



Nelson Labs™

A Sotera Health company

6280 South Redwood Road
Salt Lake City, UT 84123-6600
Tel. (801) 290-7500 Fax (801) 290-7998
www.nelsonlabs.com

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TITLE: Nelson Laboratories Quality Manual			SECTION/DEPT: Regulatory Affairs

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1.0 INTRODUCTION

1.1 Purpose: This quality manual provides employees, auditors, and customers of Nelson Laboratories, LLC (NL) with a description of the quality management system and quality policy. This manual is a primary document and references lower level procedures (SOPs) for specific subsystems and detailed procedures. The SOPs referenced are working documents and may be updated and made effective without updating this manual prior to its scheduled review. The date of this manual is the effective date as shown on the cover page.

Our mission is to help the best companies in the world improve the quality of life by providing the highest standard in laboratory testing, partnering to bring life-enhancing, innovative products to market. Our customers and employees are our most important assets.

1.2 Scope: This quality manual, and the corresponding quality management system, encompass all aspects of ISO 17025 (which encompass ISO 9001 provisions) and applicable aspects of 40 CFR Part 160, and 21 CFR Parts 11, 58, 210/211, 820, and 1271. A separate policy and procedures manual (MAN0006) exists for personnel matters.

This quality manual is applicable to the following laboratory locations:

6280 S Redwood Rd, Salt Lake City, UT 84123, USA

1500 W Thorndale Ave, Itasca, IL 60143, USA

687 S Wanamaker Ave, Ontario, CA 91761, USA

James Watt No. 22, Cuautitlan Izcalli, Estado de Mexico, CP 54730, Mexico

1.3 Justification: A quality policy is required to be established, understood, implemented, and maintained.

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2.0 RESPONSIBILITIES

- 2.1 It is the responsibility of the NL senior leadership team to ensure the quality policy is understood, implemented, and maintained. This is achieved by ensuring the policy is communicated and employees are regularly trained regarding the policy. Management is committed to comply with the ISO 17025 International Standard and applicable Federal regulations to continuously improve the effectiveness of the management system.
- 2.2 It is the responsibility of all NL employees to familiarize themselves with the quality manual, procedures, and policy and implement the policies and procedures in their work.

3.0 DEFINITIONS

- 3.1 AAMI: Association for the Advancement of Medical Instrumentation
- 3.2 AOAC: Association of Official Analytical Chemists
- 3.3 ASTM: American Society for Testing and Materials
- 3.4 CAPA: Corrective and preventive action
- 3.5 CSS: Customer Specification Sheet
- 3.6 HR: Human Resources
- 3.7 ICH: International Conference on Harmonization
- 3.8 IEST: Institute of Environmental Sciences and Technology
- 3.9 IT: Information Technology
- 3.10 KAIZEN: A method of continuous incremental improvement which is originally a Japanese management concept for incremental (gradual, continuous) change (improvement)
- 3.11 LMS: Electronic Laboratory Management System (e.g. UNIFlow)
- 3.12 LSR: Laboratory Supply Report
- 3.13 MMO: Metrology and Maintenance Operations
- 3.14 PDA: Parenteral Drug Association
- 3.15 PDD: Professional Development Department
- 3.16 QA: Quality Assurance
- 3.17 QC: Quality Control
- 3.18 QCOMM: Quality Committee (management review)
- 3.19 SD/RP: Study Director/Responsible Person
- 3.20 SOP: Standard Operating Procedure
- 3.21 STP: Standard Test Protocol

4.0 FREQUENCY

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- 4.1 This document is reviewed approximately biennially.
- 4.2 Changes to a working draft of this procedure may be proposed at any time, as needed (e.g., process changes, reference updates, etc.). The changes will be reflected in the next released revision.

