



SOUTHERN CALIFORNIA
EDISON

An *EDISON INTERNATIONAL* Company

METROLOGY LABORATORY

QUALITY MANUAL

REVISION 12

Approved _____ Signature on File _____ Date 12/30/2008
Technical Services Manager

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Manager
of
Shop Services & Instrumentation Division

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QUALITY POLICY

Quality is meeting our customer's requirements. Our practice will be to understand our customer's requirements, needs and expectations and to satisfy them on every job.

Our goal is to continuously measure and improve the processes that contribute to our effectiveness, efficiency and productivity in order to deliver quality products and services at competitive prices. Ultimately the quality of our services is the responsibility of each employee.

It is the policy of Shop Services & Instrumentation Division (SSID) to involve the work force in all aspects of issues related to their work activities. We will strive to stimulate creativity, initiative, and sense of responsibility and to provide an environment that fosters a spirit of "**pride in workmanship and teamwork**" among employees. All employees will embrace the SCE vision of Leading the Way in Electricity, and live the corporate values of respect, integrity, excellence, teamwork, and continuous process improvement.

We will provide technical and quality awareness training, approved instructions, proper tools, and the necessary management involvement to allow the work force to produce the level of quality our customers expect and deserve. Management shall ensure that all Metrology Laboratory personnel understand and implement this quality management system and are committed to the requirements defined herein.

Technical Services Manager

Manager of Shop Services and
Instrumentation Division



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STATEMENT OF AUTHORITY

Edison ESI a subsidiary of Southern California Edison, and the Metrology Laboratory recognizes the importance of quality in industry and is committed to continuous improvement in the quality of work controlled under our Quality Management System.

The Metrology Laboratory Quality Management System has been prepared to document the processes that control calibration activities and contractual agreements between the customer and Edison.

This quality management system meets the requirements of ISO/IEC 17025, NIST Handbook 150, 10CFR50 Appendix B, ANSI/NCSL Z540-1-1994, IEEE-498, Regulatory Guide 1.33 as applicable, and MIL-STD 45662A and satisfies the requirements of our accreditation organization(s). By implementing ISO/IEC 17025, the Metrology Laboratory satisfies the requirements of QS 9000 for an acceptable subcontractor.

Contractual arrangements between the customer and the Metrology Laboratory through Edison ESI which specify requirements in addition to those specified by this quality management system, shall be applied providing such requirements do not compromise the quality of our service or this quality management system.

Confidentiality and proprietary rights for customer provided information shall be respected and protected. Metrology Laboratory personnel shall not copy or otherwise reproduce any customer provided confidential or proprietary document. All customer provided confidential or proprietary documents shall be returned to the customer when the scope of work is completed.

The Metrology Laboratory has the capabilities to perform repair and calibration of measuring and test equipment (M&TE) in the following disciplines: Dimensional, Electrical, Mass, Pressure, Temperature and Humidity, Torque, Force, Gas Flow, Time, Frequency and Vibration. The management and administrative sections of this quality management system apply to all Metrology activities. Certain technical requirements apply only to accredited metrology disciplines. When requested, on-site (customer location) calibrations shall be performed in accordance with the requirements contained within the quality management system.

Section 4.0 - Management Requirements

4.1 Organization

4.1.1 Responsibility and Authority

Personnel with defined responsibilities throughout the quality management system have the authority to perform the following within their “Area of Responsibility” (AOR):

- Initiate preventative action.
- Identify and record problems.
- Initiate, recommend or provide solutions.
- Verify implementation of solutions.
- Control further processing of nonconforming conditions until corrected.

The organization is comprised of the Manager of Shop Services & Instrumentation Division (SSID), Technical Services Manager, Metrology Laboratory and Quality Assurance. Purchasing and Warehousing personnel perform support functions, when requested.

The Manager of SSID reports to the Vice President of Southern California Edison Company and is responsible for all aspects of the operation; is authorized to make contractual and binding commitments; develops policy, and is responsible for the growth and development of new business. The Manager of SSID maintains responsibility for the quality management system.

Edison ESI provides sales, marketing and purchase order negotiations to customers external to SSID and the Edison International business units. Edison ESI performs no quality affecting activity in its support of the Metrology Laboratory.

The Technical Services Manager reports to the Manager of SSID and is responsible for the implementation of Metrology Laboratory activities and for the implementation of this quality system. The deputy for the Technical Services Manager is the Metrology Services Manager.

The Metrology Services Manager reports to the Technical Services Manager and is responsible for activities in the Technical Services Processing Area, Metrology Engineering Services and the Metrology Laboratory. The Metrology Services Manager is responsible for continuous process improvement and customer satisfaction and execution of the business plan. The deputy for the Metrology Services Manager is the Metrology Supervisor.

The Metrology Supervisor reports to the Metrology Services Manager and is responsible for the Metrology Laboratory for all aspects of work performed in the laboratory and field calibration and repair of measuring and test equipment (M&TE) performed by Metrology personnel.

The Metrology Supervisor is responsible for the day to day operations in the laboratory to include administrative support service such as calibration procedure maintenance, personnel training, and ensuring the technical capability of the lab is maintained.

The Processing Area Supervisor reports to the Metrology Services Manager and is responsible for the day to day operations and administrative support such as purchase order review, directing receiving and vendor functions. The Processing Area Supervisor shall ensure timely and accurate customer communications in the area of recall and status.

The SONGS Program Manager reports to the Processing Area Supervisor, and is responsible for associated customer requests, procurement activities associated with SONGS, and reporting as outlined in the SONGS agreement with Metrology. The Metrology Supervisor shall perform functions/responsibilities in the absence of the Processing Area Supervisor.

Metrology Team Leaders report to the Metrology Supervisor and are responsible for directing calibration work assignments and priorities, review and approval of calibration documentation and procedures, calibration of M&TE and routine laboratory operations.

Customer Administrative Support personnel report to the Processing Area Supervisor and are responsible for shipping and receiving activities, order entry, contract review, and maintenance of all applicable documents and delivery of equipment to the appropriate calibration laboratory.

The Metrology Technical Specialist (Metrologists) receives direction from the Metrology Team Leader and is responsible for the calibration and repair of M&TE, the preparation, verification review and revision of calibration procedures and the review and correctness of calibration documentation.

The Metrology Engineer reports to the Metrology Supervisor and is responsible for the following duties: calibration failure evaluation, deriving equipment accuracy specifications, procedure / process review and improvement, automation of calibration processes, measurement uncertainty studies, laboratory statistical process controls (SPC), technical proficiency and compliance issues of the quality system, NVLAP accreditation and ISO registration.

