratory accreditation are the recognition of competence, benchmark of performance, marketing advantage in the global scene, and the international recognition.

Table of Contents

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Table of Contents

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This is to authorize the implementation of this Quality Manual and other related documentation effective on the date specified herein.

The management of the Laboratory Quality Management System of the division shall be represented by the Quality Manager.

Updating of this Quality Manual is the responsibility of the Quality Manager, the Document and Information Controller and the Documentation Committee, as described in General Procedure (GP) 4.3.1, "*Creation, Review, Approval, Revision and Control of Documents.*"

MARIA PATRICIA V. AZANZA, Ph.D.
DIRECTOR, DOST-ITDI

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The Quality Manual is distributed as controlled copies to the following laboratories, sections and units under its organization:

Copy No.	
Original	Quality Manager, Division Chief
1	Director, ITDI
2	Head, Biological Laboratory (BL)
3	Head, Chemistry Laboratory (CL)
4	Head, Physical and Performance Testing Laboratory (PPTL)
5	Head, Receiving and Releasing Unit (RRU)
6	Head, Microbiology Section (MS), BL
7	Head, Pharmacology and Toxicology Section (PTS), BL
8	Head, Inorganic Chemistry Section (ICS), CL
9	Head, Organic Chemistry Section (OCS), CL
10	Document and Information Controller (DIC)

Uncontrolled copies may be distributed upon the approval of the Quality Manager.

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QUALITY POLICY STATEMENT

The Standards and Testing Division of the Industrial Technology Development Institute (STD-ITDI), Department of Science and Technology (DOST) is committed to promptly and efficiently deliver quality technical services for the satisfaction of its customers.

Customers' satisfaction is guaranteed by:

a. **Conducting tests with accuracy and reliability, conforming with the PNS ISO/IEC 17025:2005 standard;**
b. **Ensuring utmost confidentiality of information obtained from the customers; and**
c. **Promoting a safe and friendly environment.**

Continual improvement of its management system is achieved by:

a. **Strengthening human, financial and physical resources;**
b. **Complying strictly with the established policies and procedures; and**
c. **Monitoring the effectiveness of its implementation.**

MARIA PATRICIA V. AZANZA, Ph.D.
Institute Director

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The Standards and Testing Division (STD) implements a Laboratory Quality Management System (LQMS) covering its testing activities. The LQMS is the framework under which the quality of the activities of the STD is defined, organized, and maintained. The LQMS documents the different policies and procedures implemented by the Division to attain the following goals:

- Ensure that all staff have a clear understanding of the policies and procedures relevant to their work;
- Enable the staff to contribute in maintaining quality in the organization and conformance to PNS ISO/IEC 17025:2005 requirements;
- Translate these policies and procedures to consistent high quality service to customers; and
- Allow for the continuous improvement of the LQMS.

The numbering in the Quality Manual follows the section numbers in the PNS ISO/IEC 17025:2005 for easy reference to the standard. The scope on improvement documents the activities to be made by the laboratory through the use of quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management reviews.

The Standards and Testing Division (STD) is one of the divisions of the Industrial Technology Development Institute (ITDI) dedicated to rendering technical services to public and private institutions and individuals. STD is covered by the Philippine Civil Service Commission (CSC) rules and regulations.

The Division has the following major functions:

- Plan, coordinate and provide biological, chemical, and physical and performance testing of materials and products;
- Validate/verify standard test methods and develop in-house methods to keep abreast with developments and requirements of various industries;
- Participate in projects of other entities relevant to standards and testing; and
- Contribute in the planning and implementation of the ITDI's programs and projects.

It also serves the following functions:

- Develop, implement and coordinate activities on Metrology in Chemistry;
- Provide proficiency testing services to laboratories; and
- Issue Formula of Conversion (FOC) certificates for tax and duty drawbacks and as a requirement of the Philippine National Police (PNP) and the Sugar Regulatory Administration (SRA)

The Division is composed of three laboratories conducting tests and analyses:

- Biological Laboratory (BL) – a laboratory which is composed of two sections, the Microbiology Section and the Pharmacology and Toxicology Section.

