Luminus Devices, Inc
Luminus Testing Laboratory
Quality Management Systems Manual

ISO/IEC 17025
NVLAP, NIST HANDBOOKS 150,150-1

1.0 PURPOSE

Luminus Devices, Inc. has set a requirement that the laboratory which forms part of its larger organization can offer services and operate to a quality management system that is compliant with NIST HB 150 and NIST HB 150-1. These handbooks incorporate the newest releases of ISO/IEC 17025 Standards.

The Luminus Testing Laboratory Quality Manual is the procedure by which Luminus Devices operates a laboratory quality management system, which is competent, and capable of performing specific tests as part of the National Voluntary Laboratory Accreditation Program (NVLAP).

The Laboratory Quality Manual will be the basis by which accreditation bodies recognize the quality management system, competence of testing and calibration methodologies by which to form the basis for their accreditation.

2.0 SCOPE

This Quality Manual applies to our laboratory facility at the following location:

Luminus Testing Laboratory
1100 Technology Park Drive
Billerica, Mass, 01821

Responsible for;

2.1 Testing performed using the IES Approved Method for Measuring Lumen Maintenance of LED Light Sources, IES LM-80.

The Laboratory Quality Manual encompasses requirements of NIST HB 150, NIST HB 150-1 the ISO /IEC 17025 Standard.

Compliance with regulatory, safety requirements and guidelines of regulatory agencies is incorporated as appropriate with respect to installation of equipment, handling of test samples and conducting tests.

Printed copies of this document are UNCONTROLLED unless they are issued and stamped by document control as specified in QSP-000002, Document and Data Control. Revision should be verified prior to use.

3.0 REFERENCE DOCUMENTS

FRM-001621 Reliability Test Request
FRM-001622 LM80 Test Report Template
LTL-001625 Control of Non-Conforming Tests
LTL-001628 Lab Test Methods
LTL-001787 External Calibration for Reference Test Station
QSP-000002 Document and Data Control
QSP-000003 Control on Nonconforming Product and Test
QSP-000004 Corrective and Preventive Action System
QSP-000005 Internal Audit
QSP-000006 Control of Records
QSP-000007 Control of Measuring and Monitoring of Equipment
QSP-000008 Purchasing
QSP-000011 Training
QSP-000012 Management Responsibilities
QSP-000015 Management Review
QSP-000020 Internal Communication
QSP-000021 Continuous Improvement
SOP-000560 Non-Disclosure Agreement Procedure

4.0 MANAGEMENT REQUIREMENTS

4.1 Organization

4.1.1 Legal Requirements

Luminus Devices, Inc. is legally responsible for the laboratory.

4.1.2 Laboratory Responsibility

It is the policy of Luminus Devices, Inc. to conform to NIST HB 150 and NIST HB 150-1 and to satisfy the needs of the customer, contract requirements, the regulating authorities or organizations providing recognition.

4.1.3 Laboratory Management System

The Laboratory Management System applies to the work carried out in the laboratory's permanent facilities located as follows:

1100 Technology Park,
Billerica, Mass. 01832.

4.1.4 Conflict of Interest Resolution

The laboratory is a part of Luminus Devices, Inc., and has a well-defined and documented organizational structure in order to identify potential conflicts of interest and prevent an involvement or influence on the testing activities of the laboratory.

Luminus Devices Inc. understands the importance of maintaining impartiality of the laboratory, and it and its personnel are free from undue commercial, financial and other pressures, which might influence their technical judgment.

It is the policy of Luminus Devices Inc. that the laboratory shall not engage in any activity that may endanger its independence of judgment and integrity in relation to its testing activities.

4.1.5 Management System Responsibilities and Requirements

a) The Luminus Testing Laboratory Manager, irrespective of other responsibilities, has the authority and resources needed to carry out his/her duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures;

b) Through organizational structure and policy, the Laboratory ensures that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

c) The Laboratory ensures the protection of its customers' confidential information and proprietary, including procedures for protection the electronic storage and transmission results as defined in rights with the use of the SOP-00560, Non-Disclosure Agreement Procedure and QSP-000002, Document and Data Control ;

d) The Laboratory policy is to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity as defined in LTL-001628 Lab Test Methods;

e) The Vice President of Engineering, in conjunction with the Laboratory Manager and supported by the President and CEO of Luminus Devices, Inc defines the management structure of the Luminus Testing Laboratory, it's place in the parent organization, and the relationship between quality management, technical operations and support service.

f) The Laboratory Manager specifies the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;

g) The Laboratory Manager, who is familiar with methods, procedures and purpose of each test and with the assessment of the test results, provides supervision of testing by persons who staff or utilize the Laboratory to conduct tests and measurements within the scope of this standard;

h) The Vice President of Engineering has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;

i) The Laboratory Manager, acting as Laboratory Quality Manager, irrespective of other duties and responsibilities, has the responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times. The Laboratory Manager has direct access to the highest level of management at which decisions are made on laboratory policy or resources;

j) The Quality Manager of Luminus Devices, Inc. is the deputy for the Laboratory Quality Manager. The Vice President of Engineering of Luminus Devices, Inc. is the deputy for the Laboratory Manager.