The Procedure Coordinator reports to the Metrology Supervisor and is responsible for the generation, revision, and maintenance of all ECI documents.

The Software Controller reports to the Technical Services Manager and is responsible for all software operations within the Metrology Department. The software controller will coordinate Metrology software and LAN operations with the Metrology Supervisor, software management, and hardware management personnel in SSID.

The Health Physics (H.P.) on-site representative administratively reports to the Technical Services Manager. The H.P. Representative administrates the Health Physics Program at SSID, designed to provide radiological health and safety controls for repair and calibration of radioactive equipment. These activities are conducted under the

provisions of Radioactive Materials License 5792-30 issued by the State of California. These activities are controlled outside of the scope of this quality system.

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The Quality Assurance Manager reports to the Manager of SSID and has the responsibility and authority for ensuring that this quality management system is implemented and followed at all times. The Quality Manager has direct access to the highest level of management at which decisions are made on laboratory policy or resources. The Quality Manager is committed to and responsible for ensuring this quality management system is compliant with NIST Handbook 150, ISO/IEC 17025, 10CFR50 Appendix B, ANSI/NCSL Z540-1-1994, IEEE-498, MIL-STD 45662A and Regulatory Guide 1.33. The Quality Manager has appointed the Quality Assurance Lead Auditor as the Deputy Quality Manager. The Deputy Quality Manager shall perform these functions/responsibilities in the absence of the Quality Manager.

Purchasing is responsible for translating Procurement Request (PREQ) requirements into purchase orders. Translation of material service requests requirements and issuance of procurement documents are corporate purchasing functions, controlled by corporate procedures, and are outside the scope of the quality management system. Metrology Laboratory personnel review requests, select approved suppliers, and inspect parts and equipment at receipt to verify compliance to procurement document requirements.

Warehouse personnel provide support services to the Metrology Supervisor, as requested.

In the event that any individual in the organization is absent or otherwise unavailable to perform functions or responsibilities, those functions and responsibilities may be performed by a superior or delegated to a qualified subordinate within the organization. The Metrology Department retains full responsibility for implementation of the quality management system.

Management is responsible for establishing and maintaining communications with Metrology Laboratory personnel regarding the effectiveness of the quality system. Management shall endeavor to ensure personnel are aware of the relevance of their activities and how they contribute to the objectives of the quality system. Additionally, Management is responsible for maintaining the integrity of the quality system as updates and modifications are developed and implemented. In so doing, management will demonstrate its commitment to good professional practices and the quality of repair, testing and calibration activities.

All employees are responsible for the quality of the products and services under their control and for following procedural requirements during all processes they are involved in. All employees have the responsibility and authority to identify quality problems; to initiate and provide solutions to quality problems; to verify implementation; and, to resolve deficiencies that affect quality.

4.1.2 Resources

- .1 The Metrology Supervisor will assign trained personnel to manage, perform and verify activities affecting quality. Personnel assigned these tasks are qualified on the basis of experience and/or training.
- .2 The Technical Services Manager shall ensure that the quality of the work performed is not influenced by any undue internal/external commercial, financial, or other pressures or influence. This is accomplished by establishing fair and reasonable departmental goals and expectations. Efficient work practices, individual accountability and adhering to the quality guidelines ensure that personnel performance eliminates negative influences.
- .3 Job descriptions have been developed for managerial, technical, and key support personnel involved in providing calibration services.
- .4 The Metrology Supervisor shall maintain documented authorization for personnel assigned to perform special calibrations, when applicable.

4.1.3 Management Representative

- .1 The Management Representative has been appointed by the Manager of SSID and Technical Services Manager and is responsible for ensuring this quality system is maintained, understood and implemented at all levels of the organization. The Management Representative is also responsible for reporting on the performance of the Quality Management System during the annual management review.

4.1.4 Quality Policy

- .1 The Quality Policy at the Metrology Laboratory is affirmed in a statement from the Manager of SSID and the Technical Services Manager and is located in the front of this Quality Manual. This policy will be understood, implemented, and maintained by all personnel. A copy of the Quality Policy has been distributed to all employees and is posted in conspicuous locations.

4.1.5 Laboratory Objectives

- .1 Maintain metrological standards of measurements within a defined scope of capability (reference edisonmetrology.com website for capabilities listing). Measurement standards and calibration devices shall be traceable to the international system of units (SI) via nationally recognized standards maintained by the National Institute of Standards and Technology (NIST), other national laboratories with which NIST has appropriate measurement agreements, or accepted values of intrinsic standards or natural physical constants.
- .2 Provide reliable and responsive calibration services over a range of measurements and to a level of uncertainty suited to the needs of our clients as dictated by the limits of our standards and capabilities.

4.1.6 Management Review

- .1 A formal management review of the quality management system will be performed annually to ensure its continuing suitability and effectiveness in satisfying the requirements of ISO/IEC 17025, NIST Handbook 150, ANSI/NCSL Z540-1-1994, MIL-STD 45662A, IEEE-498, Regulatory Guide 1.33 as applicable, 10CFR50 Appendix B and the Metrology Laboratory's Quality Policy, objectives and procedures.
- .2 The annual management review meeting will be chaired by the Quality Assurance Manager. Attending this management review meeting will be the Manager of SSID, Technical Services Manager, Metrology Services Manager, Metrology Supervisor, Processing Area Supervisor and other invited parties. The following elements of the Metrology Laboratory's quality management system are reviewed:
 - .1 Results of internal, customer and external body audits;
 - .2 Results of corrective/preventive action reports;
 - .3 Results of supplier corrective action reports;
 - .4 Customer feedback (positive and negative);
 - .5 Metrology Laboratory goals, objectives, and Quality Policy;
 - .6 Suitability and effectiveness of the quality system in meeting, ISO/IEC 17025, NIST Handbook 150, ANSI/NCSL Z540-1-1994, MIL-STD 45662A, IEEE-498, Regulatory Guide 1.33 as applicable, and 10CFR50 Appendix B;
 - .7 Training accomplishments and future training needs;
 - .8 Reports from managerial and supervisory personnel (staff observations and suggestions);
 - .9 Results of inter-laboratory comparisons and specific department metrics;
 - .10 Recommendations for improvement;
 - .11 Changes in the volume and type of work; and
 - .12 Equipment reliability and calibration failure reports.
- .3 The results of this review as well as any resulting action assignments shall be documented and transmitted to all participants. The Quality Assurance Manager is responsible for ensuring that all action items resulting from the management review are reconciled in a timely manner.
- .4 Records of the management review meeting and associated completed action items shall be maintained in accordance with documented procedures.