  The Microbiology Section (MS) conducts microbiological testing of food, water, cosmetics, disinfectant/biological products or devices, natural products, herbal products, packaging materials and allied products.

  The Pharmacology and Toxicology Section (PTS) conducts pharmacological, toxicological and bioefficacy testing of plant extracts, biologicals, chemical formulations, pesticides, insecticides, food supplements, drugs, pharmaceutical products, herbal drug and preparations, and cosmetics.

- Chemistry Laboratory (CL) - a laboratory which is composed of two sections, the Inorganic Chemistry Section and the Organic Chemistry Section.

  The Inorganic Chemistry Section (ICS) conducts testing of water and wastewater, environmental samples, construction materials, chemical specialties, and end use products.

  The Organic Chemistry Section (OCS) conducts testing of foods, feeds, beverages, natural products, fuels, paints and organic chemicals.

- Physical and Performance Testing Laboratory (PPTL) – a laboratory which determines physical properties of materials such as rubber and leather, plastics and polymers, engineering and construction materials, packaging materials, adhesives and sealants, office supplies, and concrete. It also conducts performance testing of products and load testing of construction and heavy equipment (e.g. crane, hoist, elevator, forklift, etc.)

The following are the references used in writing and updating of this Quality Manual:

PNS ISO/IEC 17025:2005	*General Requirements for the Competence of Testing and Calibration Laboratories*
ISO/IEC 9001:2008	Quality Management Systems – Definition and Vocabulary
ISO/IEC Guide 17000	Conformity Assessment-Vocabulary and General Principles
VIM	International Vocabulary of Basic and General Terms in Metrology

Laboratory Quality Management System documents are updated once latest editions of these references are released/published.

3.1 The terms used in this Laboratory Quality Management System documentation are based from ISO/IEC Guide 17000, "*Conformity Assessment –Vocabulary and General Principles*" and VIM, "*International Vocabulary of Basic and General Terms in Metrology.*"

Definitions in ISO/IEC 9001:2008 *"Quality Management Systems – "Definition and Vocabulary"* are used if definitions are unavailable in ISO/IEC Guide 17000 and VIM.

3.2 The following abbreviations are also used in this Quality Manual and related documentation:

LQMS	–	Laboratory Quality Management System
DOST	–	Department of Science and Technology
ITDI	–	Industrial Technology Development Institute
STD	–	Standards and Testing Division
BL	–	Biological Laboratory
CL	–	Chemistry Laboratory
PPTL	–	Physical and Performance Testing Laboratory
MS	–	Microbiology Section
PTS	–	Pharmacology and Toxicology Section
ICS	–	Inorganic Chemistry Section
OCS	–	Organic Chemistry Section
RRU	–	Receiving and Releasing Unit
OC	–	Office of the Chief
QM	–	Quality Manual
GP	–	General Procedure
TP	–	Technical Procedure
QR	–	Quality Records
TR	–	Technical Records

SP	–	Supplementary Procedure
TM	–	Test Method
OP	–	Operational Procedure
MP	–	Maintenance Procedure
TSR	–	Technical Services Request
QM	–	Quality Manager
DQM	–	Deputy Quality Manager
OTM	–	Over-all Technical Manager
TM	–	Technical Manager
DTM	–	Deputy Technical Manager
DC	–	Documentation Committee
DIC	–	Documentation and Information Controller
DDIC	–	Deputy Document and Information Controller
SDC	–	Section Document Custodian

3.3 The following terms are defined and being used in QMS documents:

3.3.1 Quality Manual (QM) – the top level document of the laboratory quality management system. It includes operational policies which provide answers and directions to recurring questions in the laboratory quality management system.

