

ISO/IEC 17025 QUALITY MANUAL

HIGHPOWER Validation Testing & Lab Services Inc.



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HIGHPOWER Validation Testing & Lab Services Inc. (**HIGHPOWER**) has been validating reusable medical devices for over 25 years. With an experienced staff of scientist, researchers and technicians, a new facility (opened 2012) and a corporate policy striving towards excellence, HIGHPOWER can meet our customers' needs for sterilization efficacy, cleaning, packaging and materials compatibility validation studies. With an outstanding reputation for customer service, we provide a wide range of validation and testing services, as well as sterilization consulting to medical/dental device manufacturers around the world.

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QUALITY POLICY

It is the policy of HIGHPOWER to strive for continuous improvement while performing laboratory studies that involve verification and/or validation of biological indicators, chemical indicators, packaging materials, material compatibility, sterilization efficacy and device cleaning. Recognition as a quality leader in laboratory validation testing for the healthcare industry is the reward for ultimately achieving our goal.

This quality policy complies with FDA Part 820 and is posted throughout the HIGHPOWER facility.

QUALITY POLICY STATEMENT

Purpose

HIGHPOWER Validation Testing & Lab Services Inc. (HIGHPOWER) is committed to consistently providing quality test results that meet or exceed our customers' expectations. This Quality Manual is intended to detail the philosophy, procedures and policies of HIGHPOWER's Quality System. It covers the management and technical requirements of the implementation of the Quality System to meet the ISO/IEC 17025:2005 standard for accreditation, and to continually improve the effectiveness of the quality system. It also covers additional policy requirements as established by the American Association of Laboratory Accreditation (A2LA) for accredited test methods.

Quality Policy Statement

The management of HIGHPOWER Validation Testing & Lab Services Inc is committed to good professional practice and to complying with this Quality Manual. To deliver this commitment, we have developed and documented a quality system to ensure customer satisfaction by complying with regulatory and customer requirements and by continually improving the management of the company.

The objective of this quality system is to deliver accurate, reliable, traceable test results to our customers. We are committed to training personnel to provide quality test and validation service results and to document our quality assurance activities in producing these services for our external and internal customers. Laboratory personnel receive training and instructions on the Quality System to provide an understanding of how the system will impact their daily work. Employees ensure the quality of their work meet the policies of HIGHPOWER by adhering to laboratory procedures, test protocols and by recording test related activities and data as required.

It is the responsibility of management to review and plan resource allocation and policies for HIGHPOWER. Our quality system has been designed to comply with the ISO/IEC 17025:2005 standard and other internationally accepted quality systems (e.g. FDA Part 820/ISO 13485). The management of HIGHPOWER is committed to complying with the ISO/IEC 17025:2005 standard and to continually improving the effectiveness of our management system.

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INTRODUCTION

HIGHPOWER Validation Testing & Lab Services, Inc., (HIGHPOWER) has been one of the world's leading company specializing in the validation of safe medical devices for over 25 years. Primarily serving the health care industry, HIGHPOWER has excelled at providing services to medical/dental device manufacturers, sterilizer manufacturers, pharmaceutical companies and industrial customers.

HIGHPOWER's experience enables the development of specific testing programs for products and allows us to provide continued support through regulatory submissions, their defense and approval and by offering manufacturers' access to every major FDA cleared sterilization process, we provide a single source for device cleaning, packaging and sterilization validation needs.

This manual has been prepared to define the quality system, establish responsibilities of the personnel affected by the system, and to provide general procedures and policy statements for all activities comprising the quality system. In addition, this manual is used for the purpose of informing our customers of the quality system and what specific process controls are effectively implemented to assure service quality.

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SCOPE AND EXEMPTIONS

HIGHPOWER's quality management system applies to the testing of medical/dental devices and raw materials by utilizing regulatory test methods and specific customer testing requirements.