4.1.7 Confidentiality

- .1 The Metrology Laboratory shall ensure that customer confidential information and proprietary rights are respected and protected. The Metrology Laboratory personnel shall not copy or otherwise reproduce any customer provided confidential or proprietary document. All customers provided confidential or proprietary documents shall be returned to the customer when the work is completed.

4.1.8 Conflict of Interest

- .1 Metrology Laboratory employees shall avoid any conflict of interest that jeopardizes our customer relationship (e.g., providing consulting/calibration services, sharing confidential customer information that may impact our customer's business or reputation, participating in activities that could conflict with the best interest of Edison or our customers, etc.).

4.2 Quality System

4.2.1 General

- .1 The Quality Management System described in this manual encompasses the controls necessary for qualified personnel to provide, material, and services in accordance with, ISO/IEC 17025, NIST Handbook 150, ANSI/NCSL Z540-1-1994, MIL-STD 45662A, IEEE-498, Regulatory Guide 1.33 as applicable, 10CFR50 Appendix B and contractual requirements. This quality management system provides for activities affecting quality to be achieved under controlled conditions in an appropriate environment and it takes into account the need for standards, measurement and test equipment, tools, and skills to achieve the required quality.

4.2.2 The Quality Management System consists of:

- .1 Quality Manual - describes Metrology Laboratory approach to the aforementioned requirements.
- .2 [Production Control \(Metrology\) Procedures](#) - documents specific Metrology functions and activities.
- .3 [Quality Assurance Procedures](#) - documents generalized functional responsibilities and conduct of activities.
- .4 [Chemical Control Procedures](#) - documents site controls for chemicals used at Edison ESI.
- .5 [Department Policies](#) - Administrative Policies applicable to all business units.
- .6 [Equipment Calibration Instructions](#) detailing specific calibration activities have been established.
- .7 [Controlled Forms](#).

4.2.3 Quality Planning

- .1 The Metrology Laboratory has implemented a system of procedures and instructions defining specific requirements that are implemented by trained and qualified personnel. Unique quality plans are not necessary for providing calibration services.

4.3 Document Control

4.3.1 Document and Data Approval and Issue

- .1 The Quality Manual is reviewed and approved by the Manager of SSID and the Technical Services Manager.
- .2 Review and approval of procedures and instructions are defined in implementing procedures. Forms are controlled. External documents that affect product quality and are used or referenced in the quality management system shall be controlled.
- .3 Master lists and logs identifying all quality system documentation and data by revision and date have been established. These lists and logs identify either the assigned individual or the location where the documents are located.
- .4 Control of documents and data ensures that the pertinent issues are available to all personnel performing activities. Obsolete or invalid documents are promptly removed from all points of issue and use. Historical copies shall be archived for reference and marked "Superseded" with an inked stamp on the approval page.
- .5 Quality system documents are identified by number, date, and revision. Quality management system documents shall be reviewed annually to ensure their effectiveness and current application to the scope of work performed. ECI's are reviewed upon use.
- .6 Spreadsheets generated internally are approved, controlled and revised in accordance with MET-003, "Metrology Software Control Program." External software used during the calibration activity, or to support the calibration activity, shall either be procured from the original equipment manufacturer for M&TE calibration or controller software; an approved supplier in accordance with QAP-015, "Supplier Qualification," or be commercially dedicated in accordance with QAP-024, "Commercial Grade Dedication."

4.3.2 Document and Data Changes

- .1 Revisions to documents and data shall be reviewed and approved by the original approving organization, unless specifically designated otherwise. The designated organizations shall have access to historical background information to assist in review.
- .2 Changes to documents shall be identified by use of a side bar indicating the text change. Revised documents shall be issued upon approval in accordance with QAP-002.

4.4 Review of Requests, Tenders, and Contracts

4.4.1 General

- .1 The controls defined in the quality management system applies to all customer orders received by the Metrology Laboratory. Customer orders can be by hard copy purchase order, including blanket orders, faxes, or by other instructions provided by the customer.

4.4.2 Customer Order Review

- .1 Customer Administrative Support personnel receive customer orders and review the orders to ensure that: (1) the customer procurement document agrees with the offered quote (if applicable); and, (2) Metrology Laboratory can meet the customer's technical requirements. Verbal orders are not accepted.
- .2 Approval is required for intervals of customers requiring ISO/IEC 17025.
- .3 ESI authorized personnel are responsible to review and accept customer's purchase orders for commercial terms and conditions.
- .4 If ESI is unable to meet the customer's terms and conditions, ESI authorized personnel shall contact the customer to notify them of the circumstances and attempt to resolve concerns. If resolution cannot be achieved the customer's order will not be processed and, if applicable, the customer's equipment returned.
- .5 If ESI and the Metrology Laboratory are able to meet the customer's requirements, the administrative support person shall interpret and document the type of calibration required and any special requirements in MudCats.
- .6 The equipment is then forwarded to the laboratory for calibration.
- .7 Amendments to customer orders are processed, as was the original order.
- .8 Records of contract reviews, as well as pertinent discussions with the customer, shall be maintained in accordance with documented procedures.
- .9 If the customer equipment is to be subcontracted, the supplier is to be qualified in accordance with paragraph 4.5 of this quality manual. The customer is to be notified in writing and shall be requested to provide written authorization to subcontract (if not specifically stated in the customer procurement document).

4.5 Subcontracting of Tests and Calibrations

- 4.5.1 The Metrology Laboratory may use suppliers to perform equipment calibrations that are within, or outside, our scope of calibration capabilities. Suppliers of calibration services shall be evaluated and placed on the Approved Suppliers List by one or more, of the following methods: on-site audit; Commercial Grade Dedication; review of their NVLAP certification; and/or review of their ISO/IEC 17025 accreditation certification. As applicable, suppliers will then be categorized and accepted according to their level of qualifications and specification adherence.
QAP-015, "Supplier Qualification" defines the supplier evaluation process and criteria for removal of suppliers from the Approved Suppliers List. Use of a customer-approved supplier is allowed with appropriate authorizing documentation.
- 4.5.2 The Metrology Laboratory does not subcontract work covered by our scope of accreditation. In the unlikely event that within-scope subcontracting is required; the

supplier must either submit an ISO 17025 accreditation certification or have an ISO 17025 quality management system that has been successfully audited by SSID QA and Metrology Laboratory technical personnel.

- 4.5.3 Records of acceptable subcontractors shall be maintained in accordance with documented procedures.

