QUALITY POLICY MANUAL

NATIONAL METROLOGY LABORATORY
INDUSTRIAL TECHNOLOGY DEVELOPMENT INSTITUTE
DEPARTMENT OF SCIENCE AND TECHNOLOGY

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1 General

The National Metrology Laboratory (NML) is one of the divisions of the Industrial Technology Development Institute (ITDI) of the Department of Science and Technology (DOST).

The NML is mandated by law to provide metrology and related services to industries and other sectors, and is committed to continually provide reliable and accurate service as documented in this Quality Policy Manual (QPM).

The NML accomplishes its mandate by providing the following services:

- testing, calibration and verification of measuring instruments;
- consultation and training in metrology;
- proficiency testing; and
- technical assessment of calibration laboratories.

The NML provides testing and calibration of measuring instruments in the following disciplines:

- Mass, Force and Pressure
- Length
- Viscosity, Density, Volume and Flow
- Thermometry and Hygrometry
- Electrical, Time, Frequency, and Photometry.

When requested and on meritorious cases, the NML provides on-site services at customer's location in most of the listed disciplines. All services are performed in accordance with the requirements contained in this QPM.The guidelines contained in this QPM applies to all employees of the NML and meets all the requirements set forth by the ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories".

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This Quality Policy Manual (QPM) specifies the general requirements for the competence, impartiality and consistent operation of the National Metrology Laboratory (NML).

The NML customers, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others may use this document in confirming or recognizing the competence of the NML .

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The following documents are referred to in the development and preparation of this QPM:

- JCGM 100:2008, Guide on the uncertainty of measurement
- JCGM 200:2008, International vocabulary of metrology
- ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories

Their contents constitute the requirements of this QPM. The latest edition of the referenced documents (including any amendments) applies.

NOTE The paragraph numbering used in this QPM is consistent with that used in ISO/IEC 17025:2017.

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The following terms are used in this QPM.

3.1 impartiality

presence of objectivity; objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence subsequent activities of the laboratory

3.2 complaint

expression ofdissatisfaction by any person or organization to a laboratory, relating to the activities or results of that laboratory, where a response is expected

3.3 interlaboratory comparison

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

3.4 intralaboratory comparison

organization, performance and evaluation of measurements or tests on the same or similar itemswithin the same laboratory in accordance with predetermined conditions

3.5 proficiency testing

evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons

3.6 laboratory

body that performs one or more of the following activities:

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

3.7 decision rule

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rule that describes how measurement uncertainty is accounted for when stating conformity with aspecified requirement

3.8 verification

provision of objective evidence that a given item fulfils specified requirements

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

EXAMPLE 2 Confirmation that performance properties or legal requirements of a measuring system areachieved.

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

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

NOTE2 The item may be, for example, a process, measurement procedure, material, compound, or measuring system.

NOTE 3 The specified requirements may be, for example, that a manufacturer's specifications are met.

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

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

3.9 validation

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

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

3.10 method

method as used in this document can be consideredsynonymous with the term "measurement procedure"

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4.1 Impartiality

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

4.1.2 The NML management is committed to impartiality.

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

4.1.4 The NML identifies risks to its impartiality on an on-going basis. This includes those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.

4.1.5 If a risk to impartiality is identified, the NML demonstrates how it eliminates or minimizes such risk. (see 8.5)

4.2 Confidentiality

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

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

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

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with the customer, unless agreed by the source.

4.2.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the NML's behalf, keeps confidential all information obtained or created during the performance of NML activities, except as required by law. (OM 4.2 Confidentiality and Proprietary Rights)

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5.1 The National Metrology Laboratory (NML) is one of the divisions of the Industrial Technology Development Institute (ITDI) of the Department of Science and Technology (DOST) recognized under Executive Order No. 366, series 2004 (Government Rationalization Program).ITDI and DOST are government entities created under Executive Order No. 128 of 1987 (Reorganizing the National Science and Technology Authority).

Being a governmental laboratory, NML is deemed to be a legal entity on the basis of its governmental status and is legally responsible for its activities.

The NML is covered by policies and procedures of ITDI with respect to the hiring of personnel, procurement of equipment and materials and other administrative matters.

Complimenting the ITDI policies and procedures are the NML policies and procedures contained in this Quality Policy Manual (QPM).

5.2 The NML identifies that the management has overall responsibility for the laboratory.

5.3 The NML defines and documents the range of its activities for which it conforms with this document. The NML only claims conformity with this document for its range of activities, which excludes externally provided laboratory activities on an ongoing basis. (Annex A1 Scope of Services)

5.4 NML activities are carried out in such a way as to meet the requirements of ISO/IEC 17025:2017, its customers, regulatory authorities and organizations providing recognition. This includes laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.

5.5 The NML:

a) defines the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical

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operations and support services (AnnexA2 - NML Organization);

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

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

5.6 The NML has personnel who, irrespective of other responsibilities, has the authority and resources needed to carry out their duties, including:

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

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

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

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

e) ensuring the effectiveness of laboratory activities.

5.7 NML management ensures that:

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

b) The integrity of the management system is maintained when changes to the management system are planned and implemented

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6.1 General

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

6.2 Personnel

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

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

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

6.2.4 The NML management communicates to personnel their duties, responsibilities and authorities.

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

a) determining the competence requirements;
b) selection of personnel;
c) training of personnel;
d) supervision of personnel;
e) authorization of personnel;
f) monitoring competence of personnel

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

a) development, modification, verification and validation of methods;
b) analysis of results, including statements of conformity or opinions and interpretations;

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c) report, review and authorization of results.