ISO 17025 is an international standard containing general requirements for the competence of testing and calibration laboratories. HIGHPOWER is in business only a testing laboratory and does not perform calibration services; therefore, the following exemptions apply:

Section 4.3.3.3 Document changes – HIGHPOWER's document control system does not allow for amendment of documents by hand.

Section 5.7 Sampling - is performed to the applicable regulatory test method or specific customer requirements. HIGHPOWER does not create sampling plans or procedures.

Section 5.10.4 Calibration certificates - applies only to a calibration laboratory or testing laboratory performing customer calibrations. HIGHPOWER does not perform any customer equipment calibration.

NOTE: Many of HIGHPOWER's services are customer driven and therefore require independent test protocols to be developed for the manufacturers' specific device. These protocols are reviewed and authorized by both the customer and representatives of HIGHPOWER prior to commencement of test services.

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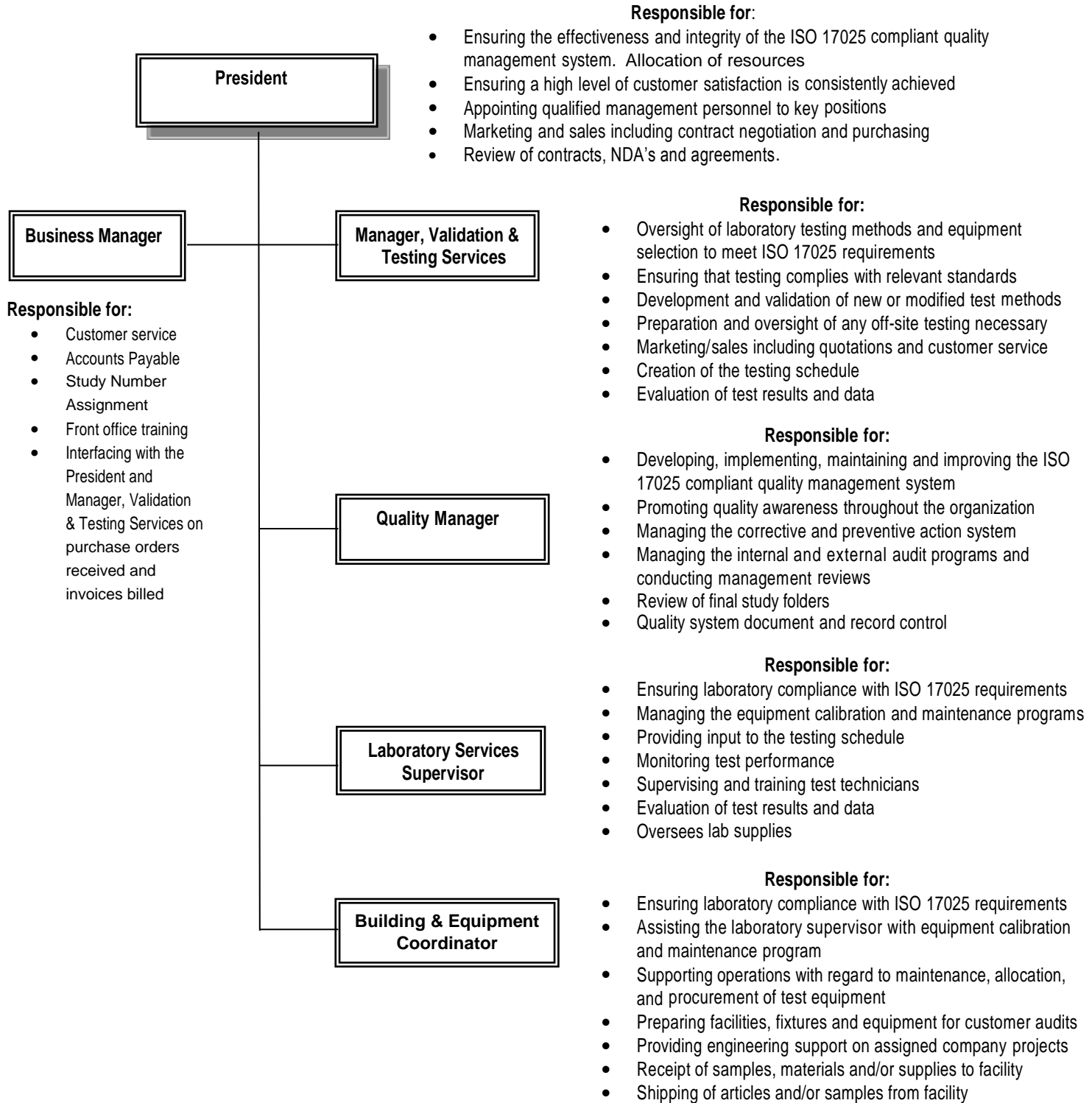
1 Quality System Management