5.0 QUALITY MANAGEMENT SYSTEM

5.1 Overview

- 5.1.1 NL's philosophy is to build in quality by design rather than by inspection. Extensive effort is made to ensure test methods are validated to ensure repeatable and reliable results can be obtained.
- 5.1.2 A customer's request for testing is documented during the sample submission process, including any special requirements. An evaluation of the request and requirements is made by the study director prior to the conduct of the testing. Any specific resources or validation efforts can then be planned for and incorporated if needed.
- 5.1.3 The customer's testing requirements are met through execution of controlled procedures, such as standard testing protocols (STP), customer specification sheets (CSS), or other forms of approved protocols.
- 5.1.4 Customer satisfaction is measured to ensure that all needs have been met. Customer feedback may trigger preventive and corrective action to ensure continual improvement.
- 5.1.5 For testing, measurement is by controls, monitors, statistical techniques or other means, as appropriate. Conformance to prescribed reference standards specifications, compliance to procedures, and customer feedback are the criteria used to evaluate effectiveness or performance.
- 5.1.6 For the quality management systems (e.g., out of specifications, retests, amended reports, deviations, internal audits, complaints, corrective and preventive action, etc.), trends, company goals, and customer feedback are the criteria used to evaluate effectiveness.
- 5.1.7 Performance of quality metrics are tracked continually and reviewed by management.

6.0 DOCUMENTATION REQUIREMENTS

6.1 General

- 6.1.1 The quality policy and objectives are contained in this quality manual. Annual goals are posted and reviewed regularly. NL maintains quality documents required by EU GMPs, ISO 17025, 21 CFR parts 820, 58, 211, 1271, and 11, and 40 CFR part 160, as applicable to our scope of services.

6.2 Distribution

- 6.2.1 The quality manual is maintained in electronic format and is available to all employees. Printed copies are available as needed. All employees are required to document that they have read and understand the quality policy

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outlined in the manual. This manual may also be distributed to client and potential clients upon request.

6.3 Control of Documents

6.3.1 Documented procedures to control documents related to the requirements of the NL quality system are established. All documents are reviewed and approved prior to being issued. Electronic documents are available at locations where they are used. Obsolete documents are properly identified and are available for historical reference when needed.

6.3.2 NL quality system documentation is comprised of a tiered documentation system.

6.3.3 Procedural and software controls ensure documents and data are reviewed and approved for adequacy by authorized personnel prior to issue.

6.3.4 An electronic document control system identifies the current revision status of documents. The controls ensure the following:

- Only current revisions of appropriate documents are available at computer locations throughout the building in order to facilitate easy access to documents needed for employees to perform their work.
- Invalid and/or obsolete documents are archived and not available for unintended use.
- Retired documents are retained in an archived state, in compliance with record retention requirements, and are suitably identified.

6.3.5 Document changes may be initiated by anyone in the organization. However, these documents are only issued by Document Control after appropriate review and approval according to the above mentioned procedures.

6.3.6 Standard operating procedures, work instructions, protocols and related documents are reviewed on an approximately biennial basis, or as the need for changes arise, to ensure continuing suitability and compliance with applicable requirements.

6.3.7 The process requires that document and data changes are reviewed and authorized by the same function that issued the original document, unless otherwise specified in the procedures.

6.3.8 Approved changes are communicated to the appropriate personnel in a timely manner. Records of changes to documents are maintained.

6.3.9 Documents are only issued after changes have been reviewed and approved by appropriate personnel.

6.3.10 Training requirements are assessed based on the magnitude of the changes. Effectivity dates are established accordingly.

6.4 Spreadsheet Templates

6.4.1 Executable copies of the NL software spreadsheet templates are maintained in a security controlled file system. All spreadsheets are validated to ensure data accuracy. Templates are normally color coded and constructed to permit

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only data entry into specific fields. The ability to change fields in the spreadsheet is password controlled.

6.5 Control of Records

- 6.5.1 Some facilities maintain an on-site record storage archive. These archive areas are only accessible by authorized personnel. Approved off-site record storage facilities may also be utilized.
- 6.5.2 Records placed into and removed from archives are logged by an approved archivist or delegate.
- 6.5.3 Data files may be electronically archived.
- 6.5.4 All raw data and required quality records or true copies thereof are maintained for a minimum of 10 years.

7.0 MANAGEMENT RESPONSIBILITIES

7.1 Management Commitment

- 7.1.1 Management is committed to all aspects of the quality system described in this manual. Management communicates, by word and example, the importance of meeting regulations and customer needs. Management inspires an attitude of quality through laboratory policies, actions, and staff. This requires a significant and ongoing commitment to training in the areas of technical capability, customer service, and quality. Documentation relating to and supporting laboratory quality are readily accessible to the entire staff through the computer network.