6.3 Facilities and environmental conditions

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

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

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

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

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

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

c) effective separation between areas with incompatible laboratory activities.

6.3.5 When the laboratory performs laboratory activities at sites or facilities outside its permanent control, it ensures that the requirements related to facilities and environmental conditions of ISO/IEC 17025:2017are met.

6.4 Equipment

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

6.4.2 When the NML uses equipment outside its permanent control, it ensures that the requirements for equipment of ISO/IEC 17025:2017 are met.

6.4.3 The NML has a procedure for handling, transport, storage, use and planned

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maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration.

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

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

6.4.6 Measuring equipment is calibrated when:

- the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or
- calibration of the equipment is required to establish the metrological traceability of the reported results.

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

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

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

6.4.10 When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks are carried out according to a procedure. Each section prepares and maintains intermediate checking procedure as needed.

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

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

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

a) the identity of equipment, including software and firmware version;

b) the manufacturer's name, type identification, and serial number or other unique identification;

c) evidence of verification that equipment conforms with specified requirements;

d) the current location;

e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;

f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;

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

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

6.5 Metrological traceability

6.5.1 The NML establishes and maintains metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.

6.5.2 The NML ensures that measurement results are traceable to the International System of Units (SI) through:

a) calibration provided by a competent laboratory; laboratories fulfilling the requirements of ISO/IEC 17025:2017 are considered to be competent; or

b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; Reference material

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producers fulfilling the requirements of ISO 17034 are considered to be competent; or

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

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

a) certified values of certified reference materials provided by a competent producer;

b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison.

6.6 Externally provided products and services

6.6.1 The NML ensures that only suitable externally provided products and services that affect laboratory activities are used when these: are intended for incorporation into the laboratory's own activities; are provided, in part or in full, directly to NML; and/or are used to support the operation of the laboratory.

6.6.2 The NML follows the procedure of ITDI in purchasing of products and services. (PM-ADM-PPMS 08-01, Procedures Manual for Purchasing of Goods)

6.6.3 The NML describes critical specifications and requirements of goods in the purchase request form and are communicated to external providers through the purchasing office of ITDI.

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7.1 Review of requests, tenders and contracts

7.1.1 The NML has a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:

a) the requirements are adequately defined, documented and understood

b) the NML has the capability and resources to meet the requirements

c) the NML does not subcontract services;

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

NOTE For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way. (Functional database)

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

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

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

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

7.1.6 If a contract is amended after work has commenced, the contract review is repeated and any amendments is communicated to all affected personnel.

7.1.7 The NML cooperates with customers or their representatives in clarifying the customer's request and in monitoring the NML's performance in relation to the work performed. Such cooperation can include reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities and preparation, packaging, and

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dispatch of items needed by the customer for verification purposes.

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

7.2 **Selection, verification and validation of methods**

7.2.1 Selection and verification of methods

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

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

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

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a laboratory. It can be necessary to provide additional documentation for optional steps in the method or additional details.

7.2.1.4 When the customer does not specify the method to be used, the NML selects an appropriate method and informs the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, are recommended. NML-developed or modified methods can also be used.

7.2.1.5 The NML verifies that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification are

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retained. If the method is revised by the issuing body, verification is repeated to the extent necessary.

7.2.1.6 When method development is required, this is a planned activity and is assigned to competent personnel equipped with adequate resources. As method development proceeds, periodic review is carried out to confirm that the needs of the customer are still being fulfilled. Any modifications to the development plan is approved and authorized.

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

7.2.2 Validation of methods

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

NOTE 1 Validation can include procedures forhandling and transportation of test or calibration items.

NOTE 2 The techniques used for method validation can be one of, or a combination of, the following:

a) calibration or evaluation of bias and precision using reference standards or reference materials;
b) systematic assessment of the factors influencing the result;
c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;
d) comparison of results achieved with other validated methods;
e) interlaboratory comparisons;
f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

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

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

NOTE Performance characteristics can include, but are not limited to, measurement range,

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accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias.

7.2.2.4 The NML retains the following records of validation:

a) the validation procedure used;

b) specification of the requirements;

c) determination of the performance characteristics of the method;

d) results obtained;

e) a statement on the validity of the method, detailing its fitness for the intended use.

7.3 Sampling

7.3.1 The NML does not carry out sampling.

7.4 **Handling of test or calibration items**

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

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

7.4.3 Upon receipt of the test or calibration item, deviations from specified conditions are recorded. When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, the NML consults the customer for further instructions before proceeding and records the results of this consultation. When the customer requires the item to be tested or calibrated acknowledging a deviation from

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specified conditions, the NML includes a disclaimer in the report indicating which results may be affected by the deviation.

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

7.5 **Technical records**

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

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

7.6 **Evaluation of measurement uncertainty**

7.6.1 The NML identifies the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, are taken into account using appropriate methods of analysis.

7.6.2 The NML evaluates the measurement uncertainty for all calibrations, including of its own equipment.

7.6.3 Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation is made based on an understanding of the theoretical principles or practical experience of the performance of the method.

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7.7 Ensuring the validity of results

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

a) use of reference materials or quality control materials;
b) use of alternative instrumentation that has been calibrated to provide traceable results;
c) functional check(s) of measuring and testing equipment;
d) use of check or working standards with control charts, where applicable;
e) intermediate checks on measuring equipment;
f) replicate tests or calibrations using the same or different methods;
g) retesting or recalibration of retained items;
h) correlation of results for different characteristics of an item;
i) review of reported results;
j) intralaboratory comparisons;
k) testing of blind sample(s).

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

a) participation in proficiency testing;

NOTE ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.

b) participation in interlaboratory comparisons other than proficiency testing.