3.3.2 General Procedures (GP) – documents which are used to deploy policies through specified way of doing things.

3.3.3 Technical Procedures (TP) – documents which provide guidance for the detailed implementation of an activity. It is divided into four categories: Supplementary Procedures (SP), Test Methods (TM), Operational Procedures (OP) and Maintenance Procedures (MP).

3.3.4 Records – accomplished documents which provide objective evidence of activities performed or results achieved. These records are generated using the various forms of LQMS documents.

3.3.5 Quality Records (QR) – records which include reports from internal audits and management reviews as well as records of corrective and preventive actions.

3.3.6 Technical Records (TR) – records of original observations, derived data, and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report issued, for a defined period.

3.3.7 Supplementary Procedures (SP) – a defined technical procedure for the conduct of activities necessary to ensure accuracy and reliability of test results.

3.3.8 Test Methods (TM) – a defined technical procedure for performing a test.

3.3.9 Operational Procedures (OP) – a defined technical procedure for the operation of equipment used for testing or for the monitoring of environmental conditions.

3.3.10 Maintenance Procedures (MP) – a defined technical procedure for maintaining equipment to ensure long-term use.

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4.1.1 Legal Responsibility

The Standards and Testing Division (STD) is a technical service division of the Industrial Technology Development Institute (ITDI) of the Department of Science and Technology (DOST) located at STD Building, DOST Compound, General Santos Avenue, Bicutan, Taguig City, Metro Manila, Philippines, reorganized in 1984 and mandated in accordance with Executive Order No. 128. The organization of STD and its place in ITDI's organizational structure is shown in Appendix QM-06-01.

The ITDI-STD maintains a Laboratory Quality Management System (LQMS) that defines the legal identity of the organization and the responsibilities of the staff working thereat.

4.1.2 Scope of Laboratory Quality Management System

The STD carries out its testing services to satisfy the needs of the customers and to meet the requirements of the regulatory authorities and organizations providing laboratory accreditation as specified in PNS ISO/IEC 17025:2005 standard. The LQMS of STD-ITDI covers all work carried out in its laboratory.

The STD is covered by the policies and procedures of the ITDI, with respect to hiring of personnel, procurement of equipment and materials, and other administrative matters. Complementing the ITDI policies and procedures are the STD policies and procedures contained in this Quality Manual and its corresponding documents.

4.1.3 Conflict of Interest

Only STD personnel are allowed to conduct all technical service activities requested to the division. Acceptance/receiving of samples should only be done at STD-RRU and will be validated and received by the designated STD personnel from the customer themselves.

The Research and Development (R&D) Divisions of ITDI concentrate in their development work and have no involvement or influence on the testing activities of the STD.

4.1.4 Legal Authority, Responsibility and Accountability

The Top Management of the STD has overall responsibility in ensuring that the LQMS is systematically and effectively executed.

4.1.4.1 Institute Director

- As Head of the Institute, he/she is the main policy and decision maker and performs management function in all the other programs and projects of ITDI, specifically: research and development, training and consultancy, technology transfers, and technical services;

- He/She ensures that non-STD personnel of ITDI and any other agencies of DOST do not have situations where they may have an opportunity to exert undue pressure to STD personnel in matters relating to testing and other technical services offered by the Division;
- He/She authorizes the implementation of the LQMS in compliance with the management and technical requirements of PNS ISO/IEC 17025:2005;
- He/she authorizes the Quality Policy and Quality Objectives;
- He/she commits and ensures that resources needed for the continued implementation and continual improvement of the LQMS and the technical competence of the staff are adequately and timely provided for; and
- He/she heads the STD Management Committee and is responsible of all its duties and functions.