4.6 Purchasing Services and Supplies

- 4.6.1 Software used in the calibration of measuring and test equipment shall be procured (after December 31, 2000) from suppliers approved in accordance with QAP-015, "Supplier Qualification." with the exception of software developed by Metrology Engineering Services (MES). MES has a quality management system that complies with the requirements of 10CFR50 Appendix B, 10CFR 21. The MES quality management system is audited annually by SSID QA. Records of acceptable suppliers shall be maintained in accordance with MET-010, "Quality Records."
- 4.6.2 Parts and components used in the repair and calibration of customer equipment are inspected at receipt and functionally tested during calibration. Suppliers of parts, components and miscellaneous materials are not required to be evaluated for placement on the Approved Suppliers List. The critical attributes of these items are that they meet purchase order requirements and that the customers' equipment can be successfully calibrated.
- 4.6.3 Receipt inspection of parts and components is defined in section titled, "Inspection and Testing" of this quality manual. Calibration is defined in the specific Equipment Calibration Instruction.
- 4.6.4 Return of customer equipment shall be by freight carriers designated by the customer or selected by the Metrology Laboratory.
- 4.6.5 Purchasing Data
- .1 Material Service Requests are used as the means of procuring parts and services. These procurement documents contain data describing the service, including where applicable: the type, class, grade, or other precise identification; calibration instructions, standards or other technical information; and, the title, number, and issue of the quality system standard to be applied.
 - .2 All Material Service Requests are reviewed and approved by authorized individuals prior to release. Amendments to procurement documents are subject to the same requirements and controls as were utilized in the preparation of the original.
- 4.6.6 Verification of Purchased Product
- .1 When source surveillance is employed as the method of product verification and release, the Material Service Request form shall identify specific requirements to the vendor.
 - .2 When specified by contract, code or federal regulations, customers shall be afforded the right to verify that product conforms to specified procurement requirements at the Metrology Laboratory supplier's facilities. When customer verification occurs,

the Metrology Laboratory shall retain the responsibility for product conformance and release.

4.7 Service to the Customer

- 4.7.1 Customer equipment received at the Metrology Laboratory for calibration shall be received and verified against the customer's supplied documents as applicable. The assigned individual shall verify that the customer's equipment is adequately identified, that there is no apparent damage to the equipment (unless pre-identified by the customer), and that the equipment identification matches the customer paperwork.
- 4.7.2 Customer equipment is tracked through the use of the serial number or unique identification.
- 4.7.3 Any concerns regarding the acceptability of the customers' equipment upon receipt shall be reconciled with the customer prior to forwarding the equipment to the calibration laboratory.
- 4.7.4 If the customer's equipment is lost, damaged, or becomes unsuitable for use due to the fault of the Metrology Laboratory after receipt, it shall be reviewed by the Metrology Supervisor to determine if corrective action documentation is required. The Metrology Supervisors shall ensure that further processing of the equipment is halted and shall consult with the customer to determine what action is to be taken (i.e. replacement or repair).
- 4.7.5 The Metrology Laboratory shall afford all customers the opportunity to clarify any request and to monitor our calibration practices and performance in relation to work performed for that customer.
- 4.7.6 The Metrology Laboratory reserves the right to prohibit customers from reviewing information, data, and/or calibration/repair activities being performed for another customer.
- 4.7.7 Customer feedback is defined in Subsection 4.8 of this quality manual.

4.8 Complaints and Communication

- 4.8.1 Complaints received from customers, or other parties shall be evaluated and if deemed to impact either work activities or customer satisfaction they shall be documented in accordance with DP-008, "Process Assessment Review for Continuous Improvement."
- 4.8.2 Positive communication received from customers in written or verbal form shall be recorded in the communication log.
- 4.8.3 Periodically, not to exceed annually, the Metrology Supervisor or ESI Account Manager may solicit customer feedback (both positive and negative) as part of the continuous improvement process. All Customer feedback shall be documented and evaluated. Negative feedback shall be documented as a customer complaint.
- 4.8.4 Records of customer complaints shall be retained in accordance with MET-010, "Quality Records."

4.9 Control of Nonconforming Testing and/or Calibration Work

4.9.1 General

- .1 Within the Metrology Laboratory nonconforming items are classified as follows:
 - Parts and/or components used in the repair of M&TE that do not meet purchase order requirements;
 - M&TE received from suppliers without proper paperwork or damaged;
 - Customer equipment received in damaged condition;
 - Discrepancies noted during calibration activities;
 - Metrology Laboratory owned equipment that has “AS-FOUND” data exceeding required acceptance criteria.

4.9.2 Review and Disposition of Nonconforming Product

- .1 A calibration failure evaluation shall be performed in accordance with the requirements of MET-001, “Calibration Production Control,” whenever the Metrology Laboratory owned equipment has as-found data exceeding documented acceptance criteria or when instances of mishandling occur which are known or suspected of having an adverse effect on calibrations.
- .2 M&TE received from suppliers with documentation problems (incorrect paperwork, missing Certificate of Calibration and/or data, etc.) shall be put into a designated hold area until the receipt inspection issues are resolved. Should the equipment be returned in a damaged or otherwise unfit condition a supplier corrective action report may be written in accordance with QAP-008, “Corrective Action.”
- .3 Customer equipment received in damaged condition shall be controlled as identified in Section titled, “Service to the Customer” of this Quality Manual.
- .4 Discrepancies observed during calibration and actions taken to resolve issues shall be noted on the calibration certificate as required by MET-001, “Calibration Production Control.”
- .5 Items reworked or repaired during calibration shall be documented on the calibration certificate.
- .6 Corrective action records are maintained as quality records in accordance with documented procedures.
- .7 Out-of-tolerance and significantly out-of-tolerance conditions are defined in MET-001, “Calibration Production Control.”

4.9.3 When activities do not conform to approved programs or policies, work may be halted by Management or Quality Assurance.

4.9.4 Management is responsible for authorizing the resumption of work after appropriate actions have been initiated.

4.10 Continuous Process Improvement

4.10.1. Metrology shall plan and implement measurement, monitoring, analysis and improvement processes needed to evaluate and improve the quality system effectiveness. Facilitation of continual improvement of the quality system is to include the use of the Quality Policy, quality objectives, audit results and analysis of data, corrective and preventive actions and the Management Review. This evaluation is conducted in accordance with MET-012, "Continuous Process Improvement.