k) The laboratory by the visibility of the quality policy ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

4.1.6 Executive Management TEAM (EMT) Responsibility

The Executive Management Team shall ensure that appropriate communication processes are established within the laboratory and the rest of the larger organization that is Luminus Devices, Inc and that communication takes place regarding the effectiveness of the

management system within the Management Review Process as described in QSP-000020, Communication.

4.2 MANAGEMENT SYSTEM

4.2.1 System Documentation Requirements

The laboratory has established, implemented and maintains a Laboratory Management System appropriate to the scope of its activities. The Laboratory Management System documents its policies, systems, programs, procedures and work instructions to the extent necessary to assure the quality of the test results. System documentation is communicated to, understood by, available to, and implemented by the appropriate personnel.

4.2.2 Quality Policy Statement

The Laboratory's Management System policies related to quality, including a quality policy statement, are defined as follows;

This Quality Policy is issued under the authority of the Luminus Testing Laboratory Manager.

Our commitment is to provide the highest level of testing services in compliance with the governing standards of this industry and ISO/IEC 17025 and demonstrate compliance by third party accreditation through NVLAP, client audits, internal audits, management reviews and an effective corrective action system.

It is laboratory management's commitment to maintain good laboratory practices and good professional practice of our testing services to our clients.

It is the policy of this laboratory that test and services shall always be carried out in accordance with stated standardized methods and/or our client's requirements.

It is a requirement that all staff concerned with test and calibration activities within the laboratory familiarizes themselves with the quality documentation and implement these policies and procedures.

4.2.3 Management Commitment

Executive Management Team (EMT) provides evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness through the QSP-000015, Management Review and QSP-000012, Management System Responsibilities.

4.2.4 Customer Satisfaction

Executive Management Team communicates to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements through QSP-000020, Communication Procedure, and through analysis of metrics for laboratory.

4.2.5 Quality Manual

This Laboratory Quality Manual makes reference to the supporting procedures including technical procedures. It outlines the structure of the documentation used in the management system. It contains references to the Quality Management Procedures that describe the processes required to implement our quality management system.

The procedures, in turn, make reference to related procedures, work instructions and forms necessary to describe the sequence and interactive nature of the processes to ensure conformity to customer specifications and requirements. The procedures also describe how process activities are controlled.

4.2.6 Responsibility for Ensuring Compliance

The Laboratory Manager has responsibility for technical management within the laboratory quality system.

The Laboratory Manager has responsibility of the Quality Manager within the laboratory quality system.

These responsibilities are included in the job descriptions for these functions, and include ensuring compliance with this standard, ISO/IEC17025 and NIST HB-150.

For detail on responsibilities see section 5.2.4 herein

4.2.7 Responsibility for System Integrity

The Laboratory Quality Manager has responsibility to ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented. All changes to the management system are generated in accordance with QSP-000002, Document and Data Control.

4.3 DOCUMENT CONTROL

4.3.1 General

The laboratory procedures are maintained in accordance with QSP-000002, Document and Data Control to control all documents that form part of its management system, internally generated or from external sources, including regulations, standards, other normative documents, test and/or calibration methods, drawings, software, specifications, instructions and manuals.

The control of data related to testing is covered in section 5.4.7 of this document. The control of records is covered in section 4.13 of this document

4.3.2 Document Approval and Issue

4.3.2.1 Document Approval and Revision Status

All documents issued to personnel in the laboratory as part of the management system are reviewed and approved for use by authorized personnel prior to issue. A master list identifying the current revision status and distribution of documents in the management system is established and readily available on the company intranet to preclude the use of invalid and/or obsolete documents.

Location: *Intranet\Quality\Documentation\Document Masterlist*

4.3.2.2 The procedure adopted ensures that:

a) Authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;

b) Documents are reviewed as needed and revised to ensure continuing suitability and compliance with applicable requirements;

c) Invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

d) Obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

4.3.2.3 Identification of Documents

All management system documents are uniquely identified as specified in QSP-000002, Document and Data Control. Such identification may include but not limited to a unique document number or document type, the date of issue, revision identification, page numbering, and the issuing authority (ies).

4.3.3 Document Changes

4.3.3.1 Review and Approval of Document Changes

Changes to documents are reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel have access to pertinent background information upon which to base their review and approval.

4.3.3.2 Identification of Alterations in Documents and Attachments

QSP-000002, Document and Data Control describes how alterations are identified.