4.1.4.2 Quality Manager

The Division Chief is the Quality Manager and has the following managerial functions:

- Has overall responsibility and authority for ensuring the policies and procedures are implemented and followed at all times, especially the technical services offered by the Division;
- Monitors and ensures that the established LQMS is implemented, maintained, and complies at all times with PNS ISO/IEC 17025:2005 and accrediting body supplementary requirements and guidance documents;
- Has direct access/communication to the Institute Director and the Deputy Director for Administrative and Technical Services (ATS) of ITDI, particularly, with regard to decisions on laboratory policies, procedures and resources;
- Ensures that the quality policy and LQMS is properly disseminated, understood and implemented;
- Has management authority over the operations and performance of all STD staff;
- Coordinate with the Laboratory, Section, and Unit Heads, as well as the other staffs of the Division in matters of management and operations of the Division;
- Update all LQMS documents in compliance with the requirements of latest regulatory standards and for continual improvement of the LQMS;
- Approves release of test results and certificate of Formula of Conversion (FOC);
- Implement Personnel Training Program as identified by Laboratory Overall Technical Managers;
- Responsible to plan, organize, and conduct the internal quality audits and management reviews of the different laboratories/sections/units of the Division;
- Holds the authority and resources in identifying occurrences of departures from the LQMS and to initiate actions to prevent or minimize such departures;
- Monitors the effectiveness of the corrective and preventive actions to non-conforming works;
- Conducts bi-annual analysis of customer feedback surveys;

- Supervises the Document and Information Controller;
- Heads the Documentation Committee and the Internal Quality Audit Team;
- Represents the Division for the various laboratory accreditations; and
- Identify, develop and implement continual improvement of the STD LQMS

4.1.4.3 STD Management Committee

Chairman	: Institute Director
Vice-Chairman	: Division Chief / Quality Manager
Members	: Deputy Quality Manager
	Document and Information Controller
	Laboratory Head, Biological Laboratory
	Laboratory Head, Chemistry Laboratory
	Laboratory Head, Physical and Performance Testing Laboratory

- Review the effectiveness and suitability of the LQMS;
- Resolve policy, procedure and resource issues; and
- Conduct Management Reviews

4.1.4.4 Technical Manager

The laboratory is headed by a Laboratory Head who acts as the Over-all Technical Manager and who holds the supervisory authority and technical responsibility over all the Technical Managers of the different sections under his/her laboratory. He/She has the overall responsibility for ensuring the control and operation of all activities in all of the sections under the laboratory being supervised. He/She holds the authority and resources in carrying out his/her duties, including the maintenance and improvement of the LQMS and identifying occurrences of departures from the LQMS and to initiate actions to correct, prevent or minimize such departures.

The Laboratory Head / Over-all Technical Manager specifically has the following functions:

- Assumes technical management of the laboratory;
- Responsible for the laboratory's overall administrative and technical operations;
- Specify and/or approve all technical procedures used by the laboratory;
- Attest to the validity of all laboratory test reports;
- Plan and coordinate with the Division Chief to ensure that resources needed to carry out the tests and deliver the required quality of laboratory operations are provided in a timely manner;
- Supervises the Technical Managers of all the laboratory sections and is responsible for their performance evaluation;
- Provide adequate supervision, instruction, and training of the laboratory staff to facilitate completion of assigned tasks;

- Identify occurrences of departures from the management system or from the procedures for performing tests, and to initiate actions to prevent or minimize such departures in the laboratory;
- Conducts analyses of trends of laboratory's performance in proficiency testing and interlaboratory comparisons; and
- Evaluate and signs work order report and final test report

Each field of testing service of STD (laboratory section) has a Technical Manager who is the Section Head and who holds the overall responsibility for ensuring the effective control and operation of all activities specific to his/her section. He/She also holds the authority and resources in carrying out his/her duties including the implementation, maintenance and improvement of the LQMS and identifying the occurrences of departures from test methods and other technical procedures, and to initiate actions to correct, prevent or minimize such departures.