4.11. Corrective Action

- 4.11.1. Conditions that are adverse to quality, item related, process, or programmatic, shall be identified documented and resolved in accordance with QAP-008, "Corrective Action", and also, if required, in accordance with QAP-010, "Reporting Problems Pursuant to 10 CFR Part 21."
- 4.11.2. When it is determined that an adverse quality condition exists, a Corrective Action Report (CAR) shall be issued. The Corrective Action Report shall identify the root cause of the issue, immediate action taken to correct the issue and action taken to prevent recurrence.
- 4.11.3. The responsible individual(s) is given 30 days from the date of issuance to respond to the corrective action or request an extension.
- 4.11.4. Quality Assurance shall then evaluate the response to ensure the root cause, immediate corrective action, and supplemental action is adequate to resolve the adverse condition. This evaluation shall be completed within five working days of QA's receipt of the response and documented on the CAR
- 4.11.5. If the Quality Assurance Manager does not concur with the proposed action, the CAR shall be returned to the responsible individual(s) with the suggested possible resolutions.
- 4.11.6. When a resolution cannot be achieved, the matter shall be elevated to the Manager of SSID or to the Technical Services Manager (if supplier related).
- 4.11.7. Within 30 days following the proposed implementation date, QA shall verify that all action items have been implemented.
- 4.11.8. The Metrology Services Manager shall request an extension, if the proposed implementation date cannot be met.
- 4.11.9. Supplier Corrective Action Reporting shall be accomplished in accordance with approved written procedures.
- 4.11.10. When a departure or a nonconformance is identified that casts doubt on Metrology's compliance with this quality management system Quality Assurance Manager shall ensure that the appropriate areas of activities are audited as soon as possible.

4.12. Preventive Action

- 4.12.1. The Quality Assurance Manager is responsible for evaluating preventive actions reported through the corrective action system. During the audit of the quality system the Quality Assurance Manager shall evaluate work operations; customer complaints; previous audit results and corrective action documents to determine if a negative trend has developed. Actions will be taken to eliminate negative trends.
- 4.12.2. A proactive process for identifying potential negative programmatic or technical issues and needed improvements shall be implemented. Potential sources for preventive action implementation, either technical or concerning this quality management system, shall be identified by one or more of the following:
 - .1 Implementation of the “employee idea” database that includes process/program improvement suggestions;
 - .2 Customer feedback database;
 - .3 Results of department metrics;
 - .4 Results of inter-laboratory comparisons; and/or
 - .5 Results of calibration certificates review.
- 4.12.3. Records of corrective and preventive actions shall be maintained as quality records and shall be reviewed by executive management during the periodic management review of the quality management system.

4.13. Control of Records

- 4.13.1. Procedures have been developed to define controls for the identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality and technical records. The records shall include at least the following: results of management reviews, inspections, tests, audits, corrective and preventive action reports, contract review records, records of acceptable subcontractors, records of calibration including derived data, and training records. All observations, letters of authorization, calculations, notes, factors affecting uncertainty and staff records associated with the equipment calibration are recorded on the work traveler, or in MudCats, and maintained.
- 4.13.2. Records shall be legible and stored in a manner that permits adequate retrievability and prevents damage, deterioration and loss. Record retention times have been established for all records identified in MET-010, “Quality Records.”
- 4.13.3. Metrology Laboratory customers are granted free access to all records controlled under the auspices of this quality system that are relevant and that pertain to the particular customer.
- 4.13.4. All Metrology Laboratory personnel have been instructed to transmit calibration results and information regarding a particular customer only to that customer (individual will be identified). No allowances for customers to review or receive other customer’s records will be permitted.

4.14. Audits

4.14.1. General

- .1 Personnel who do not have direct responsibility for performing the activities audited shall perform audits in accordance with documented procedures or checklists.
- .2 Audit results shall be documented, reported to, and reviewed by the Quality Assurance Manager.
- .3 These requirements are applicable to both internal and supplier audits.

4.14.2. Audit Scheduling

- .1 The Metrology Laboratory Quality Program shall be assessed annually to ensure continuous compliance to committed requirements.

4.14.3. Audit Personnel

- .1 The Quality Manager shall assure that audit team members are trained.

4.14.4. Audit Performance

- .1 Audits shall be performed in accordance with QAP-017, "Audits and Surveillances."
- .2 Auditors shall have access to previous audit results to aid in audit preparation.
- .3 Selected program elements shall be evaluated against specific requirements.
- .4 Objective evidence shall be examined to the depth necessary to determine if program elements are effectively implemented.

4.14.5. Audit Reporting

- .1 Audit reports shall be written and issued within 30 calendar days of audit completion.
- .2 Audit finding reports shall contain a listing of each audit finding.

4.14.6. Audit Response

- .1 The Metrology Services Manager shall investigate internal audit findings and determine corrective action and measures to be taken to prevent recurrence of the adverse conditions. Customers shall be notified should the results of the audit indicate that calibrations are affected.
- .2 Corrective action and measures necessary to prevent recurrence shall be documented on the finding report or on documents traceable to the report and shall specify completion dates.

4.14.7. Audit Follow-Up

- .1 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.
- .2 Records of audits and associated corrective actions shall be maintained as required by documented procedures.

4.15. Product Identification and Traceability

- 4.15.1. A unique identification number distinctive to the customer is assigned to the customer's equipment if not already identified. This unique number is referenced on the traveler and associated paperwork to provide traceability directly to the equipment throughout the process.
- 4.15.2. All Metrology Laboratory M&TE and measurement standards shall be assigned a unique identification number. This number is referenced on all associated calibration documents to provide traceability directly to the equipment throughout the calibration process.
- 4.15.3. Parts and/or components used in the repair of M&TE do not require unique identification and/or traceability to the end use.

4.16. Process Control

- 4.16.1. MudCats software combines several databases to provide current information for managing the flow of work through the Metrology department. MudCats is used to track the equipment status through the Metrology Laboratory, permits generation of work travelers, shipping documentation, etc., and provides management with cost and manpower data.
- 4.16.2. Repair and adjustment activities are performed by personnel using controlled equipment manufacturers manuals and OEM provided controlling software. Repair and adjustment activities are not critical to product quality since the final calibration validates the conformance of the equipment. Calibrations shall be performed in accordance with issued work travelers.
- 4.16.3. Equipment used in the calibration of M&TE shall be calibrated at defined intervals that assure measurement standards and calibration devices are traceable to the international system of units (SI) via nationally recognized standards maintained by National Institute of Standards and Technology (NIST), other national laboratories with which NIST has appropriate measurement agreements, or accepted values of intrinsic standards or natural physical constants. A system for mandatory recall has been established. Preventive maintenance of M&TE shall be performed when required by the associated Equipment Calibration Instruction (ECI) or OEM operations manual.
- 4.16.4. Environmental conditions such as temperature, humidity, and electrostatic discharge shall be in accordance with written instructions and procedures. Materials used for the calibration of M&TE and Standards which are environmentally or date sensitive are identified with an S1 number and controlled in the Metrology recall system.
- 4.16.5. Acceptance criteria shall be documented in procedures or work instructions.
- 4.16.6. Personnel performing repair and calibration activities shall be qualified in accordance with criteria established in approved procedures.