4.3.3.3 Hand Amendment of Documents

The laboratory document control system does not allow for the hand amendment of documents.

4.3.3.4 Control of Electronic Documents

QSP-000002, Document and Data Control describes how changes in documents maintained in computerized systems are made and controlled.

4.4 REVIEW OF REQUEST, TENDERS AND CONTRACTS

4.4.1 Procedure for Review of Requests, Tenders and Contracts

The operation of the laboratory is suited to respond to requests since all testing and measurement is in response to requirements of internal customers. External Tenders and Contracts are not applicable. The laboratory uses FRM-001621, Reliability Test Request and LTL-001628, Lab Test Methods to document and review requests. The policies and procedures for these reviews ensure that;

a) The requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);

b) The laboratory has the capability and resources to meet the requirements

c) The appropriate test method is selected and is capable of meeting the customers' requirements (see 5.4.2)

Any differences between the submitter of the request and the laboratory shall be resolved before any work commences. Each request shall be acceptable to both the laboratory and the customer.

4.4.2 Maintenance of Records

Records of reviews, including any significant changes, are maintained in accordance with QSP-000006, Control of Records.

Records are also maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the request.

In the case of review of routine and other simple tasks, the date and identification (e.g. the initials) of the person in the laboratory responsible for carrying out the request are considered adequate.

For repetitive routine tasks, the review needs be made only at the initial enquiry stage or on granting of the request for on-going routine work performed under a general agreement with the customer, provided that the customer's requirements remain unchanged, such as might be the case for requests for production photometry. For new, complex or advanced testing tasks, a more comprehensive record is maintained.

4.4.3 Review of Subcontracted Work

The laboratory does not currently subcontract work. In the case that the laboratory does contract work because of unforeseen reasons, the work will be reviewed.

4.4.4 Communication of Deviation from Request

The customer will be informed, in advance, of any deviation from the request.

4.4.5 Request Amendment

If the request needs to be amended after work has commenced, the same request review process is repeated and any amendments communicated to all affected personnel.

4.5 SUBCONTRACTING OF TESTS

4.5.1 Subcontractor Competency

The laboratory does not currently subcontract work. In the case that the laboratory does contract work because of unforeseen reasons, the work will be placed with an accredited LM-80 test subcontractor for the work in question. .

4.5.2 Notification to Customer of Subcontracted Work

The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.

4.5.3 Laboratory Responsibility for Subcontracted Work

The laboratory is responsible for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.

4.5.4 Register of Subcontractors

A list of approved subcontractors will reside on the Luminus approved supplier list following QSP-000008, Purchasing Procedure. Should circumstances in the future require the use of such subcontractors for

tests and/or calibrations, record of ISO/IEC 17025:2005 accreditation shall be required..

4.6 PURCHASING SERVICES AND SUPPLIES

4.6.1 Selection and Purchasing of Services and Supplies

The laboratory must follow corporate policies and procedure(s) as outlined in QSP-000008, Purchasing for the selection and purchasing of services and supplies it uses that affect the quality of the tests. Procedures exist for the purchase, reception and storage of laboratory consumable materials relevant for tests and calibrations.

4.6.2 Incoming Inspection

QSP-000008, Purchasing procedures ensure that purchased supplies and consumable materials that affect the quality of tests are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.

4.6.3 Purchasing Information

Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

4.6.4 Supplier Evaluation

The laboratory evaluates suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and maintains records of these evaluations and list those approved as outlined in QSP-000008, Purchasing.

4.7 SERVICE OF THE CUSTOMER

4.7.1 Customer Communication

The laboratory is part of the parent organization and cooperates with customers in requests for testing and related work. At all times the laboratory ensures confidentiality to customers. The laboratory

communicates any delays or major deviations in the performance of the tests as needed.

4.7.2 Customer Feedback

The laboratory shall seek feedback, both positive and negative from its customers. The feedback shall be used and analyzed to improve the management system, testing and calibration activities and customer service. Examples of such feedback include a review of test reports with customers or metrics such as test proficiency and maintenance of accreditation developed for the Management Review system. The laboratory seeks feedback as defined in LTL-001628 Lab Test Methods.

4.8 COMPLAINTS

The Laboratory shall maintain a log of all complaints received from customers or other parties as defined in LTL-001628, Lab Test Methods. Records shall be maintained of all concerns/complaints and of the investigations and corrective actions taken by the laboratory (see also 4.11) and controlled as specified in QSP-000006, Control of Records.

4.9 CONTROL OF NONCONFORMING TESTING and or WORK

4.9.1 Nonconforming Tests

The laboratory has procedure QSP-000003, Control of Non-Conforming Product/Test that shall be implemented when any aspect of laboratory testing work, or results of this work, do not conform to procedures or the agreed requirements of the customer. The policy and procedures shall ensure that:

a) The responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified;

b) An evaluation of the significance of the nonconforming work is made;

c) Correction is taken immediately, together with any decision about the acceptability of the nonconforming work;

d) Where necessary, the customer is notified.

e) The responsibility for authorizing the resumption of work is defined.