The Section Head / Technical Manager specifically has the following functions:

- Assumes technical management of the laboratory section;
- Responsible for the section's administrative and technical operations;
- Specify and/or approve all technical procedures used by the laboratory;
- Assign only competent analysts or personnel to perform tests, and issues work order to laboratory section's analysts;
- Attest to the validity of all laboratory test reports;
- Provide adequate supervision, instruction, and training of the laboratory staff and trainees to facilitate completion of assigned tasks;
- Formulates goals or education, training and skills of laboratory section's personnel;
- Responsible for the evaluation of performance of all staffs of the laboratory section;
- Ensure that good laboratory practices are implemented in the laboratory;
- Ensures that resources needed for laboratory section's operations are of required quality;
- Ensures competence and give authority to laboratory section's personnel who operate specific equipment, perform tests, evaluate results and sign work order reports;
- Identify occurrences of departures from the management system or from the procedures for performing tests, and to initiate actions to prevent or minimize such departures in the laboratory; and
- Evaluate and attests to the validity of work order report and final test report.

4.1.4.5 Document and Information Controller (DIC)

The DIC has the over-all responsibility in ensuring that all current versions of LQMS documents and records are properly controlled. Specifically, the responsibilities of the DIC are:

- Controls all documents and records of STD LQMS;
- Prepares new documents and revise existing documents (once approved in the Document Review) of the Quality Manual (QM) and General Procedures (GP);
- Assigns codes to newly prepared documents and controls copies of these documents;
- Keeps master lists of all STD LQMS documents;
- Facilitates the request for revision of LQMS documents;
- Organizes the Document Review for the QM and GP;
- Authorizes the issue of uncontrolled copies of any document and records, upon approval of the Quality Manager; and
- Retrieves and files the obsolete copies of LQMS documents

4.1.4.6 Section / Laboratory Document Custodian (DC)

The DCs of each section or laboratory assists the DIC in the proper documentation of the LQMS. In addition, the responsibilities of the DCs are:

- Controls all documents and records, esp. Technical Procedures (TP) and corresponding technical records generated by each laboratory or section;
- Updates the master lists of documents when new documents are prepared or existing documents are revised;
- Facilitates the request for revision of TPs;
- Ensures that all documents, esp. TP forms like work sheets, to be used by each section / laboratory staff are the current versions;
- Retrieves obsolete documents and surrender these to the DIC; and
- Constantly updates the DIC for changes in the section / laboratory documents.

4.1.4.7 Internal and External Pressures

STD has strict compliance to Civil Service Commission (CSC) rules and regulations that ensures that all personnel are free from any undue internal and external commercial, financial or other pressures and influences, which may adversely affect the quality of testing and other technical services rendered to its customers. Internal pressure would mean that the personnel must not become involved in activities. This includes:

- Giving of unplanned work and more responsibilities other than the normal workload affecting the quality of their work;
- Causing diminished confidence in the laboratory's competence, impartiality, judgment or operational integrity; and
- Adversely influencing the laboratory's compliance with the requirements of PNS ISO/IEC 17025:2005.

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4.1.5 Organization and Management Structure

The organizational structure of DOST-ITDI STD is shown in Appendix QM-06-01. The organizational chart shows the relationship between STD and the financial and administrative support services.

4.1.6 STD Supervision

The Technical Managers and Philippine Accreditation Bureau (PAB)-approved signatories provide adequate supervision to STD staff and trainees on test methods and procedures, purpose of each test, and with the assessment of the test results.

4.1.7 Appointment of the Quality Manager

The Quality Manager reports to the Institute Director on matters pertaining to LQMS. Refer to 4.1.10.2 for the roles and responsibilities of the Quality Manager, irrespective of the duties assigned by the Institute Director.