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

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7.8 Reporting of results

7.8.1 General

7.8.1.1 The results are reviewed and authorized prior to release.

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

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

7.8.2 Common requirements for reports (test, calibration or sampling)

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

a) a title (e.g. "Test Report", "Calibration Certificate");
b) the name and address of the laboratory;
c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities;
d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;
e) the name and contact information of the customer;
f) identification of the method used;
g) a description, unambiguous identification, and, when necessary, the condition of the item;

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

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

j) the date of issue of the report;

k) a statement to the effect that the results relate only to the items tested, calibrated;

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

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

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

NOTE Including a statement specifying that the report shall not be reproduced except in full without approval of the laboratory can provide assurance that parts of a report are not taken out of context.

7.8.2.2 The NML is responsible for all the information provided in the report, except when information is provided by the customer. Data provided by customer are clearly identified. In addition, a disclaimer is stated on the report when the information is supplied by the customer and can affect the validity of results.

7.8.3 Specific requirements for test reports

7.8.3.1 In addition to the requirements listed in 7.8.2, test reports , where necessary for the interpretation of the test results, include the following:

a) information on specific test conditions, such as environmental conditions;

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

c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:

- it is relevant to the validity or application of the test results;
- a customer's instruction so requires, or
- the measurement uncertainty affects conformity to a specification limit;

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

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e) additional information that may be required by specific methods, authorities, customers or groups of customers.

7.8.4 Specific requirements for calibration certificates

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

a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);
b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;
c) a statement identifying how the measurements are metrologically traceable (see Annex A);
d) the results before and after any adjustment or repair, if available;
e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);
f) where appropriate, opinions and interpretations (see 7.8.7).

7.8.4.2 The NML does not carry out sampling.

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

7.8.5 Reporting sampling – specific requirements

The NML does not carry out sampling.

7.8.6 Reporting statements of conformity

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

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

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

a) to which results the statement of conformity applies;

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

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

7.8.7 Reporting opinions and interpretations

The NML does not include in its test reports/calibration certificates interpretations or opinions about the calibration result.

7.8.8 Amendments to reports

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

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

Such amendments meet all the requirements of ISO/IEC 17025:2017.

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

7.9 Complaints

7.9.1 The NML has a documented process to receive, evaluate and make decisions on complaints.

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

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

a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;
b) tracking and recording complaints, including actions undertaken to resolve them;
c) ensuring that any appropriate action is taken.

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

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

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

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

7.10 Nonconforming work

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

a) the responsibilities and authorities for the management of nonconforming work are defined;
b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;
c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;

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d) a decision is taken on the acceptability of the nonconforming work;

e) where necessary, the customer is notified and work is recalled;

f) the responsibility for authorizing the resumption of work is defined.

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

7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, the NML implements corrective action.

7.11 Control of data and information management

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

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

NOTE Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.

7.11.3 The NML information management system(s):

a) is protected from unauthorized access;

b) is safeguarded against tampering and loss;

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

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

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

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actions.

7.11.4 The NML does not manage and maintain information management system off-site or through an external provider.

7.11.5 The NML ensures that instructions, manuals and reference data relevant to its information management system(s) are made readily available to personnel.

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

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8.1 Management System Option

8.1.1 General

The NML establishes, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17025:2017 and assuring the quality of its results. In addition to meeting the requirements of Clauses 4 to 7, the NML implements a management system in accordance with Option A of ISO/IEC 17025:2017.

8.1.2 Option A

As a minimum, the management system of the NML addresses the following:

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

8.2 Management system documentation

8.2.1 NML management establishes, documents, and maintains policies and objectives for the fulfillment of the purposes of this document and ensures that the policies and objectives are acknowledged and implemented at all levels of its organization.

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

8.2.3 NML management provides evidence of commitment to the development and implementation of the management system and continual improvement of its effectiveness.

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8.2.4 All documentation, processes, systems, records, related to the fulfillment of the requirements of ISO/IEC 17025:2017are included in, referenced from, or linked to the management system.

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

8.3 Control of management system documents

8.3.1 The NML controls the documents (internal and external) that relate to the fulfillment of ISO/IEC 17025:2017.

NOTE In this context, "documents" can be policy statements, procedures, specifications, manufacturer's instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.

8.3.2 The NML ensures that:

a) documents are approved for adequacy prior to issue by authorized personnel;
b) documents are periodically reviewed, and updated as necessary;
c) changes and the current revision status of documents are identified;
d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
e) documents are uniquely identified;
f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

8.4 Control of records

8.4.1 The NML establishes and retains legible records to demonstrate fulfillment of the requirements in ISO/IEC 17025:2017.

8.4.2 The NML implements the controls needed for the identification, storage, protection,

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back-up, archive, retrieval, retention time, and disposal of its records. The NML retains records for a period consistent with its contractual obligations. Access to these records is consistent with the confidentiality commitments, and records are readily available.

NOTE Additional requirements regarding technical records are given in 7.5.

8.5 Actions to address risks and opportunities

8.5.1 The NML considers the risks and opportunities associated with its activities in order to:

a) give assurance that the management system achieves its intended results;

b) enhance opportunities to achieve its purpose and objectives;

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

d) achieve improvement.

8.5.2 The NML plans:

a) actions to address these risks and opportunities;

b) how to:

- integrate and implement these actions into its management system;
- evaluate the effectiveness of these actions.

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

8.6 Improvement

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

NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.

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

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customer service.

NOTE Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.