4.17. Inspection and Testing

4.17.1. Receipt Inspection

- .1 Parts, components and miscellaneous materials used in the repair of M&TE shall be inspected at receipt by trained personnel to ensure that the items procured meet procurement document requirements.
- .2 M&TE sent out for calibration shall be inspected at receipt by qualified personnel to ensure the items meet procurement document requirements. If the item is unacceptable, it is put on hold in Metrology until adequate reconciliation is performed. If the item is acceptable, the Metrology Calibration Certificate shall be stamped or initialed to indicate acceptance. The Metrology Supervisor shall make the determination if a Supplier Corrective Action Report is to be issued in accordance with QAP-008, "Corrective Action."
- .3 Material Service Requests are maintained in Metrology as quality records.

4.17.2. In-Process and Final Tests

- .1 Final tests are performed by qualified personnel in accordance with MET-001 and the applicable calibration work instruction. In-process inspections and tests are not applicable to Metrology Laboratory calibration services.

4.17.3. Inspection and Tests Records

- .1 Receiving and final test and inspection records shall be maintained in accordance with documented procedures.

4.18. Inspection and Test Status

- 4.18.2. Receiving inspection status for parts, components and Metrology Laboratory owned equipment shall be documented on the Material Service Request forms associated with the particular item. Only acceptable parts, components and equipment shall be released to requester.
- 4.18.3. Receiving inspection status for customer equipment shall be documented on the customers shipping documents. Only customer equipment received in proper condition and accepted at receipt will be released to the appropriate lab.
- 4.18.4. Tests status for M&TE shall be documented via the calibration report.
- 4.18.5. Unsatisfactory conditions identified during the calibration process shall be documented in the remarks section of the calibration report along with actions taken to correct the unsatisfactory condition.

4.19. Statistical Techniques

- 4.19.2. Statistical techniques and analysis are employed at the primary level for certain disciplines in order to maintain control of secondary level equipment.
- 4.19.3. Statistical techniques used during the calibration process are to monitor measurement uncertainties, drift, and to provide data for analysis to ensure process control where needed.
- 4.19.4. The methods used are described and maintained in MET-008, “Statistical Process Controls.”

4.20. Design Control

- 4.20.1. Design Control activities are not applicable to Metrology Laboratory calibration services.

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Section 5.0 - Technical Requirements

5.1 Personnel

5.1.1 Training Requirements

- .1 All personnel are qualified based on their training, demonstrated abilities, and/or experience. Records of training and qualification for personnel who performed and verified work affecting quality are available.

5.1.2 Qualifications

- .1 Personnel performing activities described in this quality manual shall meet the requirements established in their job description. Prior to performing activities affecting quality, each employee shall receive hands-on training and be observed performing the task. The Metrology Supervisor and Processing Area Supervisor shall maintain records of employee qualifications.

5.1.3 Indoctrination and Training

- .1 Personnel (permanent/contractor) employed by the Metrology Laboratory that are involved in activities affecting quality shall be indoctrinated in the requirements of the Quality Program. Personnel will be retrained in the program requirements at the discretion of the Quality Assurance Manager.
- .2 Personnel shall also be trained in the requirements of procedures and instructions that are pertinent to their area of activity. Training shall be current, documented and maintained as quality records as required by this quality manual.
- .3 The Metrology Supervisor and Processing Area Supervisor are responsible for ensuring that the status of personnel qualification and training is current.

5.1.4 Job Descriptions

- .1 Job descriptions shall be maintained for managerial, technical, and key support personnel involved in the tests and/or calibrations.

5.2 Accommodation and Environmental Conditions

5.2.1 Environmental conditions such as temperature and humidity shall be maintained in accordance with written procedures and recorded. Date sensitive materials used in the repair and calibration of measuring and test equipment shall be managed as defined in MET-001. Energy supply and lighting conditions are adequate for the performance of acceptable calibrations.

5.2.2 As necessary, electrostatic discharge controls shall be in place to prohibit damage to customer and laboratory owned equipment.

5.2.3 Access to the laboratory shall be controlled. Authorized personnel and accompanied guest are allowed in the laboratory area. Each access point shall be marked accordingly.

5.2.4 Housekeeping requirements are defined in MET-001, "Calibration Production Control."

- 5.2.5 The calibration environment at the customer's site, when applicable, shall be monitored for both humidity and temperature using a calibrated device. The technician shall ensure that conditions appropriate to the calibration to be performed at a customer's site meet the minimum specification for the type of device being calibrated or apply compensation corrections when appropriate. Environmental conditions must be recorded, if not, then monitored and stated, or a statement of not monitored included on the calibration report.
- 5.2.6 Calibrations shall be separated by discipline, where applicable, and be performed in the area in which it has been determined optimum for that discipline.

5.3 Test and Calibration Methods and Method Validation

- 5.3.1 Calibration procedures may take the form of OEM manuals, internally generated equipment calibration instructions (ECI), or industry standards. The latest valid edition shall be used unless it is inappropriate or not possible to do so.
- 5.3.2 Equipment calibration instructions shall contain:
- .1 The range and accuracy of the device under test; however stated;
 - .2 The range and accuracy of the devices used to test; however stated;
 - .3 The generic description of the devices used to test; however stated; and
 - .4 Generic description of methodologies used.
- 5.3.3 Deviations from approved calibration procedures shall be documented on the calibration report, technically justified, reviewed by the Metrology Supervisor and offered to the customer for acceptance.
- 5.3.4 Metrology Laboratory adopts procedures developed by other organizations or develops our own procedures that incorporate standard methods. Metrology Laboratory generally does not independently develop calibration methods. Calibrations are performed using approved calibration procedures or a Report of Calibration. Non-standard calibration methods require customer approval prior to performing calibrations unless method has previously been used for customer's equipment. Sampling is not part of the calibration process.
- 5.3.5 ECIs have been proven by historical use. Validation criteria for calibration processes are defined in MET-005, "Preparation and Control of Equipment Calibration Instructions (ECIs)."
- 5.3.6 Measuring and test equipment shall have their uncertainty documented and maintained by the Metrology Engineer. Methods for performing uncertainty analysis are described in MET-011, "Uncertainty Analysis and Maintenance of Error Budgets." Uncertainty calculations shall be subjected to appropriate checks and documented.
- 5.3.7 Calculations and data transfers shall also be subjected to appropriate checks and documented by the Metrology Supervisor.
- 5.3.8 Internally generated spreadsheets affecting calibration results shall be independently verified and maintained in accordance with MET-003, "Metrology Software Control Program." External software used in conjunction with a calibration must be procured in

accordance with Section 4.6 of this quality manual. Software used as part of a calibration is listed in the approved ECI. Software is approved for use upon approval of the ECI.