4.1.8 Deputies of Key Managerial Personnel

In the absence of the Key Managerial Personnel, the deputies automatically take over the functions in relation to the operations of STD. In case of signing test reports, whenever the Division Chief/Quality Manager is absent, the designated Officer-in-Charge signs for the Division Chief/QM. The following are authorized deputies:

Key Managerial Positions	1st Level Deputies*	2nd Level Deputies**
Institute Director	Officer-in-Charge/ Deputy Director for ATS	Division Chief/Quality Manager
Division Chief	Officer-in-Charge/Deputized Laboratory Head	Laboratory Section Head
Quality Manager	Deputy Quality Manager	Document and Information Controller
Laboratory Head/Over-all TM, BL	Section Head/TM, PTS or MS	Section Deputy TM, PTS or MS
Laboratory Head/Over-all TM, CL	Section Head/TM, ICS or OCS	Section Deputy TM, ICS or OCS
Laboratory Head/TM, PPTL	Laboratory Deputy TM	Deputized PPTL Staff
Document and Information Controller	Deputy Document and Information Controller	Section/Laboratory Document Custodians

* Depends on the deputization assigned by the Key Managerial Position
** Depends on the field of test considered

4.1.9 Personnel Awareness

The Over-all Technical Manager, and/or Technical Manager of each laboratory, ensures that personnel awareness on the relevance and importance of their activities and how it contributes to the achievement of the objectives of the LQMS is disseminated during the staff and regular meetings. The Technical Managers remind the personnel of the performance of their duties and responsibilities in the operations and systems of laboratory.

4.1.10 Appropriate Communication Processes

The Quality Manager and his/her deputy conduct Division staff meetings through a General Assembly once every semester and include among its agenda the communication of the effectiveness of the LQMS. Observations and feedbacks from all personnel of the Division are also discussed in these meetings. The Quality Manager disseminates to all personnel the results of the management review. Designated staff writes the minutes of the meeting in a logbook for every General Assembly. The procedure on the conduct and recording of the Management Review is stated in GP 4.15 "Management System Reviews."

Each unit, section and laboratory conducts regular Technical and Operations Meetings to ensure proper dissemination of information and communication and solicit comments, suggestions and areas for improvement from all staffs of the unit/section/laboratory. This is recorded in a logbook.

4.1.11 Protection of Customers' Confidential Information and Proprietary Rights

STD implements policies and procedures to ensure the protection of customer's confidentiality and proprietary rights. In order to maintain the confidentiality of information and proprietary rights of customers with respect to tests performed, STD follows GP 4.1.1 "Protection of Customers' Confidentiality and Proprietary Rights."

STD ensures the customers' confidential information and proprietary rights, through securing access and proper arrangement of facilities such that customers and other non-STD personnel cannot possibly view computers where computations, results and other technical data of testing and other technical services are being processed.

STD requires personnel and division trainees to make a formal pledge of protecting customers' confidential information and proprietary rights including protection of all documents and records from unauthorized reproduction and use.

A procedure is made to cover the electronic storage and transmission of test results (see GP 4.1.1). STD may store test results electronically and provide a procedure on how to protect the electronic results in all computers in the premises against unauthorized access.

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4.1.12 Competence, Impartiality, Judgment and Operational Integrity

All STD personnel commit to avoid activities that would diminish the competence, impartiality, judgment and operational integrity of the Division.

4.2.1 Management System Documentation

The STD has established a Laboratory Quality Management System (LQMS) and continually implements and maintains it to support the conduct of its tests. This Quality Manual and related documentation describe the management system. The LQMS is communicated to, made understood by, and implemented by all laboratory personnel through awareness programs, staff technical and management meetings, and quality discussions.

4.2.2 Quality Policy

4.2.2.1 Quality Objective

The overall objectives of the LQMS implemented in STD are established and reviewed during the management review in accordance with QM-04-15 "Management System Reviews."

The laboratory in all its operation complies with the PNS ISO/IEC 17025:2005 "General Requirements for the Competence of Testing and Calibration Laboratories."