Company Organization and Management Responsibility

- HIGHPOWER Validation Testing & Lab Services Inc. is a registered Corporation in the State of New York and holds legal responsibility for its operation.
- HIGHPOWER is a privately held company, not part of any other company or organization.
- HIGHPOWER is organized to operate in accordance with the requirements of ISO/IEC 17025, whether carrying out work in its permanent facilities or at off-site locations. It is the responsibility of all employees to work in accordance with the quality policies while satisfying the needs of our clients.
- HIGHPOWER is not part of an organization performing activities other than testing; therefore, there is no potential conflict of interest amongst its personnel.
- All HIGHPOWER employees are responsible to conduct themselves in a manner that does not diminish the confidence in our competence, impartiality, judgment or operational integrity as viewed by both HIGHPOWER employees and our customers. This responsibility includes activities both in and outside of normal operations at HIGHPOWER.
- Assignment of Responsibility:
 - In the absence of the Quality Manager, the President will assume these duties.
 - In the absence of the President concerning corporate issues, the Business Manager will assume these duties.
 - In the absence of the President concerning technical issues, the Manager Validation & Testing Services will assume these duties.
 - In the absence of the Business Manager, the Operations Assistants will assume these duties.
 - In the absence of the Manager Validation & Testing Services, the Laboratory Services Supervisor will assume these duties.
 - In the absence of the Laboratory Services Supervisor, the Senior Microbiology Technician will perform laboratory supervision.

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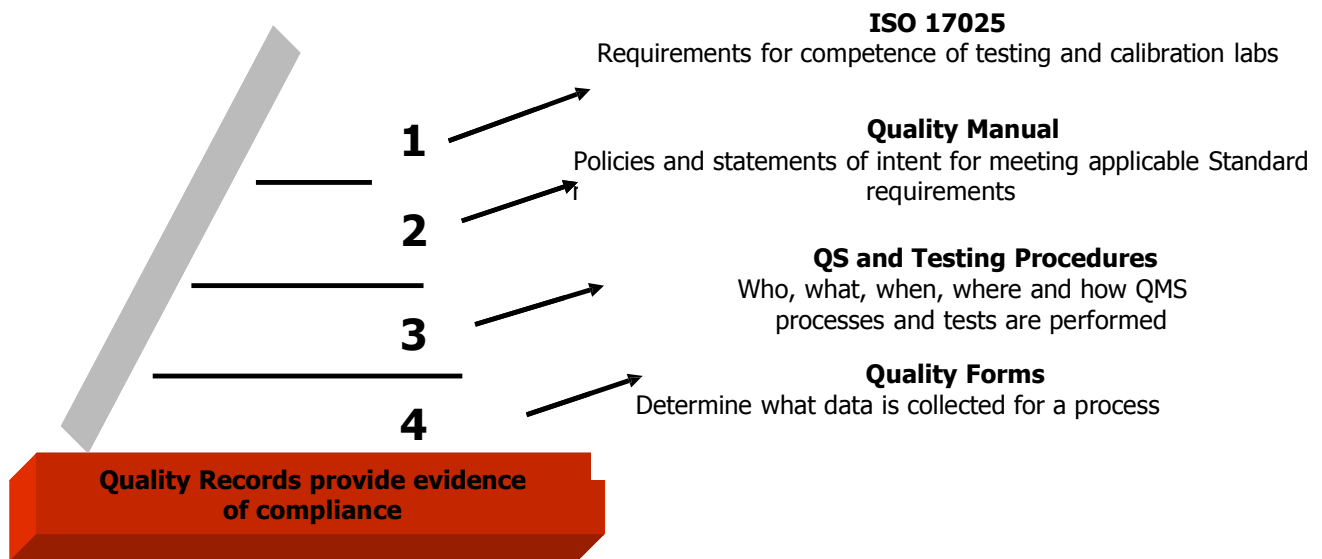
The organizational responsibilities of HIGHPOWER personnel are summarized below:



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- Gifts or favors from suppliers, customers or internal activities that may benefit from “in-spec” test results are prohibited to avoid any perception of conflict of interest and are addressed through HIGHPOWER’s employee handbook, employee orientation and employee confidentiality agreements.
- Proprietary rights and confidential information for both MPS and its customers are adequately secured per the HIGHPOWER employee handbook, employee orientation and employee confidentiality agreements.
- Job descriptions are maintained for all personnel detailing responsibility, authority, and education and training requirements per HP CSOP 025 *Job Descriptions*.
- The Quality Manager ensures that the integrity of the quality system is maintained when changes to the system are planned and implemented.

2 Quality System Documentation



- **The Quality Manual** is the governing document that defines the quality system policies and statements of intent of HIGHPOWER and is based on ISO 17025:2005 requirements.
- **The Quality Procedures and Test Instructions** describe who, what, when, where and how quality management system and testing processes are performed. A complete listing of documents is outlined in HIGHPOWER Index/Table of Contents for HP CSOP, LSOP, MSOP and QC Forms.
- **Quality Forms (QC)** related to quality procedures and test instructions are used for data collection.
- **Quality Records** are retained as objective evidence of compliance to the requirements of ISO 17025 and HIGHPOWER procedures and test instructions per *HP CSOP 014 Document Change Control* and *HP CSOP 015 Good Document Practices*.

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Document Control

- - The Quality Manual and all documented procedures are readily available at the point of use and controlled per *HP CSOP 014 Document Change Control* and *HP CSOP 015 Good Document Practices*.
 - The document control procedure ensures documents are approved for adequacy, uniquely identified (including revision status), periodically reviewed and updated, legible and protected from damage.
 - Approvers perform document reviews and approvals based on pertinent information available to them by virtue of their position in the company.
 - Documents of external origin are identified and controlled.
 - Obsolete or down rev documents are not available for use in testing and are segregated from current revisions if they are retained for any purpose.

Document Changes

- - Document changes are controlled per *HP CSOP 014 Document Change Control*. A description of the change is recorded in the revision history.
 - Document changes are reviewed by the same functions that performed the original review and approval unless specifically designated otherwise.

Quality Record Control

- - *HP CSOP 014 Document Change Control* and *HP CSOP 015 Good Document Practices* define the means needed to identify, collect, index, access, file, store, maintain and dispose of quality and technical records.
 - Records are legible, stored in a suitable environment to prevent damage or deterioration and are readily retrievable. Records may be in hard copy or electronic format. Electronic data is protected, backed up, stored and access controlled per *HP CSOP 014 Document Change Control* and *HP CSOP 015 Good Document Practices*.
 - All records are held securely and in confidence.
 - HIGHPOWER retains records of original observations, derived data and sufficient information to establish an audit trail.
 - Observations, data and calculations are recorded at the time they are made and are identifiable to the specific task.