8.7 Corrective actions

8.7.1 When a nonconformity occurs, the NML:

a) reacts to the nonconformity and, as applicable:
   - takes action to control and correct it;
   - addresses the consequences;

b) evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
   - reviewing and analyzing the nonconformity;
   - determining the causes of the nonconformity;
   - determining if similar nonconformities exist, or could potentially occur;

c) implements any action needed;

d) reviews the effectiveness of any corrective action taken;

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

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

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

8.7.3 The NML retains records as evidence of:

a) the nature of the nonconformities, cause(s) and any subsequent actions taken;

b) the results of any corrective action.

8.8 Internal audits

8.8.1 The NML conducts internal audits at planned intervals to provide information on whether the management system:

a) conforms to:
   - its own requirements for its management system, including the laboratory activities;

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– the requirements of ISO/IEC 17025:2017;

b) is effectively implemented and maintained.

8.8.2 The NML:

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

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

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

d) retains records as evidence of the implementation of the audit programme and the audit results.

8.9 **Management reviews**

8.9.1 The NML management reviews its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfillment of ISO/IEC 17025:2017.

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

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

b) fulfillment of objectives;

c) suitability of policies and procedures;

d) status of actions from previous management reviews;

e) outcome of recent internal audits;

f) corrective actions;

g) assessments by external bodies;

h) changes in the volume and type of the work or in the range of laboratory activities;

i) customer and personnel feedback;

j) complaints;

k) effectiveness of any implemented improvements;

l) adequacy of resources;

m) results of risk identification;

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n) outcomes of the assurance of the validity of results; and

o) other relevant factors, such as monitoring activities and training.

8.9.3 The outputs from the management review record all decisions and actions related to at least:

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

b) improvement of the laboratory activities related to the fulfillment of the requirements of ISO/IEC 17025:2017;

c) provision of required resources;

d) any need for change.

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The DAkkS Accreditation Scope of the Mass, Pressure, Volume and Temperature Standards Section are as follows:

Permanent Laboratory

Measured quantity / Calibration item	Range	Measurement conditions / Procedure [1]	Best measurement capability [2]	Remarks
Conventional Mass	1 mg to 5 mg	OIML R 111-1:2004 (E) without density determination	0.002 mg	For weight pieces according to OIML R 111-1, up to Class E_2
	10 mg		0.002 mg	
	20 mg		0.003 mg	
	50 mg		0.004 mg	
	100 mg		0.005 mg	
	200 mg		0.006 mg	
	500 mg		0.008 mg	
	1 g		0.010 mg	
	2 g		0.012 mg	
	5 g		0.016 mg	
	10 g		0.020 mg	
	20 g		0.025 mg	
	50 g		0.03 mg	
	100 g		0.05 mg	
	200 g		0.10 mg	
	500 g		0.25 mg	
	1 kg		0.50 mg	
	2 kg		1.0 mg	
	5 kg		2.5 mg	
	10 kg		5.0 mg	
	20 kg		10 mg	
	50 kg		25 mg	
	100 kg		160 mg	For weight pieces according to OIML R 111-1, up to Class F_1
	200 kg		300 mg	
	500 kg		2500 mg	For weight pieces according to OIML R 111-1, up to Class M_1
Conventional Mass	1 mg to 10 mg	OIML R 111-1:2004 (E) without density determination	0.008 mg	For free nominal values m_c = conventional mass
	>10 mg to 20 mg		0.010 mg	
	>20 mg to 50 mg		0.012 mg	
	>50 mg to 100 mg		0.016 mg	
	>100 mg to 200 mg		0.020 mg	

Approval is evidenced by a signature in all pages.	Prepared by: MISalazar Date: 2020-01-10	Approved by: MMRuiz Date:

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	>200 mg to 500 mg		0.025 mg	
	>500 mg to 1 g		0.03 mg	
	>1 g to 2 g		0.04 mg	
	>2 g to 5 g		0.05 mg	
	>5 g to 10 g		0.06 mg	
	>10 g to 20 g		0.08 mg	
	>20 g to 50 g		0.10 mg	
	>50 g to 100 g		0.16 mg	
	>100 g to 50 kg		$1.7 \cdot 10^{-6}\ m_c$	
	>50 kg to 500 kg		$5 \cdot 10^{-6}\ m_c$	
Gauge Pressure, p_e	-95 kPa to <0.0 kPa	DKD-R-6-1:2014 EURAMET cg-17 Version 3.0	65 Pa	Pressure Medium: Gas
	0.0 kPa to <0.2 MPa		$5 * 10^{-5} \cdot p_e$, but not less than 25 Pa	
	0.2 MPa to 4 MPa		$7.1 \cdot 10^{-5} \cdot p_e$, but not less than 25 Pa	
	> 4 MPa to 20 MPa		$7.1 \cdot 10^{-5} \cdot p_e$	
	1.25 MPa to 6.8 MPa		$1.1 \cdot 10^{-4} \cdot p_e$, but not less than 410 Pa	Pressure Medium: Liquid
	> 6.8 MPa to 100 MPa		$8.3 \cdot 10^{-5} \cdot p_e$, but not less than 630 Pa	
Absolute Pressure, p_{abs}	0.1 MPa	DKD-R-6-1:2014 EURAMET cg-17 Version 3.0 Principle of measurement $p_{abs} = p_e + p_{amb}$	$7.1 \cdot 10^{-5} \cdot p_{abs}$, but not less than 25 Pa	Pressure Medium: Gas p_{abs} : measured pressure in MPa The unccertainty of the atmospheric pressure p_{amb} (barometer) has to be added.
	0.2 MPa to 4.1 MPa			
	>4.1 MPa to 20.1 MPa		$7.1 \cdot 10^{-5} \cdot p_{abs}$	
	0.1 MPa		$1.1 \cdot 10^{-4} \cdot p_{abs}$, but not less than 410 Pa	Pressure Medium: Liquid p_{abs} : measured pressure in MPa The unccertainty of the atmospheric pressure p_{amb}(barometer) has to be added.
	1.25 MPa to 6.9 MPa			
	>6.9 MPa to 100 MPa		$8.3 \cdot 10^{-5} \cdot p_{abs}$, but not less than 630 Pa	
Measured quantity / Calibration item	Range	Measurement conditions / Procedure [1)]	Best measurement capability [2)]	Remarks