All staff are always guided in all their work by the following objectives:

4.2.2.1.1 To employ only qualified and adequate resources in the conduct of tests for customers, which includes the following:

- Trained and competent technical staff
- Validated test methods
- Verified or calibrated equipment
- Appropriate accommodation and environmental condition;

4.2.2.1.2 To accept work which they are capable, competent and where resources are available;

4.2.2.1.3 To maintain quality on all activities (sample receiving and handling, sample preparation, conduct of tests, reporting and release of results) that affect the accuracy of the test results;

4.2.2.1.4 To implement a systematic program for monitoring the reliability of its test results and include quality control on method implementation and participation in proficiency testing;

4.2.2.1.5 To be familiar with the quality documentation and implement policies and procedures in their work;

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4.2.2.1.6 To protect confidentiality of customers' results and proprietary rights;

4.2.2.1.7 To isolate from undue pressure, if any, that may influence their technical judgment.

4.2.2.1.8 To emphasize the prevention of quality problems in their plans, decisions, and actions, rather than correction of problems after they occur; and

4.2.2.1.9 To closely monitor the activities of the Division for early detection of problems and potential problems, and conduct appropriate corrective and preventive actions, including periodic quality audits.

4.2.2.2 Quality Policy Statement

The Standards and Testing Division of the Industrial Technology Development Institute (STD-ITDI), Department of Science and Technology (DOST) is committed to promptly and efficiently deliver quality technical services for the satisfaction of its customers.

Customers' satisfaction is guaranteed by:

a. **Conducting tests with accuracy and reliability, conforming with the PNS ISO/IEC 17025:2005 standard;**
b. **Ensuring utmost confidentiality of information obtained from the customers; and**
c. **Promoting a safe and friendly environment.**

Continual improvement of its management system is achieved by:

a. **Strengthening human, financial and physical resources;**
b. **Complying strictly with the established policies and procedures; and**
c. **Monitoring the effectiveness of its implementation.**

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MARIA PATRICIA V. AZANZA, Ph.D.
Institute Director

4.2.2.3 Mission

The Standards and Testing Division ensures quality life and products through testing.

4.2.2.4 Vision

The Division envisions uplifting the socio-economic well-being of the Filipino people and to ensure sustainability for future generations by being an excellent provider of technical services. It aims to lead the global race for better and safer high quality products through provision of globally-competitive testing services.

4.2.3 Top Management Commitment

The top management of ITDI-DOST commits to:

- **Develop and implement the Laboratory Quality Management System and continually improve its effectiveness;**
- **Establish and authorize the quality policy;**
- **Communicate the importance of customer satisfaction;**
- **Ensure compliance with statutory and regulatory requirements; and**
- **Maintain integrity of the Institution, especially during planned changes brought about by the management reviews and by providing needed resources for such activities.**

MARIA PATRICIA V. AZANZA, Ph.D.
Institute Director

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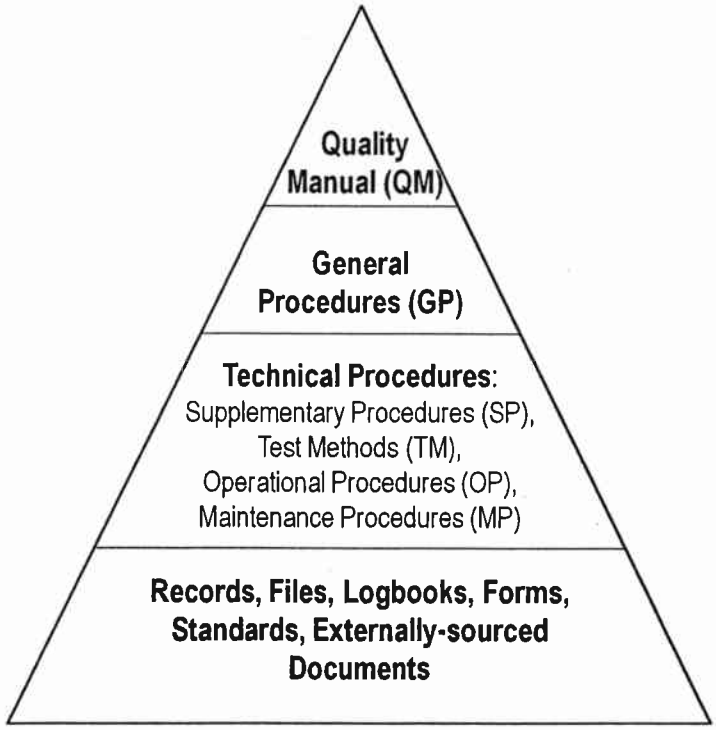
4.2.4 Top Management Communication