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3 Contract Review and Purchasing

- Contract review is a primary function and an integral part of the quality system at HIGHPOWER. All contracts/orders are reviewed and accepted only if the requirements are clearly understood, and the company has the capability and capacity to fulfill customer expectations. Reference *HP CSOP 018* Supplier Quality & Purchasing Controls.
- Communication is maintained with the client from the time a request for quote is processed through commencement of work. This includes informing the client of any deviation from the accepted PO or the completed customer sample submission form and obtaining approval prior to beginning testing.
- If a PO needs to be amended after work has commenced, the same contract review process is repeated. Any amendments are communicated to affected personnel and the customer.
- Subcontracting Testing Services
 - From time to time HIGHPOWER may subcontract work based on workload, expertise or temporary incapacity or to ensue new business relationships. As required, HIGHPOWER will make the appropriate arrangements to ensure that the customer's and ISO 17025 requirements are met per HP LSOP 070 Lab Services Subcontracting.
 - The contract review process applies to any work that is subcontracted out.
 - The subcontractor will be an approved supplier per HP LSOP 070 Lab Services Subcontracting
 - HIGHPOWER informs all clients of the arrangement to subcontract, and if appropriate, obtains customer signatures as approval to subcontract.
 - HIGHPOWER is responsible for the subcontractor's work, except when the customer or a regulatory authority specifies the subcontractor.
 - HIGHPOWER occasionally utilizes off-site testing facilities. In these instances, tests are performed by HIGHPOWER personnel. If the off-site testing facility's equipment is used, the test setup and calibration are verified for compliance to ISO 17025.
 - Calibration of HIGHPOWER test and measuring equipment is subcontracted to an ISO 17025 accredited calibration laboratory or inspected, verified or calibrated internally.
- Purchasing Services and Supplies
 - The HIGHPOWER purchasing department maintains approved suppliers for the purchase of supplies and services that have a direct effect on the quality product and testing performed. Reference *HP CSOP 018* Supplier Quality & Purchasing Controls.

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- Purchased services, supplies and consumable materials directly affecting testing quality are not used until an incoming inspection is performed to ensure compliance with specified requirements per *HP LSOP 059 Purchasing and Receiving Procedure* and in conjunction with *HP LSOP 059 Purchasing and Receiving Procedure*, *HP LSOP 039 Contract Sterilization and Lab Services Flow Chart*.

4 Customer Service

- HIGHPOWER does everything possible to assure that customers receive the best possible service while maintaining the utmost in confidentiality when required. Customer service may include but is not limited to the following:
 - Affording customers access to the laboratory to witness testing when requested.
 - Preparing, packaging and dispatching test items and reports as required by our customers for verification purposes.
 - Advising, guiding and communicating with our customer on technical matters, providing opinions and interpretations for testing performed or to be performed.
 - Communicating to our customers any major deviations in testing being performed.
 - Communicating to customers any delays that may result in the customer not receiving their testing in a timely manner.
 - Notifying customers of any event that casts doubt onto the validity of results supplied to them. Performing periodic customer surveys.
- Customer Complaints

Complaints, both verbal and written, are documented in accordance with *HP CSOP 031 Complaint Handling Procedure*, which addresses the methods for documenting, investigating and resolving complaints to the customer's satisfaction.

5 Quality System Monitoring and Measurement

- Control of Nonconforming Testing
 - The control of nonconforming/out of specification testing and/or work is to ensure reliable test results and to provide a standard procedure for containing and correcting results that do not conform to the agreed requirements of the customer.
 - Employees are responsible for halting nonconforming/out of specification work, notifying their direct supervisor and following *HP CSOP 023 Out Of Specification Procedure* for resolutions.
 - The control of nonconforming items or materials received from vendors is covered under *HP CSOP 003 Control of Nonconforming Items or Materials*.
- Continual Improvement

HIGHPOWER is committed to continually improving the quality management system for process improvement. Continual improvement is accomplished through management team's actions by:

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- Reviewing and updating the Quality Policy.
- Reviewing internal and external audit results for improvement opportunities.
- Analyzing quality data and customer survey results and using this data to set new quality objectives or modify existing ones.
- Ensuring corrective and preventive actions are implemented and effective.
- Performing periodic management reviews to evaluate the system per HP CSOP 017 *Management Responsibility*.
- Corrective Action
 - *HP CSOP 016 Corrective and Preventive Action* describes the methods for taking action when nonconformities have been identified.
 - Root cause analysis is performed and action taken to eliminate the cause and prevent recurrence.
 - Corrective action is selected to eliminate the root cause of the nonconformity and for effectiveness to prevent recurrence.
 - Corrective actions are monitored and evaluated for effectiveness.
 - Where the identification of nonconformance raises doubt on HIGHPOWER' compliance with its own policies, procedures, or with ISO 17025, additional internal audits are performed to determine if gaps exist. If gaps are identified, corrective action is taken to bring the system back into compliance.
- Preventive Action
 - Preventive action is a pro-active process to identify process and quality system improvement opportunities. Once an improvement opportunity has been identified *HP CSOP 016 Corrective and Preventive Action* describes the methods for taking appropriate action to improve performance.
 - Preventive action implementation is monitored to verify that the needed improvements have been realized and are effective.
 - Quality walk-throughs may also be performed in the lab, warehouse & shipping/receiving areas to identify process and quality system improvement opportunities.

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■ Internal Audits

- Periodic audits of HIGHPOWER operations are performed in accordance with *HP CSOP 012 Quality Audit Procedure*.
- If audit findings cast doubt on the effectiveness of the operations or the correctness or validity of the HIGHPOWER test results, HIGHPOWER takes timely corrective action, and notifies customers in writing if investigations show that the test results may have been affected.

■ Management Review

- Management Review meetings are periodically held to assess the effectiveness and continuing stability of the Quality System to satisfy the requirements of ISO/IEC 17025 and HIGHPOWER's Quality Policy and Objectives. Detailed rules for scheduling, conducting and the recording of management reviews are specified in per HP CSOP 017 *Management Responsibility*.
- Minutes of the meeting of Management Review are recorded with action items identified and plans for implementing them defined.

6 Technical Requirements

- HIGHPOWER acknowledges that many factors determine the accuracy and precision of the tests performed by a laboratory. These factors include contributions from:

- human factors
- accommodation and environmental conditions
- test methods and method validation
- equipment
- measurement traceability sampling
- handling of test items

■ Testing Personnel

- HIGHPOWER's management ensures the competency of all who operate specific equipment, perform tests, evaluate results and sign test reports. Adequate supervision is provided for staff undergoing training. Personnel performing specific tasks are qualified on the basis of appropriate education, training, experience, and/or demonstrated skills, as required. Reference HP CSOP 013 *Training* and HP CSOP 025 *Job Descriptions*.
- All personnel utilized within the laboratory are employed by or under contract to HIGHPOWER.
- HIGHPOWER maintains current job descriptions per HP CSOP 025 *Job Descriptions* for all managerial, technical, and key support personnel.

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- Training Qualification Records and individual technical/procedural training records are also maintained.

■ Accommodation and environmental conditions

- Environmental controls for the test laboratory are appropriate for the test(s) being performed. A temperature-controlled environment is maintained as required by those tests being performed. Environmental conditions that can affect test results are listed in the technical procedures and documented. Human factors relating to light, ventilation and space are considered with respect to performing required tasks safely and effectively. For each area that requires a controlled environment, HIGHPOWER documents the conditions that might affect the test.
- Environmental factors that may adversely affect test measurements are controlled to the degree necessary so as not to invalidate test results or increase the measuring uncertainty. Tests are stopped when the environmental conditions jeopardize the results of the tests.
- Calibrated temperature-monitoring devices are available and operating whenever testing necessitating temperature is being performed. Areas requiring environmental control have their temperature recorded and maintained on file. Reference HP LSOP 024 Temperature and Humidity Monitoring.
- Effective separation of test environments is maintained in work areas for safety and quality purposes.
- Access to the laboratory is limited to authorized personnel and approved visitors. Visitors must sign in and out of the building and are supervised at all times.
- It is the policy of HIGHPOWER to maintain all areas in a clean and orderly manner.