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Measured quantity / Calibration item	Range	Measurement conditions / Procedure [1]	Best measurement capability [2]	Remarks
Volume of liquids/Piston-operated pipette with variable volume	1 µL to < 10 µL	Gravimetric Method according to DIN EN ISO 8655:2002 and DKD R 8-1:2011	a. 2.0 % b. 1.5 % c. 1.0 %	Measurement uncertainty stated are for the corresponding test volumes a. Upper test volume b. Middle test volume c. Lower test volume
	10 µL to < 100 µL		a. 0.45 % b. 0.34 % c. 0.23 %	
	100 µL to < 1 200 µL		a. 0.23 % b. 0.17 % c. 0.12 %	
	1 200 µL to 10 mL		a. 0.15 % b. 0.11 % c. 0.075 %	
Volume of liquids/Piston-operated pipette with fixed volume	1 µL to < 10 µL		2.0 %	
	10 µL to < 100 µL		0.45 %	
	100 µL to 1 200 µL		0.23 %	
	1 200 µL to 10 mL		0.15 %	
Volume of liquids/Dispenser	1 µL to < 10 µL	Gravimetric Method according to DIN EN ISO 8655:2002 and DKD R 8-2:2017	a. 2.0 % b. 1.5 % c. 1.0 %	Measurement uncertainty stated are for the corresponding test volumes a. Upper test volume b. Middle test volume c. Lower test volume
	10 µL to < 100 µL		a. 0.45 % b. 0.34 % c. 0.23 %	
	100 µL to < 1 200 µL		a. 0.23 % b. 0.17 % c. 0.12 %	
	1 200 µL to < 10 mL		a. 0.15 % b. 0.11 % c. 0.075 %	
	10 mL to 100 mL		a. 0.075 % b. 0.056 % c. 0.038 %	
Volume of liquids/Volumetric Instruments made of glass, "Ex"	0.1 mL to 1 mL	Gravimetric Method according to DIN EN ISO 4787:2011	0.30 %	
	>1 mL to 10 mL		0.085 %	
	>10 mL to 100 mL		0.045 %	
Volume of liquids/Volumetric Instruments made of glass, "In"	1 mL to 10 mL		0.085 %	
	>10 mL to 100 mL		0.050 %	
	>100 mL to 1 000 mL		0.045 %	
	> 1 L to 5 L		0.042 %	
Density Hydrometer	600 kg/m^3 to 2000 kg/m^3	Hydrostatic Method	0.100 kg/m3	Scale division of 0.2 kg/m3 (or less than 0.5 kg/m3)
	600 kg/m^3 to 2000 kg/m^3		0.125 kg/m3	Scale division of 0.5 kg/m3

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Measured quantity / Calibration item	Range	Measurement conditions / Procedure [1]	Best measurement capability [2]	Remarks
	600 kg/m^3 to 2000 kg/m^3		0.25 kg/m3	Scale division more than 0.5 kg/m3
Specific Gravity Hydrometer	0.590 sp/gr to 2.025 sp/gr		0.00010 sp/gr	
API hydrometer	-1 °API to 101 °API		0.030 °API	
Brix Hydrometer	0 °Brix to 90 °Brix		0.30 °Brix	
Baume Hydrometer	0 Be to 100 Be		0.030 Be	
Alcoholometer	0 % vol to 100 % vol		0.10 % vol	
Grade 0 Gauge Blocks	0.5 mm to 100 mm	Mechanical comparison	0.06 µm	
Grade 1 Gauge Blocks	0.5 mm to 100 mm		0.06 µm	
Grade 2 Gauge Blocks	0.5 mm to 100 mm		0.06 µm	
Industrial Platinum Resistance Thermometers	-70 °C to 0 °C	TP-S7-IPRT: version 3 Cryostatic Bath	25 mK	Comparison with standard platinum resistance thermometer. Determination of polynomial coefficients according to IEC 60751
	> 0 °C to 90 °C	Water Bath	25 mK	
	> 90 °C to 250 °C	Oil Bath	65 mK	
	0 °C (Ice Point)	Ice Bath	10 mK	
Liquid-in-Glass Thermometers	-70 °C to 0 °C	TP-S7-LIGT: version 2 Cryostatic Bath	45 mK	Comparison with standard platinum resistance thermometer
	> 0 °C to 90 °C	Water Bath	45 mK	
	> 90 °C to 250 °C	Oil Bath	70 mK	
Digital Thermometers	-70 °C to 0 °C	TP-S7-DT: version 2 Cryostatic Bath	30 mK	Comparison with standard platinum resistance thermometer
	> 0 °C to 90 °C	Water Bath	30 mK	
	> 90 °C to 250 °C	Oil Bath	65 mK	
	300 °C to 1050 °C	TP-S6-TC-01 3-Zone Furnace	840 mK	Comparison with Type R Thermocouple with cold junction
Relative Humidity Meters	40 %rh to 80 %rh	TP-S6-RH-01 Climatic Chamber with Air Temperature Conditions of 23 °C	0.83 %rh at 40 %rh 1.4 %rh at 60 %rh 2.4 %rh at 80 %rh	Comparison with chilled mirror
	20 °C to 30 °C	TP-S6-RH-01 Climatic Chamber	330 mK at 20 °C 440 mK at 25 °C 560 mK at 30 °C	Comparison with Pt100