7.2 Customer Focus

- 7.2.1 Management ensures that customer service is a constant focus, as described in the quality policy and throughout this manual. Management ensures that customer service training is carried out frequently and that customer feedback is reviewed, communicated and addressed. Management tracks any failure to follow customer requests, and quality issues and complaints are tracked to prevent repeated problems.

7.3 Quality Policy

- 7.3.1 Quality Policy Statement: We are united in our commitment to build relationships of trust, deliver service excellence, provide value through quality, and constantly increase our productivity (RSVP). We are passionate about our clients' needs, listen closely to feedback and solve problems fairly with a focus on the long term partnership. We strive to be audit ready by complying with all governing regulations and procedures. We act with integrity, impartiality, and independence and can be trusted to do things right the first time. We monitor our quality management system and foster a culture of continuous improvement.
- 7.3.2 Mission Statement: We help the best companies in the world improve the quality of life by providing the highest standard in laboratory testing, partnering to bring life-enhancing innovative products to market.
- 7.3.3 Values:

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- **Safety** - We are uncompromising in our commitment to health and well-being.
- **Customer Focus** – We are driven to fulfill our customers’ needs with the highest quality and care.
- **People** – We value our people who are part of a global team that is diverse, respectful, passionate and collaborative.
- **Integrity** – We are honest, reliable and accountable in everything we do.
- **Excellence** – We exceed the expectations of our stakeholders and continue to improve and innovate in everything we do.

7.3.4 NL's goal is to provide the highest quality laboratory results with a high level of value and to make every effort to provide the results when the customer needs them. We treat all of our customers as they would like to be treated. We endeavor not to make unnecessary rules for our customers. We do whatever it takes, without compromising quality, to complete the job on time and as expected. We always strive to provide “knock their socks off” service. Every NL employee is a customer service representative.

7.3.5 To accomplish turnaround time (TAT) goals and communicate with sponsors, NL management:

- Monitors TAT performance
- Sets TAT goals with employees
- Maintains lists of TATs

7.3.6 To accomplish quality goals, NL management:

- Maintains a commitment to hiring excellent quality staff and providing them with the tools and resources they need to do their job well.
- Maintains a full-time professional development department (PDD) to ensure that new employees are trained appropriately
- Verifies the effectiveness of training through initial qualifications, ongoing proficiency testing, examination, evaluation, or other means of proving competency
- Maintains state-of-the-art laboratory facilities
- Maintains a sophisticated metrology laboratory with NIST-traceable standards
- Provides easy document accessibility
- Analyzes trends and critical systems to ensure continuous improvement
- May perform Kaizen (i.e., continuous improvement) events to continually refine and improve processes

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- Sets goals for quality performance and quality improvement
- Trains staff to always carry out testing in accordance with the NL standard operating procedures, protocols and other documents and as stated in customer-specific requirements
- Requests client feedback via surveys, customer service and sales visits, on-site audits, and the NL website
- Ensures the integrity of the management system when changes are made by the use of a formal change management system
- Collaborates with our customers to ensure we clearly understand their expectations and testing requirements

7.3.7 The quality system is designed to provide a documented framework for providing world class quality service and to comply with good laboratory practice (GLP), good manufacturing practice (GMP), good tissue practice (GTP), and requirements of ISO 17025: General Requirements for the Competence of Testing and Calibration Laboratories.

7.3.8 NL is committed to good professional practice, providing the highest quality service, and striving for continuous improvement. The quality policy is reviewed annually, and quality goals are reviewed in annual management review meetings. Goal performance is reviewed regularly by the quality committee, by area supervisors, and management. The quality policy is given to all new employees, is posted in the laboratory, and is regularly included in employee training.

8.0 PLANNING

8.1 Quality Objectives

8.1.1 The quality objectives are the values outlined in the quality policy (7.3). Specific, measurable quality goals are set annually by the staff and monitored throughout the year by management.

9.0 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

9.1 Management communicates responsibilities to employees via job descriptions which are signed by the appropriate supervisor. Authority is communicated directly and documented in the organizational chart.

9.2 Organizational Charts: Top management ensures that responsibilities and authority are defined and communicated. A copy of the organizational structure outlines these responsibilities and is available upon request. The organizational structure is outlined using organizational chart format and shows interactions important to the quality system. Organizational charts are reviewed and updated routinely.