■ Test methods and method validation

- All instructions, standards, manuals and reference data relevant to the work of the laboratory are part of the document control system.
- Current test methods are controlled and stored in a specific location within the lab.
- Testing instructions are provided by the customer or written by HIGHPOWER staff and approved by the customer for the test performed. Any deviations from test instructions must be accepted by the customer and recorded.
- Where the customer does not specify a testing method, the Manager, Validation and Testing Services will select a published national or international standard or United States FDA guidance document. Methods that have not been established as a standard are fully documented, statistically validated and agreed to by the involved parties.
- When HIGHPOWER must develop a procedure for performing a test, a test plan or protocol is developed. The test plan/protocol must identify how the test will progress from start to finish. Whatever testing plan/protocol is used, it must be documented. If the customer

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requests a test method that is not optimal, HIGHPOWER will inform the client that the method is not optimal (i.e. inappropriate or out of date). However, if after notification the client still wants to proceed, the test could be performed with the written approval of the customer.

■ Estimation of Measurement Uncertainty

- The extent to which the factors contribute to the total uncertainty of measurement differs considerably between types of tests. HIGHPOWER takes into account these factors in developing test methods and procedures, and in the selection and calibration of the equipment it uses.
- When estimating measurement uncertainty, the requirements and tolerances stated in the applicable test procedure, as well as customer requirements, are reviewed to determine any potential measurement uncertainty. If any critical measurement uncertainty exists, or there is a customer or regulatory requirement, it will be included in the analysis of the test results and stated in the test final report. Reference HP LSOP 098 Estimating Measurement Uncertainty.

■ Control of Data

- Calculations and data transfer are subject to checks by someone other than the person performing the work, prior to reporting the data to the customer.
- HIGHPOWER utilizes computers and automated equipment for the capture, processing, manipulation, recording, reporting, storage and retrieval of test data.
- HIGHPOWER utilizes no specialized software that requires validation for use. Currently, only commercial off the shelf software is utilized. Procedures are established to ensure integrity and confidentiality of data entry and data collection, data storage, and data transmission. Reference *HP CSOP 014 Document Change Control* and *HP CSOP 015 Good Document Practices*.

■ Test Equipment

- The HIGHPOWER laboratory is furnished with all items of sampling, measurement and test equipment required to correctly perform all testing specified.
- To assure that equipment used for testing complies with specification requirements and are capable of achieving the accuracy required for each test performed, the following procedures, and the systems associated with them, have been instituted to assure compliance with specifications relevant to the tests concerned:
 - *HP CSOP 014 Process Validation*
 - *HP CSOP 010 Inspecting, Measuring and Testing of Equipment*
 - *Multiple company LSOP's concerning equipment preventive maintenance and repair*

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- Only authorized personnel are permitted to operate laboratory equipment. Relevant manuals provided by the manufacturer of the equipment are controlled and are made readily available for use by personnel. Instructions on the use and maintenance of all equipment are kept up to date and are readily available.
- Gages, measuring and test equipment are uniquely identified and labeled to identify the calibration status.
- Calibration, inspection and verification records for measurement test and operational equipment are maintained per the respective procedures:
- Measuring Equipment is handled safely, transported, stored, used and maintained to ensure proper functioning and to prevent contamination and deterioration.
- Equipment that has been damaged, overloaded, shown by verification or otherwise found to be producing suspect or defective results is identified as such and removed from service. Defective equipment activities are evaluated for any affect the equipment may have had on previously reported test results. Appropriate action is taken in accordance with HP CSOP 023 - Out Of Specification Procedure.
- **Measurement Traceability**
 - Measuring and test equipment having an effect on the accuracy or validity of tests are calibrated and traceable to a national or international standard.
- **Sampling**
 - HIGHPOWER meets the sample size requirements as defined or is historically accepted by the United States Food and Drug Administration she should.
 - Where client requires deviations, additions, or exclusions from the documented sample size, these deviations are recorded and included in all documents containing test results and are communicated to the appropriate personnel.
- **Handling of test items**
 - The transportation, receipt, handling, storage, retention and/or disposal of all test items are defined in HP LSOP 026 Processing Customer Supplied Samples, *HP LSOP 059 Purchasing and Receiving Procedure* and *HP LSOP 039 Contract Sterilization and Lab Services Flow Chart*.
 - Unique and permanent identification of test items is maintained throughout the life of the test.
 - Any abnormalities of departures from normal or specified conditions as described in the methods and are recorded. When there is doubt as to the suitability of an item for test, or when an item does not conform to the description provided, HIGHPOWER consults with the client for further instructions before proceeding.