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On-site calibration

Measured quantity / Calibration item	Range	Measurement conditions / Procedure [1)]	Best measurement capability [2)]	Remarks
Non-automatic electronic weighing instruments	up to 60 kg	EURAMET cg-18 Version 4.0	$1 \cdot 10^{-6}$	Using OIML Class E_2 weight pieces
	up to 60 kg		$6 \cdot 10^{-6}$	Using OIML Class F_1 weight pieces
	up to 200 kg		$2 \cdot 10^{-5}$	Using OIML Class F_2 weight pieces
	up to 300 kg		$6 \cdot 10^{-5}$	Using OIML Class M_1 weight pieces

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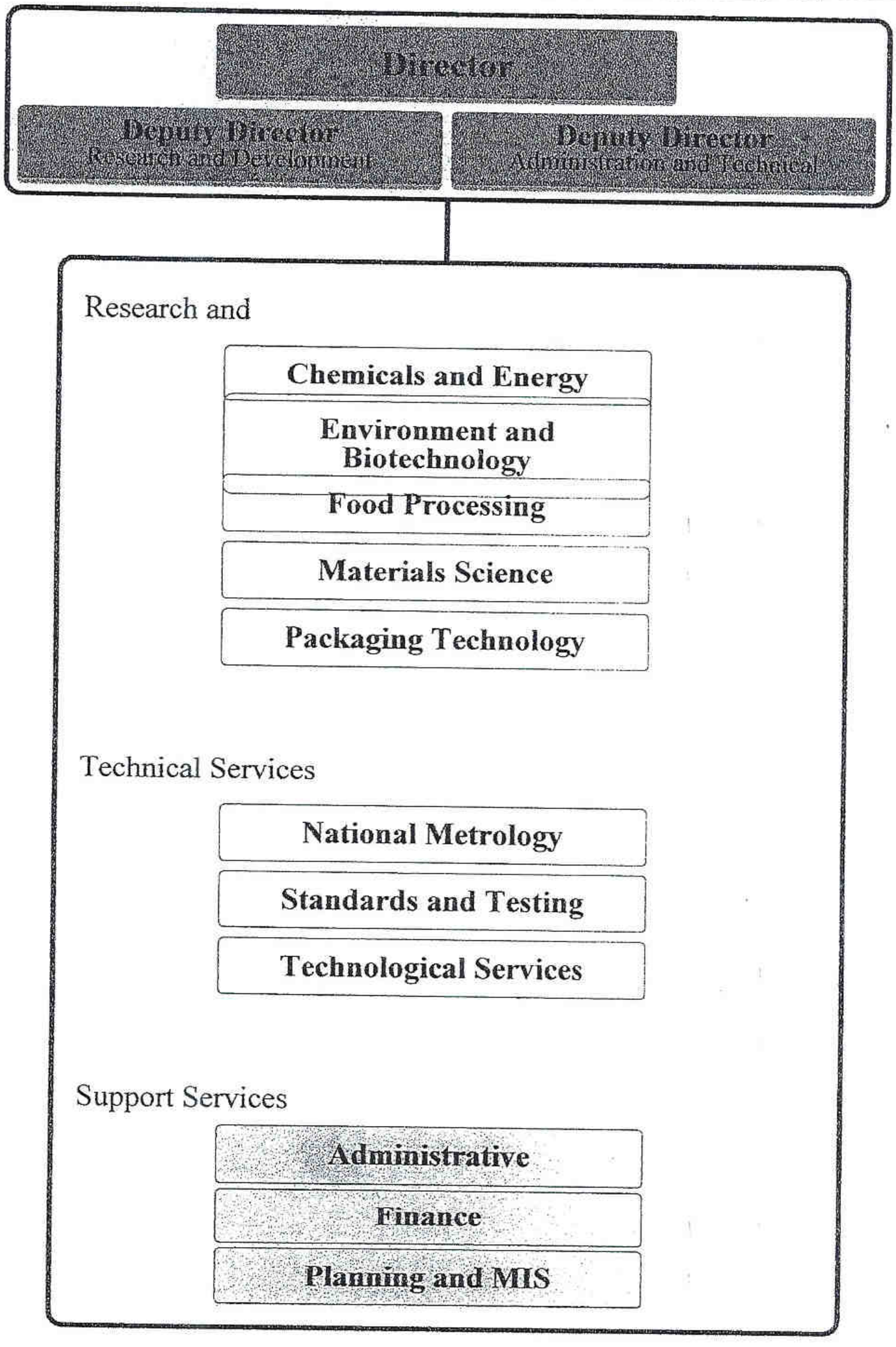