9.3 President: The president is responsible for all operations and for the strategic vision and direction of Nelson Laboratories. The president must ensure the company acts in accordance with its mission and values and is meeting the corporate expectations. The senior leadership team (see below) reports to the president. The president may also supervise other functions when necessary.

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- 9.4 Senior Leadership Team: The senior leadership team consists of the President, Vice President (VP) of Operations, Senior Director of Information Technology, Vice President of Human Resources, Vice President of Finance, Vice President of Strategy, Vice President of Quality, and Vice President of Sales. This group meets regularly with the President to advise on strategy, report on company performance, plan resources, and set company direction. These managers maintain an open door policy to provide easy access for all staff members.
- 9.5 VP of Finance: The VP of Finance is responsible for all financial issues, including monthly and annual financial statements, preparing budgets and monthly variance reports, preparing cash forecasts, setting up and maintaining departmental cost systems, taxes, and supervising and training accounting personnel. When applicable, purchasing from an approved source and ensuring received items are quarantined until proper QC is performed and released.
- 9.6 Senior Director of Information Technology: The Senior Director of IT is responsible for managing the architecture and information technology functions of the company.
- 9.7 VP of Human Resources: The VP of Human Resources is responsible for the supervision of the HR and professional development managers and management of talent, leadership development, and succession planning for the company.
- 9.8 VP of Operations: The VP of Operations for each geolocation is responsible for supervising the directors of laboratory operations, validation manager and MMO manager, providing laboratory resources, managing routine scheduling of studies, assessing staffing needs, etc. The VP of Operations may assign a Director of Lab Operations as his deputy.
- 9.9 VP of Quality: The VP of Quality is responsible for all quality issues pertaining to laboratory operations. The VP of Quality supervises the Quality Assurance (QA), Reporting, Continuous Improvement and Document Control (DC) departments. Responsibilities include ensuring the quality system is implemented and followed at all times and overall compliance with applicable regulations and ISO standards, review of standard operating procedures, regulatory compliance, ISO 17025 compliance, controls, validation efforts, and overall company quality. The VP of Quality may assign a Senior Director/Director of Quality as his deputy.
- 9.10 VP of Sales: The VP of Sales is responsible for overseeing the customer relationship and value proposition and institutionalizing the customer care culture, sales efforts of the company.
- 9.11 Senior Director of Quality Assurance: Reports to the VP of Quality. Responsibilities include ensuring the quality system is implemented and followed at all times and overall compliance with applicable regulations and ISO standards. Quality systems include management review, complaints, corrective actions, change management, and audits.
- 9.12 Director of Quality Assurance (QA): Reports to the Senior Director of Quality. Responsibilities include ensuring proper final product release of GLP reports, inspection of data, preparation of final test reports, and trending of laboratory quality metrics. The Director of QA is responsible for ensuring that the quality system is implemented and followed at all times. The Director of QA is also

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responsible for SOP and validation review and approval. Authority to release GLP final report data is delegated only to QA and is the ultimate responsibility of the Director of QA. The Director of QA may delegate the specific responsibilities to staff. The QA Manager is a deputy for the director.

- 9.13 Directors of Laboratory Operations: Directors of Laboratory Operations report to the VP of Operations and have responsibility for oversight of the laboratory sections. They work closely with section leaders to ensure effective resource management, quality in operations, and delivery consistency for customers.
- 9.14 Senior Lab Operations Managers (SLOMs): SLOMs manage specific laboratory departments. Their responsibilities include all phases of laboratory management for the specific section. SLOMs report to Directors of Laboratory Operations.
- 9.15 Function Leaders: Function leaders manage non-laboratory departments. Their responsibilities include managing the specific department functions, supervising personnel, ensuring appropriate resources are available and ensuring compliance with applicable procedures.
- 9.16 Professional Development Manager: The professional development manager is responsible for new employee training, laboratory training, NL Academy courses, update training, and procedure review. The professional development manager must have a technical degree and be skilled in teaching.
- 9.17 Validation Manager: The validation manager is responsible for software and method validations, equipment, facility and systems (EFS) qualifications, maintenance of installation, operational, and performance qualification records, proficiency testing, control charts, and for assisting the MMO department in the completion of those records. This manager is also responsible for establishing specifications for laboratory supplies.
- 9.18 Signatories
 - 9.18.1 General management signatories may include all of the following managers: members of senior leadership team, laboratory managers, section leaders, department managers, directors, and function managers, as identified on the organizational chart. Technical authorization is given to the study directors, who are responsible for individual studies from start to finish, as stated in the SOP. Every final report must be signed by the study director.
- 9.19 The roles and responsibilities of the technical and quality managers outlined herein are overviews. Additional information regarding certain departmental or individual role responsibilities are outlined in the applicable procedure.
- 9.20 Management Representative: The VP of Quality has primary responsibility and the Directors of Quality have secondary responsibility to ensure that the quality system is adequate and effective. Performance trends and improvement needs are reported to top management. The management representative also has direct access to the senior leadership team, including the President.
- 9.21 Internal Communication
 - 9.21.1 Internal communication is outlined in the system summary (9.0). In addition, the following communication measures are implemented.