Top management communicates to STD personnel the importance of meeting customer, statutory, and regulatory requirements through:

- the distribution of this Quality Manual and other related documentation;
- dissemination of relevant correspondence;
- memoranda;
- notices;
- use of bulletin boards; and
- through meetings, assemblies and conferences

4.2.5 Quality Manual

The quality documentation hierarchy is structured below through the following documents: Quality Manual (QM), General Procedures (GP), Technical Procedures (TP), and other supporting documents. This provides structure for preparation, organization, distribution and revision of documents, and ease of understanding thereof. These documents are defined in QM-03 "Terms and Definitions" under section 3.3.



4.2.6 Management Responsibilities

The roles and responsibilities of the Quality Manager and Technical Manager, and their deputies, are defined in QM-04-01 "Organization", under section 4.1.5.

4.2.7 Management System Integrity

Top management ensures the integrity of the management system whenever policies, procedures and other related documents are changed. This is done by adhering to the policies and procedures outlined in QM-04-03 "Documentation and Information Control" and QM-04-15 "Management System Reviews."

4.2.8 PAB Approved Signatories, Scope of Laboratory Accreditation and the Use of PAB Laboratory Accreditation Endorsement

4.2.2.1 The STD uses Philippine Accreditation Bureau (PAB) laboratory accreditation endorsement or symbol in its test reports only for tests listed in the scope of accreditation and when signed by at least one (1) PAB approved signatory in the test reported. The list of approved test parameters and corresponding approved signatories of each laboratory of STD is shown in QM-06-03 "Laboratory Accreditation Certificates."

4.2.2.2 Use of the PAB accreditation symbol should be in the required format, size, color and wording as shown below:

PAB
PAO ACCREDITED
TESTING LABORATORY
PNS ISO/IEC 17025:2005
LA-YYYY-XXXZ

In this symbol, LA-YYYY-XXXZ, shown below the standard (PNS ISO/IEC 17025:2005), is the STD laboratory's current accreditation number, wherein "YYYY" is the year the accreditation was issued, "XXX" is the accreditation number of the specific STD laboratory, and "Z" corresponds to a letter of the English alphabet which indicates the number of issuance of the accreditation. When this symbol is used, any enlargements or reductions shall retain the same proportions as shown in the image above.

4.2.2.3 This accreditation symbol is only used in test reports once accreditation or renewal of accreditation has been granted by PAB. When accreditation of any STD accredited laboratory has been suspended, expired and not applied for renewal, and withdrawn or terminated by PAB, the use of the PAB accreditation symbol is immediately ceased in the issuance of test reports and other materials displaying this symbol.

4.2.2.4 The PAB accreditation symbol shall be used related to or associated only with testing services covered by the scope of accreditation. The STD distinguishes the accredited test results from those which are not.

4.2.2.5 The approved signatory/ies of STD accepts personal responsibility for ensuring that the reported tests are carried out in full compliance with PAB accreditation criteria.

4.2.2.6 The PAB accreditation symbol is also used by STD, aside from test reports, only to the following materials:

- letterheads for communication and quotations/proposals which involves testing included in the scope of accreditation
- brochures
- tarpaulins
- organization publications, and
- website and social networking sites which are utilized by STD for promotion of its technical services.

This symbol shall not be more prominent than any other logo used in the documents earlier mentioned.