Fig. A2.1 ITDI Organizational Chart

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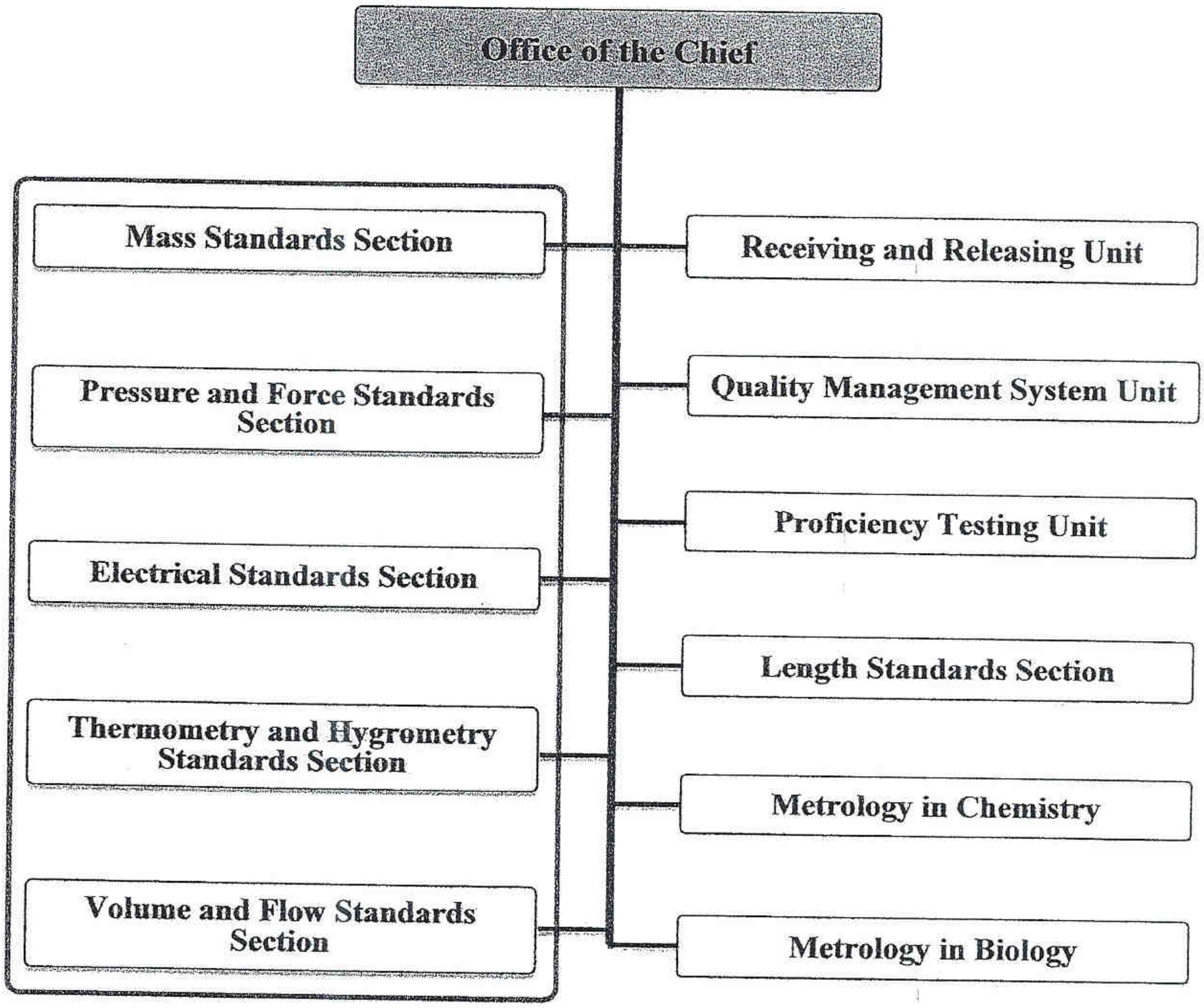

Fig. A2.2NML Organizational Chart

(Sections with DAkkS Accredited Scope are enclosed in the solid line)

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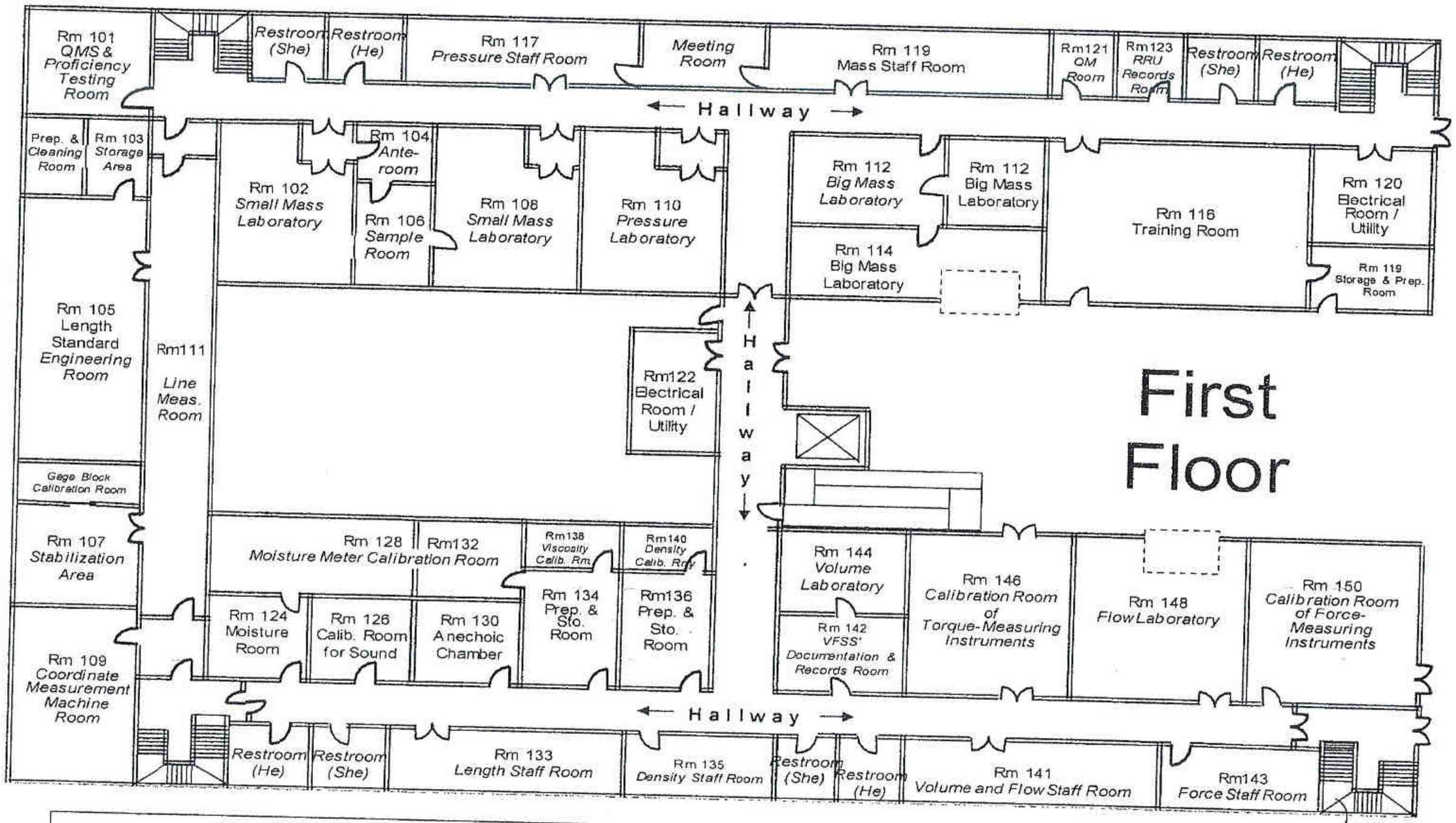