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- Information related to quality issues is disseminated approximately monthly. Areas of focus may include corrective and preventive actions, customer complaints, audits, trend analysis, or other sources. This provides a mechanism to achieve knowledge transfer of best practices.
- Company goals are set annually and are communicated. Performance is then posted regularly. Performance against these goals is regularly reviewed by management.
- A suggestion system is maintained for employees who wish to help improve the organization.

10.0 MANAGEMENT REVIEW

10.1 General

10.1.1 The quality committee meets regularly to review the quality management system to ascertain its adequacy and effectiveness and to assess opportunities for improvement. An in-depth review of the entire laboratory quality system is conducted semiannually. A review of company goal performance is conducted annually. Minutes of quality committee meetings are maintained for evidence of review and actions taken.

10.2 Review Input

10.2.1 Quality indicators, constraints, performance metrics, customer feedback, and other items are reviewed by the Quality Committee.

10.3 Review Output

10.3.1 Output from management review may result in one or more of the following; corrective action, preventive action, assigned tasks, training, or procedural changes. Management review actions items are officially assigned and tracked to completion.

11.0 RESOURCE MANAGEMENT

11.1 The senior leadership team meets regularly to determine, review, and discuss company strategy and the implementation thereof. Members of the senior leadership team review change management requests. Senior Laboratory Operations Managers are expected to make assessments of their sections' resource needs, allocate those resources, and report to the management team on issues they are not able to resolve. The quality committee may also assess resource needs when appropriate.

11.2 Provision of Resources

11.2.1 The identification and acquisition of controls, processes, equipment, fixtures, and resources that may be needed to achieve the desired quality and turnaround time are routinely reviewed. This process allows input to the quality process by all employees.

11.3 Human Resources

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11.3.1 General

11.3.1.1 Employees are hired with an appropriate combination of education, training, skills, and experience for their position. The quality of the analytical process is directly related to the technical skills of the persons performing the process. Control of the total process can be improved by increasing the technical skills of the section leaders, study directors, lab analysts and other lab personnel. This is facilitated by a full-time professional development manager.

11.3.2 Competence, Awareness, and Training

11.3.2.1 Routine proficiency testing, control samples, and quizzes are used to measure competence. The staff is made aware of how their activities contribute to meeting quality objectives through training.

11.3.2.2 Prior to entering the laboratory, all personnel must complete basic training. This training includes, but is not limited to, training in science, safety, quality regulations, and company policy. The basic training is in a variety of formats including videos, reading, and hands-on sessions. Employees are given examinations on important aspects of this training.

11.3.3 Training Intervals

11.3.3.1 New employees' training consists of a rigorous curriculum comprised of regulations, culture, policies and procedures, and on the job training. Thereafter, an employee's training record is reviewed annually by the employee and training needs are reviewed regularly by the supervisor and employee. Training requirements are audited during applicable system internal audits. Specific time frames for re-training are detailed in test procedures as applicable. GXP training is also conducted approximately annually as applicable to each facility.

11.3.4 Training System

11.3.4.1 Documentation is maintained for all training events. These records may be maintained electronically.

11.3.4.2 NL's professional development department is responsible for overseeing all training. The department is responsible for orientation of new or transferring employees and works in collaboration with the employee's supervisor for identification of their training needs, preparation and maintenance of training videos and similar materials, and scheduled training classes.