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- Where test items need to be stored or maintained under specific environmental conditions, the conditions are monitored, maintained and recorded.

■ Test Quality Assurance

- There is no external proficiency test available for the services provided by HIGHPOWER. Therefore, HIGHPOWER has incorporated into our training program the following system to monitor the validity of tests:
 - Employees read the written procedures (i.e. LSOP) on a task they are being trained to perform and then document that they understand the procedure with signature and date.
 - Employee in training watches an experienced employee (an employee signed off to perform the task) perform the task one or more times.
 - When judged by their supervisor to have gained enough knowledge about the task, the employee in training will perform the task under observation of the supervisor or their designee.
 - When possible, the employee in training will have the results of their task compared to the results of the experienced employee who performed the same task.
 - Depending on the outcome of the results from the employee in training, this sequence may be repeated one or more times until the employees' direct supervisor acknowledges the competency of the employee in training to perform the task and signs off in the employees' training binder with signature and date.
- Employees are asked to keep track of the total time required to perform a test on an "Activity Tracking" form. These forms are reviewed and data is generated for comparison with past test performed by the employee, test performance between technicians, overall efficiency etc. and can be analyzed for detectable trends.
- Completed test go through a technical review and a quality review to check the accuracy and proficiency of the test performed by each employee. The signatures and dates of the review are documented.
- In addition to periodic audits, testing quality assurance is an ongoing process. Data is compiled on the proper completion of test documentation and can be reviewed for detectable trends. Test quality and any trends are monitored and results are included in the Management Review process.

■ Reporting Test Results

- Test results are reported accurately, clearly, unambiguously and objectively on test specific forms or on HP QC 042 Miscellaneous Data Forms. These results and forms are kept within the individually identified specific customer study folder.

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- If testing is subcontracted, the subcontractor will provide hard copy or electronic test reports to HIGHPOWER. When HIGHPOWER test reports include testing performed by subcontractors, the subcontractor lab results are clearly identified.
- Test Reports contain the following information (at a minimum):
 - Title
 - Name and address of the testing laboratory and location(s) where testing occurred
 - Unique identification of the test report by number, and on each page an identification in order to ensure that the page is recognized as part of the report
 - The name and address of the client
 - Identification of the test method used
 - Description of and identification #'s of the items tested
 - The date(s) of performance of the test
 - Reference to the sampling plan and procedures used by HIGHPOWER where relevant
 - The test results and appropriate units of measurement
 - The name(s), function(s) and signature(s) or equivalent identification of person(s) performing the test and those authorizing the final test report
 - Where relevant, a statement to the effect that the test results relate only to the items tested

- Interpretation of test results

Testing interpretation includes the following:

- Deviations from, additions to, or exclusions from the test methods and information on specific test conditions, such as environmental conditions
- Where relevant, a statement a compliance/non-compliance with requirements and/or specifications
- Where necessary, a statement of the estimated uncertainty of measurement
- Where appropriate and needed, opinions, discussions and interpretations
- Additional information which may be required by specific methods, clients or groups of clients

- Opinions and Interpretations

When opinions and interpretations are included, HIGHPOWER documents the basis upon which the opinions and interpretations have been made. Opinions and interpretations are clearly marked as such and may also be identified in a discussion section.

END OF THE
DOCUMENT