Approval is evidenced by a signature in all pages.	Prepared by: MISalazar Date: 2020-01-10	Approved by: MMRuiz Date:

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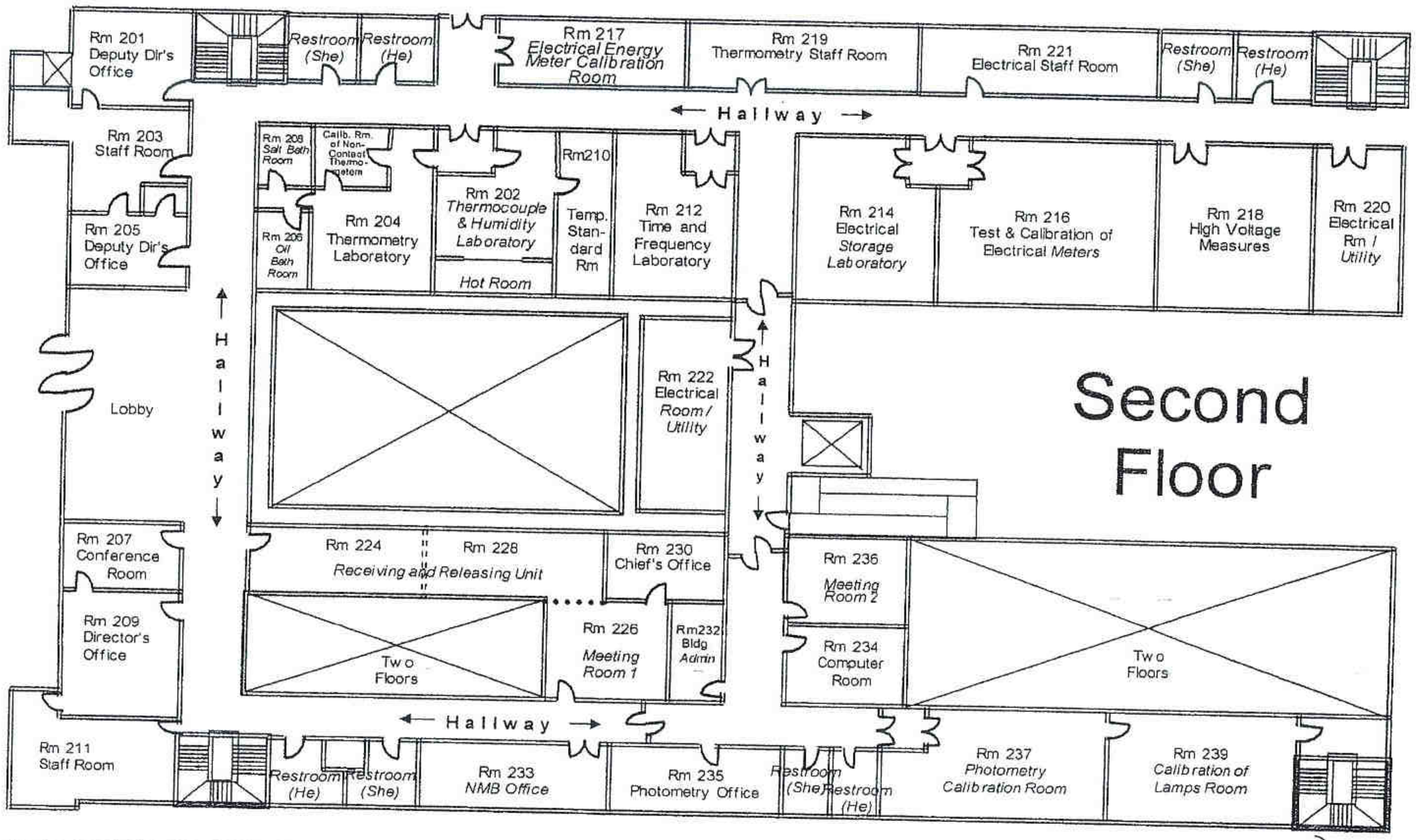

Approval is evidenced by a signature in all pages.	Prepared by: MISalazar Date: 2020-01-10	Approved by: MMRuiz Date:

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