4.9.2 Recurring Nonconforming Work

Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 shall be promptly followed.

4.10 IMPROVEMENT

The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions. Improvement is a significant topic in management review. See QSP-000021, Continuous Improvement Procedure

4.11 CORRECTIVE ACTION

4.11.1 General

The appropriate authority for implementing corrective action when nonconforming work or departures from the policies and procedures in the Laboratory Management System or technical operations have been identified is outlined in QSP-000004, Corrective and Preventive Action System.

4.11.2 Cause Analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem. Cause analysis is applied to customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.

4.11.3 Selection and implementation of Corrective Action

Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence. Corrective actions shall be to a degree appropriate to the magnitude and risk of the problem. The laboratory shall document and implement any required changes resulting from corrective action investigations.

4.11.4 Monitoring of Corrective Action

The laboratory monitors the results to insure that the corrective actions taken is effective before closure in accordance with QSP-000004, Corrective and Preventive Action System. Results or the corrective action process are reviewed as part of the QSP-000015, Management Review

4.11.5 Additional Audits

Where the identification of nonconformities or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with accredited test methods, the laboratory will ensure that the appropriate areas of activity are audited in accordance with QSP-000005, Internal Audit.

4.12 PREVENTIVE ACTION

4.12.1 Identification of Needed Improvements

When improvement opportunities are identified as a result of nonconformities, either technical or concerning the management system and preventive action is required, action plans are developed, implemented and monitored in accordance with QSP-000004, Corrective and Preventive Action System where applicable to reduce the likelihood of the re-occurrence of such nonconformities and to take advantage of the opportunities for improvement.

4.12.2 Preventive Action Procedure

QSP-000004, Corrective and Preventive Action System include the initialization of such actions and the application of controls to ensure that they are effective.

4.13 CONTROL OF RECORDS

4.13.1 General

4.13.1.1 Procedures for Quality Records

QSP-000006, Control of Records establishes procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records.

4.13.1.2 Retention and Retrieval of Records

Test records are to be legible and are stored and retained in such a way that it is readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention time is specified in QSP-000006.

4.13.1.3 All records are held secure and in confidence.

4.13.1.4 Electronic Records

Measurements are electronically recorded with some manual input. The laboratory in conjunction with IT, stores, protects and back-ups records that are stored electronically and prevents unauthorized access or amendment of these records. Printed copies of results are provided from the electronic record and are not controlled.

4.13.2 Technical Records

4.13.2.1 Record Retention

The laboratory retains 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 for a defined period of time depending on the test. The records for each contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test to be repeated under conditions as close as possible to the original. The records include the identity of personnel responsible for the performance of each test and checking of results. Records are maintained as specified in QSP-000006, Control of Records

4.13.2.2 Recording of Observations, Data and Calculations

Observations, data and calculations are recorded at the time they are made and identifiable to the specific test.

4.13.2.3 Corrections and Preservation of Original Data

It is the laboratory policy that when mistakes occur in records, each mistake is crossed out, not erased, not made illegible and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data. (Sec. 5.2)

4.14 INTERNAL AUDITS

4.14.1 Frequency, Content and Responsibility for Internal Audits

The internal audit program described in QSP-000005 addresses all elements of the management system, including the testing and/or calibration activities. It is the responsibility of the audit administrator to plan and organize audits as required by the schedule and requested by management. Such audits are carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

The cycle for internal auditing shall be completed once per year.

4.14.2 Corrective Action for Internal Audits

When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify interested parties or customers in writing if investigations show that the laboratory results may have been affected as described in QSP-000004, Corrective and Preventive Action System.

4.14.3 Documentation of Audits

The area of activity audited, the audit findings and corrective actions that arise from them is recorded per QSP-000005, Internal Audit System.

4.14.4 Verification of Internal Corrective Action

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken prior to the corrective action being closed.

4.15 MANAGEMENT REVIEW

4.15.1 Review of Laboratory Management System

The Executive Management Team conducts a review of the laboratory's management system and testing activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements as defined in QSP-000015, Management Review

The review takes account of:

- The suitability of policies and procedures;
- Reports from managerial and supervisory personnel;
- The outcome of recent internal audits;
- Corrective and preventive actions;
- Assessments by external bodies;
- The results of inter-laboratory comparisons or proficiency tests;
- Changes in the volume and type of the work;
- Customer feedback;
- Complaints;
- Recommendations for improvement;
- Review of work instructions for testing, safety, and equipment operation.
- Other relevant factors, such as quality control activities, resources and staff training.