12.0 INFRASTRUCTURE

12.1 Appropriate building, work space, and associated facilities are provided. NL carries out analytical activities at its permanent facilities, with the exception of certain tests being performed at the customer's site upon request (e.g., sterilization validation).

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Equipment is calibrated and maintained as required for the test system. Hardware and software are provided to accomplish testing and documentation to a high standard of quality. Supporting services include phones, e-mail, internet access, communication boards, meeting rooms, bulletin boards, etc.

12.2 Work Environment

12.2.1 NL takes active steps to ensure the work environment promotes positive attitudes, cooperation, ergonomic comfort, and overall quality.

12.3 Environmental Control

12.3.1 NL has a wide range of environmental control procedures and systems to ensure that environmental control is maintained. Environmental Temperature Control

12.3.1.1 Critical environments are controlled and monitored. In most instances, an automated monitoring system is used to continuously monitor critical environmental conditions such as temperature and humidity. The system is set with establish limits and out of range criteria, thus allowing the system to identify approaching out of range conditions. As limits are approached, the system notifies personnel of the approaching condition to allow proactive measures to be taken. Out-of-range (OOR) values are addressed via a formal procedure which details the equipment item, nature of OOR, customer notification requirements, and resolution.

12.3.2 Environmental Microbial Monitoring

12.3.2.1 NL performs extensive microbial monitoring. The environmental monitoring includes both fallout and surface contact plate monitoring throughout the laboratories.

13.0 PRODUCT REALIZATION

13.1 The product produced by NL is a test result documented in the form of a final report.

13.2 Product Realization Planning

13.2.1 Each study has a quality plan. Objectives, processes, resources and documents for each study are defined in the STP, protocol, or standard method. For new non-compendial methods, objectives, processes, resources, and documents are identified prior to performance of the test via the validation process.

13.2.2 The delivery of quality laboratory services consists of providing both quality and rapid results. Therefore, it is necessary to monitor and publish achieved performance, set turnaround time goals for employees, advise customers of expected turnaround time upon receipt of samples, correlate sponsor turnaround time requirements with laboratory capabilities, and identify samples which require expedited reporting.

13.2.3 NL subscribes to a variety of technical, industry and regulatory publications. These include publications such as Pharmacopeia Forum,

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Pharm-Europa, and the AOAC Journal, which identify pending method revisions with sufficient advance notice to allow the laboratory to make appropriate method, instrumentation, and paperwork changes. Staff members serve on AAMI, ASTM, PDA, IEST and other technical committees, allowing input and early knowledge of new or revised standards.

13.2.4 All tests are performed by following written procedures. Testing procedures are normally taken from applicable national and international standards. Tests incorporate, whenever possible, negative and positive controls and/or reference materials. All tests are evaluated for compliance with the written STP or protocol and whether or not the results expected for the controls or reference materials have been produced.

13.2.5 The identification and preparation of quality records are defined within individual STPs and protocols. Each STP and protocol has a records section which specifies the records to be maintained. Each STP and protocol has archive release forms. These forms contain a checklist of the items that are required to be included in the final study file.

13.3 Customer-Related Processes

13.3.1 Determination and Review of Product Requirements

13.3.1.1 NL performs all tests in accordance with STPs or specific written protocols.

13.3.1.2 Test codes are provided by NL on the price list and quotes and are accompanied by a written description of the service. Test codes are included on the sample submission form to request specific services. The test code and accompanying description are used to identify the responsible department and the appropriate STP.

13.3.1.3 For studies performed under STPs, the submission form or letter requesting a standard test is considered the contract. Occasionally, clients may have specific requests in addition to the STP for their particular product or project. These client specific requests may be captured on the sample submission form, customer specification sheet (CSS), or on another approved format that accompanies the study.

13.3.1.4 When work requires a client specific protocol, a protocol is written, reviewed internally, and then submitted to the sponsor for review and approval.

13.3.1.5 Amendments to contracts regarding testing requests are made by amending the study protocol. This process is defined by written NL procedures.

13.3.1.6 Other contract reviews are performed as directed by the customer or NL needs. These include non-disclosure agreements, confidentiality agreements, consulting agreements,

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quality agreements, change agreements, and master service agreements.