5.4 Equipment

5.4.1 Equipment Availability

- .1 The Metrology Supervisor shall ensure equipment availability to perform correct calibrations. Use of equipment outside the laboratory's permanent control is prohibited unless the provider of the equipment is qualified and placed on the Approved Suppliers List or the equipment is recalibrated by the laboratory or an approved supplier. Customer supplied equipment may be used for calibration support at customer facility. Use of such equipment shall be documented on the calibration report at the discretion of the Metrology Supervisor.

5.4.2 Equipment Selection

- .1 All Metrology Laboratory equipment selections and calibrations are based on factors affecting measurement uncertainty.

5.4.3 Equipment Identification

- .1 Measures shall be established in procedures to ensure that Metrology owned measuring and test equipment being calibrated is properly identified.
- .2 Measuring and test equipment, and associated software, shall be identified to provide unique traceability to associated calibration records, and to indicate the calibration status of the measuring and test equipment. All active measuring and test equipment must be calibrated prior to use.
- .3 All measuring and test equipment shall be properly maintained. Any item which has been subjected to overloading or mishandling, or which gives suspect results, or is shown to be defective shall be taken out of service.
- .4 If measuring and test equipment is found to be out-of-tolerance, an evaluation shall be made to determine the acceptability of previous calibration results of instruments that were calibrated with the measuring and test equipment in question. This evaluation shall be documented. Where results of previously calibrated measuring and test equipment are affected, customers shall be notified in writing. When measuring and test equipment is found to be out-of-tolerance it shall be repaired, recalibrated, or replaced in accordance with MET-001, "Calibration Production Control."
- .5 Obsolete or damaged beyond repair equipment are identified and removed from the laboratory. Equipment may be sold or discarded.

5.4.4 Status Indicators

- .1 All measuring and test equipment that require calibration (new and customer owned) shall be subjected to test, calibration, and inspection as required. The acceptance status of each instrument shall be maintained through the use of status indicators such as tags, physical location, and or documented records of test, calibration and/or inspection as applicable.

5.4.5 Authorized Personnel

- .1 Only authorized personnel identified by the Metrology Supervisor are authorized to apply, remove, and/or revise inspection status indicators and/or use measuring and test equipment to complete work activities.

5.4.6 Equipment Calibration Records

- .1 Records shall be maintained for each piece of measuring and test equipment used by the laboratory and shall include:
 - .1 Description of the equipment and applicable software;
 - .2 Manufacturer, model number, serial number, and asset number, where applicable;
 - .3 All items are assumed to be in the laboratory, in the possession of a technician, or out for calibration unless otherwise noted;
 - .4 Dates and results of calibrations and/or verifications and date when the calibration and/or verification expires;
 - .5 Results of maintenance, as applicable;
 - .6 Manufacturers instructions, if applicable, or reference to their location; and
 - .7 Maintenance performed on equipment including any damage, malfunction, modification, or repair to the equipment.

- 5.4.7 Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments that would invalidate the test and/or calibration results.

5.5 Measurement Traceability

- 5.5.1 Calibrations shall be performed in accordance with approved procedures using standards traceable to the international system of units (SI) via nationally recognized standards, accepted intrinsic values, or natural physical constants where such standards exist. Where such standards do not exist, calibration shall be performed to meet the manufacturer's recommended specifications or the basis for calibration shall be documented (Report of Calibration).

- 5.5.2 The Metrology Laboratory maintains two types of reference standards:

- .1 Primary standards that are calibrated by approved suppliers or by Metrology; and
- .2 Secondary standards (which are calibrated by the Metrology Laboratory using primary standards) used to calibrate measuring and test equipment, if applicable, or customer equipment.

- 5.5.3 Reference materials shall be maintained within the laboratory. Reference materials shall be checked by the Metrologist prior to use to ensure its acceptability.

- 5.5.4 Inter-laboratory comparisons and proficiency testing is described in MET-002, "NVLAP Accreditation Program."

- 5.5.5 Quality checks needed to maintain confidence in the calibration status of reference, primary, and working standards is defined in MET-008, "Statistical Process Control."

5.6 Sampling

5.6.1 Sampling is not part of the calibration process employed by the Metrology Laboratory.

5.7 Handling of Test and Calibration Items

5.7.1 Measuring and test equipment shall be handled in a manner not to negatively affect readings or accuracy. Carts may be used to move heavy pieces of measuring and test equipment around the calibration laboratory. Lighter pieces of measuring and test can be hand carried to points of destination.

5.7.2 Items shall be stored as follows:

- .1 Items are staged on shelves, carts, or on the floor in the original container, until the calibration laboratory receives the equipment.
- .2 Parts and/or components are stored in bins, boxes or manufacturer envelopes and are identified by part number or description.
- .3 Items in the process of calibration shall be staged on work benches or shelving in a manner not to cause damage or deterioration to the equipment.
- .4 Items being shipped are staged on tables, shelves, or floor for larger items in the processing area until completion of the data package.
- .5 Protective environments, including moisture and temperature parameters have been established as defined in MET-001, "Calibration Production Control."

5.7.3 As necessary, all measuring and test equipment shall be packaged in foam, peanut insulation, etc., to limit impact and damage during shipment.

5.7.4 The methods and controls for assuring that equipment is delivered in a safe manner are described in MET-004, "Administrative Processes."

5.7.5 From time of receipt all measuring and test equipment shall be stored on tables, work benches, shelves, or on the floor in the original manufacturer's container, if provided, to ensure that the integrity of the unit is preserved.

5.8 Assuring the Quality of Test and Calibration Results

5.8.1 Review checks may be performed as follows:

- .1 Review checks may be performed to ensure the validity of measurements. The Metrology Supervisor may, at any time, have a piece of measuring and test equipment re-calibrated in part, or whole, by a qualified technician. These checks shall be documented on the applicable work order or traveler as to parameter checked and pass/fail status.
- .2 When a measurement is in doubt, personnel shall notify another technician who shall check the validity of the measurement and annotate it on the calibration report. Any disparity shall be documented and resolved prior to equipment release.