4.15.2 Corrective and Preventive Actions from Management Review

Findings from management reviews and the actions that arise from them are recorded. The management ensures that those actions are carried out within an appropriate and agreed timescale

5.0 TECHNICAL REQUIREMENTS

5.1 GENERAL

5.1.1 Correctness and Reliability of Tests

Correctness and reliability of the tests and/or calibrations performed by the laboratory are affected by many factors. These factors may include but are not limited to:

- Human factors (5.2):
- Accommodation and environmental condition (5.3):
- Test and calibration methods and method of validation (5.4):
- Equipment (5.5):
- Measurement Traceability (5.6):
- Sampling (5.7): Not Applicable to Luminus Testing Laboratory
- The handling of test and calibration items (5.8)

5.1.2 Accounting for Factors that contribute to Total Uncertainty

The test and calibration methods used by the Laboratory take account of these factors in the development of procedures, training and qualification of personnel and in the selection and calibration of the equipment used.

5.2 PERSONNEL

5.2.1 Training

To ensure the competence of personnel who operate laboratory equipment, perform tests and/or calibrations, evaluate results, and sign test reports, personnel will be trained and certified for each test in accordance with the guidelines set forth in QSP-000011, Training. This procedure shall be applicable for staff and new hires. Appropriate supervision shall be provided by the Lab Manager or his designate during training.

5.2.2 Identification

Laboratory management in conjunction with Human Resources (HR) formulates the goals with respect to the education, training and skills of the laboratory personnel. Procedure QSP-000011, Training outlines the policy and procedures for identifying training needs and providing training of personnel, including the effectiveness of the training activities, which shall monitored and evaluated and certified by test.

5.2.3 Contract Employees

The laboratory employs personnel who are employees of Luminus Devices, Inc. When needed, the laboratory may use contracted employees Contract employees receive the same training as employees. The Laboratory Manager supervises employees and ensures they are competent and that they work in accordance with the laboratory's management system.

5.2.4 Job Descriptions

HR maintains current job descriptions for laboratory managerial, technical and key support personnel as described in QSP-000011, Training Procedure.

Laboratory Managers responsibilities include but not limited to:

- Manage all aspects of the test laboratory including budgeting, supervision of engineers/technicians and reporting to senior management.
- Responsible for development, documentation and maintenance of the laboratory quality system and test methods in compliance with ISO17025 and NIST HB-150.
- Develop and/or oversight of test methods for LEDs that comply with industry standard practices such as IES LM-80, Mil STD and JEDEC standards.
- Supervise and/or perform LED testing, test planning and reporting.
- Meet with customers to define test requirements.
- Analyze and report results of parametric verification, LM-80 and other reliability tests on LEDs.
- Conduct failure mode analysis and problem solving to identify test or equipment issues.

- Identify and Recommend test equpment.
- Oversite of the calibration, qualification and maintenance of test.

Laboratory Quality Manager:

The Luminus CEO has appointed the Laboratory Quality Manager as the management representative who, irrespective of other responsibilities, has the responsibility and authority for:

a) ensuring that processes of the quality management system are established, implemented and maintained;
b) reporting to top management on the performance of the quality management system, including needs for improvement;
c) promoting awareness of customer requirements throughout Luminus Testing Laboratory;
d) liaison with external parties on matters relating to the quality management system;
e) organizational freedom to resolve quality matters;

5.2.5 Responsibility and Authorization

Laboratory management authorizes specific personnel to perform test and/or calibration procedures, to issue test reports, to give opinions and interpretations and to operate particular types of equipment. HR maintains records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel. This information is readily available and includes the date on which authorization and/or competence is confirmed.

5.3 TESTING FACILITIES ACCOMODATION AND ENVIRONMENTAL CONDITIONS

5.3.1 Maintenance of Environment

Laboratory facilities have little or no influence in testing as the test systems have independent temperature controls and measurements to facilitate correct performance of the tests. The laboratory environmental conditions are maintained so as to not adversely affect the lifetime of the test and measurement equipment as well as to allow for a safe and comfortable work environment.

5.3.2 Monitor and Control of Environment

The laboratory shall monitor and control environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention is paid to minimize dust in photometry spheres, electromagnetic disturbances, UV radiation, electrical supply stability, humidity, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations are stopped when the environmental conditions jeopardize the results of the tests and/or calibrations. LTL-001628, Lab Test Methods outlines the recording of environmental conditions.

5.3.3 Separation of Incompatible Activities

There are effective separations between neighboring areas in which there are incompatible activities.

5.3.4 Control of Laboratory Access

Access to the laboratory and use of instrumentation affecting the quality of the tests are controlled.

5.3.5 Housekeeping

Measures are taken to ensure good housekeeping in the laboratory.