13.3.2 Customer Communication

13.3.2.1 NL communicates with clients through several channels of our business. Changes to customer specific protocols must be approved by the sponsor before proceeding. Changes to STPs are documented internally. The revision of the procedure followed is added to each final report so the sponsor has a written record of the procedural reference. Non-conformities or deviations that affect customers must be communicated to the customer.

13.4 Design Qualification

13.4.1 Design processes ensure that non-compendial test methods include required elements such as, review, approval, quality control requirements, training, safety requirements, inputs, and method validation requirements.

13.4.2 The need to develop a new STP may be expressed by NL personnel or by sponsors who have a specific need in the evaluation of their products. Management determines when the development of a new test method is undertaken.

13.5 Purchasing

13.5.1 Supplier Management

13.5.1.1 NL applies a risk based approach for the evaluation and selection of potential suppliers, subcontractors, and consultants, based on their ability to meet the specific needs and quality requirements.

13.5.1.2 Supplier level risk is designed as a means to gather sufficient information about a supplier's organization, management, technical staff, facility, quality system and equipment (including reference standards and materials) as required for the supplies or services being requested by NL. Supplier qualification is maintained on a Qualified Supplier List. Ongoing assessments of a supplier are performed and documented periodically..

13.5.1.3 Risk is also used to manage supplies.. Depending on the nature of the supply or service being provided, quality and/or change notification agreements are also established with the supplier or subcontractor.

13.5.1.4 If problems occur with supplier products, the issue is reviewed for the need for supplier corrective actions. Issues are tracked until resolution is completed. Issues with a supplier are also trended and feed into the risk assessment of that supplier that drives the type and frequency of audits conducted for the supplier.

13.5.1.5 Tests which are not performed at NL may be subcontracted to an acceptable facility after approval by the sponsor, (e.g., animal

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tests, packaging, and some analytical and calibration tests).
Subcontractors are periodically assessed for evaluation status.

13.5.2 Purchasing Information

13.5.2.1 Each laboratory supply is assigned a unique identifier and appropriate specifications are established.

13.5.3 Verification of Purchased Products

13.5.3.1 Upon receipt, laboratory supplies are processed according to specifications. Items requiring quarantine may be achieved either by quarantine labels or by placement of items into designated quarantine areas. The extent of inspection and/or testing is determined by the specification written for the particular item received.

13.5.3.2 Inspection of all incoming laboratory supplies and other purchased products consists of confirmation of ordered and received item count, confirmation of proper catalogue number of supply item, and a physical inspection of the item and packaging, as a minimum. Traceability for chemicals, reagents, and media is accomplished by the assignment of a unique number upon receipt.

13.6 Production and Service Provision

13.6.1 Validation

13.6.1.1 NL has a validation department which is responsible for scheduling and reporting on all validation issues. The validation manager is responsible for the validation master plan.

13.6.2 Identification and Traceability

13.6.2.1 Upon receipt in the laboratory, all samples received for evaluation are assigned a unique number. The unique number is then used for traceability and to document all records associated with the study

13.6.2.2 The unique identifier is maintained on any laboratory phase samples such as Petri dishes, bottles, etc. Any samples removed from the original container, or specimens resulting from the study, are also identified with this number.

13.6.2.3 Discrepancies in sample ID, count, or condition are promptly communicated to the client to determine the course of action for that sample.

13.6.3 Customer Property

13.6.3.1 NL does not routinely use products or equipment supplied by sponsors. However, under certain circumstances, it may be necessary to use sponsor-supplied equipment. Procedures for receiving, identifying, accessing, monitoring, and returning sponsor-supplied equipment are available.

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13.6.4 Preservation of Product

13.6.4.1 Individual study files are generated during sample receipt. Sample identification, item count, and other sample information are recorded. The forms necessary for recording data for the requested testing are generated from a document control system as needed. Some laboratory tests are automated through computer systems. Data are recorded in specific computer files and final reports are generated in programmed formats. All NL reports are sent to the customer via courier delivery, e-mail, first class mail, or accessed via a secure client server. Measures are taken to provide the most rapid delivery possible.

13.6.4.2 Final reports and associated raw data are archived on paper or optically scanned and maintained in a digital archive for a minimum of 10 years.