5.8.2 Inter-laboratory comparisons are performed as specified in MET-008, "Statistical Process Control."

5.9 Reporting of Results

5.9.1 Results of each calibration shall be accurately, clearly, unambiguously, and objectively reported on a Calibration Certificate and attachments, as necessary.

5.9.2 Calibration Certificates shall include the following information:

- .1 Title, e.g., "Calibration Report," "Calibration Certificate," or "Report of Calibration;"
- .2 Name and address of laboratory, and location where the calibration was carried out if different from the address of the Metrology Laboratory;
- .3 Unique identification of the certificate or report and of each page, and the total number of pages;
- .4 Name and address of customer;
- .5 Description and identification of the item calibrated;
- .6 Characterization and condition of the calibration item;
- .7 Date of receipt of the calibration item where this is critical to the validity and application of the results and the date on which the calibration was completed;
- .8 Identification of the calibration procedure used or manufacturer specification used to determine in/of tolerance of measuring and test equipment;
- .9 Any deviation from, additions to, or exclusions from the calibration procedure, and any other information relevant to the calibration, such as environmental conditions that may influence the calibration;
- .10 As-found and As-left data, when appropriate;
- .11 The assigned calibration interval or customer requested calibration interval;
- .12 The designated limits of permissible error;
- .13 The standards used to perform the calibration and their calibration due date;
- .14 A statement of accuracy and uncertainty (when appropriate);
- .15 Details of any servicing, adjustments, repairs, or modifications performed;
- .16 Any limitation in use;
- .17 Printed name and stamp or initials; or signature; and title of the person accepting responsibility for the content of the certificate and date of issue;
- .18 A statement that the certificate shall not be reproduced except in full, without the written approval of the Edison Metrology Laboratory;
- .19 A statement that the report must not be used by the client to claim product endorsement by any accreditation body or any agency of the U.S. Government;
- .20 Signature, or initials, of reviewing party;
- .21 Traceability statement; and
- .22 Opinions and/or interpretations, as applicable.

5.9.3 Amendments

- .1 Material amendments to a Calibration Certificate, after issue, shall be made only in the form of another document. A statement "Corrected Copy" shall appear identifying the amended copy.

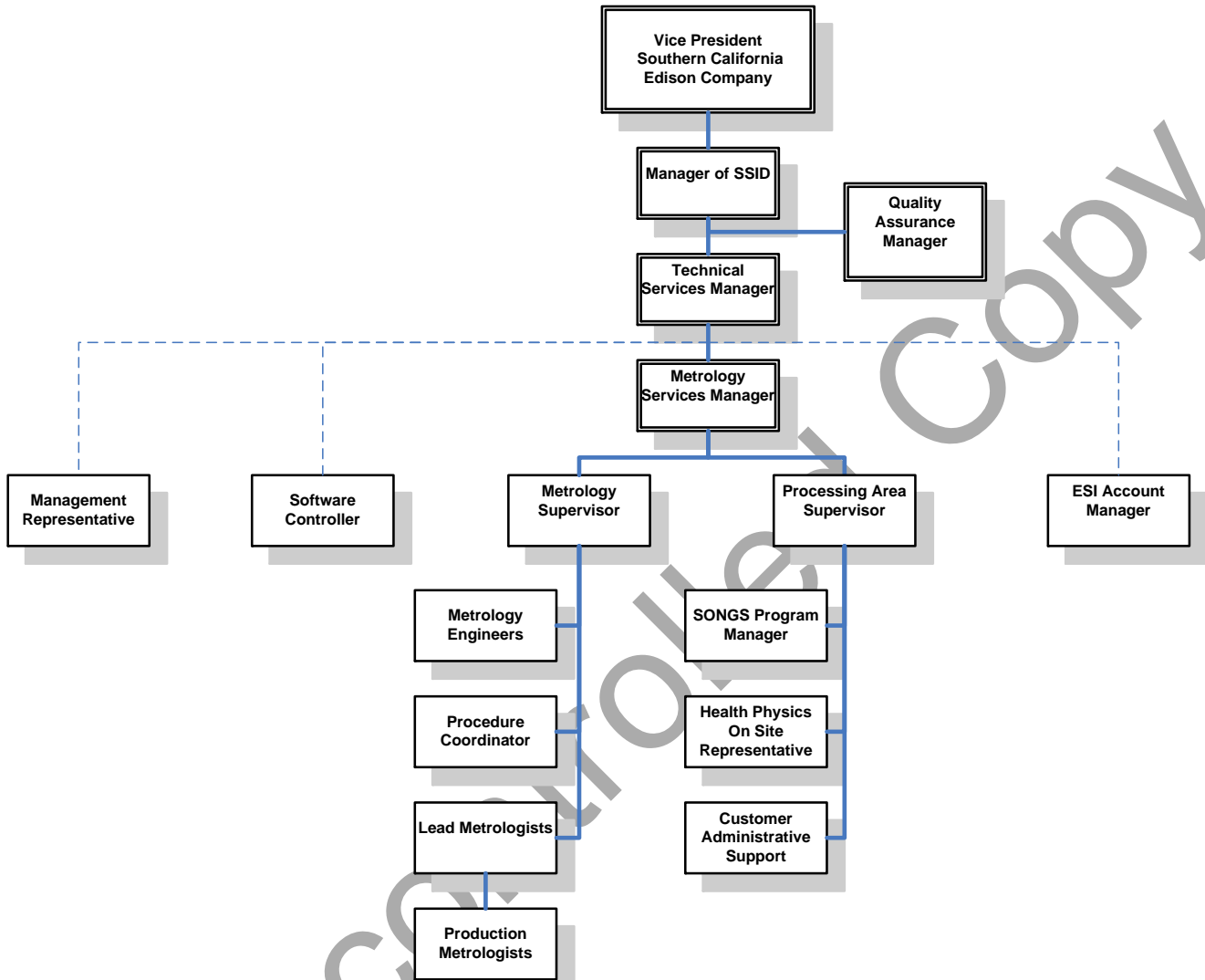
5.9.4 Transmission of Results to Customers

- .1 Should the Metrology Laboratory be requested to electronically transfer results of calibrations to the customer the individual transmitting the information shall complete a facsimile sheet identifying the individual the information is sent to and a statement of confidentiality.

- 5.9.5 When subcontractors perform calibrations, the Metrology Laboratory shall issue a Calibration Certificate identifying the subcontractor and shall attach the subcontractor's calibration certificate.

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Metrology Organization Chart



ATTACHMENT 1