5.4 TEST AND CALIBRATION METHODS AND METHOD VALIDATION

5.4.1 General

The laboratory uses appropriate methods and procedures for tests within its scope. These include handling, transport, storage and preparation of items to be tested, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test data. The laboratory maintains instructions on the safe and appropriate use and operation of all relevant equipment, and on the handling and preparation of items for testing. All instructions, standards, manuals and reference data relevant to the work of the laboratory are kept up to date and are available to personnel. Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

5.4.2 Selection of Methods

The laboratory uses the IES LM-80 test method that is incorporated into the Luminus Test Laboratory test methods. When necessary, the standard is supplemented with additional details to ensure consistent application.

5.4.3 Laboratory-developed Methods

Test methods developed by the laboratory are assigned to qualified personnel equipped with adequate resources.

5.4.4 Non-standard Methods

When it is necessary to use methods not covered by standard methods, these are subject to agreement with the customer and includes a clear specification of the requirements and the purpose of the test. The method developed is validated before use. Refer to FRM-001621, Reliability Test Request.

5.4.5 Validation of Methods

5.4.5.1 Validation is confirmed by examination of the data produced and that the requirements were fulfilled.

5.4.5.2 Laboratory management validates that non-standard laboratory-designed or developed methods, standard methods used outside their intended scope, amplifications and modifications of standard methods, are fit for the intended use.

5.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, are relevant to the customer.

5.4.6 Estimation of Uncertainty of Measurement

Reported measurement results are accompanied by quantitative statements of uncertainty when requested. The contributing factors and estimating uncertainty of measurement are outlined in LTL-001628, Lab Test Methods.

5.4.7 Control of Data

5.4.7.1 Calculations and data transfers are subject to appropriate checks in a systematic manner. All test software is controlled as defined in LTL-001628, Lab Test Methods.

5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory ensures that:

a) Computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use.

b) Procedure LTL-001628, Lab Test Methods and QSP-000006, Control of Records are used for protecting the data including data integrity and confidentiality, entry or collection, data storage, data transmission and data processing.

c) Computers and equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test data.

5.5 EQUIPMENT

5.5.1 Equipment Availability

The laboratory shall be furnished with instruments and related equipment required for the correct performance of the tests including, preparation of test and/or calibration items, processing and analysis of test data. In those cases where the laboratory needs to use equipment outside its permanent control, it ensures that the requirements of this manual are met.

5.5.2 Accuracy Requirements

Equipment and its software used for testing shall be capable of achieving the accuracy required and complies with specifications relevant to the tests concerned. Calibration and maintenance programs are established for the instruments where these properties have a significant effect on the results. Before being placed into service, equipment is calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. (see 5.6).

5.5.3 Operation Of Equipment

Equipment shall be operated by authorized certified personnel. Up-to-date instructions on the use and maintenance of equipment, including any relevant manuals provided by the manufacturer of the equipment, are readily available for use by the laboratory personnel.

5.5.4 Identification of Equipment

Each item of equipment and its software used for testing and significant to the result is uniquely identified.

5.5.5 Records of Equipment

Equipment record lists and calibration schedules are defined controlled by QSP-000007, Control of Measuring and Monitoring Equipment.

5.5.6 Maintaining and Handling of Equipment

Instruction LTL-001628, Lab Test Methods describes the safe handling, transport, storage, use and planned maintenance of measuring equipment and aging racks to ensure proper functioning and to prevent contamination, deterioration and safety.

5.5.7 Containment of Equipment

Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, is taken out of service. It is isolated by physical removal from the laboratory, boxed and identified, until it has been repaired and shown by calibration or test to perform correctly or otherwise de-commisioned. Work instructions define the responsibility for identification and communication of non-compliant equipment requiring maintenance, calibration or repair. The laboratory examines the effect of the defect or departure from specified limits on previous tests and/or calibrations and institutes the procedure LTL-001625, Control of Nonconforming Test.

5.5.8 Calibration of Equipment

All equipment under the control of the laboratory and requiring calibration is labeled, to indicate the status of calibration, the date when last calibrated and the date or expiration criteria when recalibration is due. Reference QSP-000007, Control of Measuring and Monitoring Equipment. .

5.5.9 Inspection of Equipment

In the event that equipment goes outside the direct control of the laboratory, the laboratory ensures that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

5.5.10 Calibration Status

Intermediate checks are performed as described in LTL-001628, Lab Test Methods Procedure.

5.5.11 Correction Factors

Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g. in computer software) are correctly updated. Currently no correction factors are used.

5.5.12 Prevention of Adjustment

Where possible, test and calibration equipment, including both hardware and software, are safeguarded from adjustments which could invalidate the test results as specified in QSP-000007, control of Measuring and Monitoring Equipment.

5.6 MEASUREMENT TRACEABILITY

5.6.1 General

All equipment used for tests, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test or calibration are to be calibrated before being put into service. Reference QSP-000007, Control of Measuring and Monitoring of Equipment.

5.6.2 Specific Requirements

5.6.2.1 Calibration

We are not a calibration laboratory. The requirements of 5.6.2.1 do not apply.

5.6.2.2 Testing

5.6.2.2.1 The laboratory shall ensure that the equipment used can meet the specifications provided in the test method.

5.6.2.2.2 Where traceability of measurements to SI units is not possible and/or irrelevant, the same requirements for traceability to certified reference, agreed methods and/or consensus standards, are required. (see 5.6.2.1.2).

5.6.3 Reference standards and reference materials

5.6.3.1 Reference standards

The laboratory uses procedure LTL-001787 External Calibration for Reference Test Station for the testing of reference standards.

5.6.3.2 Reference materials

The lab does not use reference materials.

5.6.3.3 Intermediate checks

LTL-001787 is used to define the intermediate checks.

5.6.3.4 Transport and storage

LTL-001787 is used to define the storage and transportation of reference standards.

5.7 SAMPLING

Our laboratory does not do sampling. We measure all samples supplied by the customer.

5.8 HANDLING OF TEST AND CALIBRATION ITEMS

5.8.1 Handling of Test Item

LTL-001628, Lab Test Methods Procedure outlines procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test items, including all provisions necessary to protect the integrity of the test item, and to protect the interests of the laboratory and the customer.

5.8.2 Identification of Test Item

FRM-001621, Reliability Test Request Form and Procedure LTL-001628, Lab Test Methods outlines the system for identifying test items. The identification is retained throughout the life of the item in the laboratory. The system is designed and implemented so as to ensure that items cannot be confused physically or when referred to in records or other documents.

5.8.3 Abnormal Test Items

Upon receipt of the test item, abnormalities or departures from normal or specified conditions, as described in the test method, are recorded. Reference LTL-001628, Lab Test Methods when there is doubt as to the suitability of an item for test or when an item does not conform to the description provided, or the test required is not specified in sufficient detail. The laboratory shall consult the customer for further instructions before proceeding and shall record the discussion.

5.8.4 Preservation of Test Items

The laboratory has appropriate facilities for avoiding deterioration, loss or damage to the test item(s) during storage, handling and preparation. Handling instructions provided with the item shall be followed. When items have to be stored or conditioned under specified environmental conditions, these conditions are maintained and monitored.

5.9 ASSURING QUALITY OF TEST AND CALIBRATION RESULTS

5.9.1 Validation of Testing Proficiency

The laboratory uses LTL-001628, Lab Test Methods to assure the validity of the tests and calibrations taken. Trends from analysis of tests and calibrations are used to monitor the validity of the results.

- The lab will participate in inter-laboratory proficiency testing.

5.9.2 Analysis of Calibration Data

Quality control data shall be analyzed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported. Nonconforming Tests are handled in accordance with QSP-000003, Control of Nonconforming Product and Test.

5.10 REPORTING THE RESULTS

5.10.1 General

The results of each test or series of tests are reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test methods. The results are reported in a standardized form/format test report and include all the information requested by the customer. Upon completion of the review process, it

is the responsibility of the Test and Measurement Laboratory Manager to ensure the electronic version of the report is tamper-proof by generating a “read-only” formatted copy for distribution.

5.10.2 Test Report Structure

The test report structure is shown by FRM-001622, LM80 Test Report Template. The form template contains the following information as a minimum.

a. Title
b. The name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory.
c. Unique identification of the test report and on each page an identification in order to ensure that the page is recognized as a part of the test report and a clear identification of the end of the test report.
d. The name of the originator of the test request (or customer & address).
e. Identification of the method used
f. A description of, the condition of, and unambiguous identification of the item(s) tested.
g. The date of receipt of the test item(s)
h. The test or calibration results with, where appropriate, the units of measurement.
i. The name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test.

5.10.3 Test Report

5.10.3.1 In addition to the requirements listed in 5.10.2, test reports may include the following:

a) Deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions.

b) Where relevant, a statement of compliance/non-compliance with requirements and/or specifications.

c) When requested, a statement on the estimated uncertainty of measurement will be given.

d) When requested, opinions and interpretations (see 5.10.5) will be given.

e) Additional information which may be required by the customer

5.10.4 Calibration Certificate

We are not a calibration laboratory.

5.10.5 Opinions and Interpretations

When opinions or interpretations are requested by the customer, the laboratory documents the basis upon which the opinions and interpretations have been made and are clearly marked as such in the test report.

5.10.6 Testing results obtained from subcontractors

Subcontractors are not used.

5.10.7 Electronic transmission of results

In the case of transmission of test results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this document are to be met (see also 5.4.7). PDF format should be used wherever possible to prevent edits by the receiver.

5.10.8 Format of report certificates

FRM-001622, LM80 Test Report Template is used for the report format for LM80 testing.

5.10.9 Amendments to test reports

Material amendments to a test report after issue are re-issued as a new test report. The new test report shall be uniquely identified and contain a reference to the original that it replaces.

ANNEX A

Referencing NVLAP accreditation

It is the policy of the Luminus Testing Laboratory of Luminus Devices Incorporated (hereafter referred to as "the Laboratory") to control the use of the term NVLAP and the NVLAP logo as described explicitly in Annex A of the NIST Handbook 150 (latest edition). The Laboratory Manager, acting in the capacity of Quality Manager for the Laboratory Management System, is responsible for control and authorized usage of the term NVLAP and the NVLAP logo.

- Both the term and symbol will not be used in a manner that brings NVLAP into disrepute or misrepresents the Laboratory's scope of accreditation or accredited status.
- When the term NVLAP is used to reference the Laboratory's accredited status, it shall be accompanied by the NVLAP Lab code.
- When the NVLAP logo is used to reference the Laboratory's accredited status, it shall be accompanied by the NVLAP Lab Code in an approved caption.
- When used, the form of the NVLAP logo will not be combined with any other logo, symbol or graphic.
- The name of the Laboratory Manager, an Approved Signatory, will appear on any test report that bears the NVLAP symbol or references NVLAP accreditation. If a computer-generated report does not bear the handwritten signature of an Approved Signatory, it will bear the printed name of an Approved Signatory with the results and cannot be generated and distributed without the review and consent of that Approved Signatory.
- A test report that contains both data covered by our accreditation and data not covered by our accreditation clearly identified the data not covered by the accreditation by displaying the following statement at the beginning of the report; "This report covers data not covered by the NVLAP accreditation."
- Each test report bearing the term or symbol will include a statement that the recipient of that report must not use the report to claim certification, approval or endorsement by NVLAP, NIST or any agency of the Federal Government.
- While the Laboratory does not currently, should procedures change and contracts or proposals are used, the term and/or symbol will be accompanied by a description of the Laboratory's scope of accreditation and current accreditation status. The Laboratory recognizes and will use the correct term when referencing our NVLAP accreditation or conformance to ISO 17025 requirements; accredited.

ANNEX B

Implementation of traceability policy

B.1 Policy Overview

It is the policy of Laboratory that the results of all calibrations and the results of all calibrations required to support accredited tests shall be traceable to national and international standards of measurement

Calibration certificates received by NVLAP-accredited testing and calibration laboratories with new or recalibrated equipment shall meet the requirements of ISO/IEC 17025. The certificates include the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof.

B.2 General

a) The laboratory uses appropriate LED standards with traceability directly to NIST. Documentation is filed appropriately and maintained.

b) For calibration of its test equipment, the laboratory currently uses only ISO/IEC 17025 accredited calibration service providers.

B3 Demonstration of traceability

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B3.1 The laboratory submits LED standards to NIST per LT-001787 External Calibration for Reference Test Station Procedure.

B3.2 NA for the laboratory. We are not a calibration laboratory.

B3.3 When the laboratory does not demonstrate traceability per B3.1 then the laboratory shall use accredited calibration services wherever available.

B3.4 NA for the laboratory

B3.5 NA for the laboratory

Table 1. Documentation Matrix

Document Number	Title	Documents shared between Luminus Test Lab and Luminus Devics, Inc.	Applicable section herein
FRM-001621	Reliability Test Request		4.4, 5.4.4, 5.8.2
FRM-001622	LM80 Test Report Template		5.10.2, 5.10.8
LTL-001625	Control of Non-Conforming Tests		4.9,5.5.7
LTL-001628	Lab Test Methods		4.1.5, 4.4, 4.7.4, 4.8,5.3, 5.4, 5.5, 5.5.10, 5.8, ,5.8.2, 5.8.3, 5.9
LTL-001787	External Calibration for Reference Test Station		5.6.3
QSP-000002	Document and Data Control	√	4.1.5c, 4.2.7, 4.3.1, 4.3.2
QSP-000003	Nonconforming Product and Test	√	4.9, 5.5.7
QSP-000004	Corrective and Preventive Action (CAPA) System	√	4.11, 4.12
QSP-000005	Internal Auditing System	√	4.14
QSP-000006	Control of Records	√	4.4.2, 4.8, 4.13, 5.4
QSP-000007	Control of Measuring and Monitoring of Equipment	√	4.9, 5.5.5, 5.5.8, 5.5.12, 5.6.1
QSP-000008	Purchasing	√	4.6
QSP-000011	Training	√	5.2
QSP-000012	Management Responsibilities	√	4.2.3
QSP-000015	Management Review	√	4.15
QSP-000020	Communication	√	4.1.6,4.2.4
QSP-000021	Continuous Improvement	√	4.10
SOP-000560	Non-Disclosure Agreement Procedure	√	4.1.5c