13.7 Control of Monitoring and Measuring Devices

13.7.1 All equipment, measuring and reference items are assigned a unique number upon receipt and labeled "OUT OF SERVICE" when the item is not ready for use. Items are inspected and qualified before being placed in service. After an equipment item has been calibrated and/or maintained, the item is released for use. Calibration is performed regularly, or as necessary, on all equipment items used to obtain data values to ensure proper performance of the equipment or test. Maintenance is routinely performed on laboratory equipment.

13.7.2 Calibration and maintenance schedules are maintained either on the computer or on paper for each facility.

13.7.3 NL maintains a sophisticated metrology and maintenance operations (MMO) laboratory with many NIST-traceable standards. Management also supports the philosophy of maintaining current state-of-the-art equipment, whether for equipment calibration or sample processing. The MMO manager or delegate at each site is responsible for receipt and installation of new equipment, documentation, equipment operation and performance qualification, generation and performance of calibration and maintenance procedures, and facilities management. Publication of calibration and maintenance procedures is the responsibility of the document control department. Monthly calibration and maintenance is verified by quality assurance.

14.0 MEASUREMENT, ANALYSIS, AND IMPROVEMENT

14.1 General

14.1.1 NL employs basic statistical techniques for routine monitoring, and trend and problem analysis. Some of these techniques are outlined below:

1 - Cause and effect diagrams

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- # 2 - Flow chart
- # 3 - Correlation or scatter charts
- # 4 - Pareto charts
- # 5 - Run charts
- # 6 - Histograms
- # 7 - Control charts

15.0 MONITORING AND MEASUREMENT

15.1 Customer Satisfaction

15.1.1 Customer satisfaction is measured using customer feedback surveys, internet feedback system, and complaints. Each complaint is investigated, and a formal resolution plan is sent in writing to the client for review. Closure of a complaint is based on customer's acceptance of the plan. During the Management Review process, trends are analyzed and actions taken as necessary. Internal Audits

15.1.1.1 Internal audits are conducted according to a pre-determined schedule to evaluate the performance of applicable systems, functions and regulatory clauses to ensure compliance with applicable regulations and standards, SOPs, and training requirements. The audit schedule may be modified to re-arrange the order of assessments if quality system monitors indicate significant issues with compliance in a particular area.

15.1.2 Monitoring and Measurement of Processes

15.1.3 In-process inspections of studies (data integrity audits), laboratory systems (internal audits), and logbooks are performed. Phases of laboratory studies are monitored and inspected by QA (GLP audits and internal audits)

15.1.4 Monitoring and Measurement of Product

15.1.4.1 The product is considered to be the test result, as documented in the final report. In addition to the study director, QA reviews all GLP studies for compliance, accuracy, and completeness. Non GLP designated studies require a second person to review the record for accuracy, completeness, and compliance with established standards. Formats are governed by 21 CFR 58 (FDA GLP), 40 CFR 160 (EPA GLP), and ISO 17025 reporting requirements.

15.1.4.2 All changes to final reports are made by reissue of the report with an amended code after the study number.

15.1.4.3 Test and inspection data, are stored in an approved record retention location or in the digital NL archives. The archive areas are only accessible by authorized personnel. Laboratory records are removed from working lab areas and transferred to archives or Document Control at frequent intervals.

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15.2 Control of Nonconforming Product

15.2.1 Purchased Supplies

15.2.1.1 Purchased laboratory supplies, reagents, or media may be subjected to physical condition and specification verification. Accepted items are transferred to supply storage or laboratory areas. Nonconforming materials are stored in a designated area, until arrangements can be made for disposition.

15.2.1.2 The warehouse supervisor or designee is responsible for receipt, quarantine, acceptance of items, and control of nonconforming purchased products.

15.2.2 Out of Specification (OOS) Procedures

15.2.2.1 OOS procedures are different for a test laboratory than for a product manufacturer, and therefore, NL handles OOS using multiple unique systems.

15.2.2.1.1 Environmental conditions that go out of specification require a formalized response dictated by procedure.

15.2.2.1.2 Non-temperature related environmental conditions such as microorganism specifications that go out of specification require responses outlined in the applicable procedures.

15.2.2.1.3 When controls or reference materials do not perform as expected, or when a protocol, SOP/STP, or sponsor instruction is not followed, the appropriate actions are taken corresponding to the governing procedure. These actions may include the following:

- Deviation: A deviation is documented if the result is justified as valid, and approved.
- Retest: If the result is invalid, a retest should be done.
- Study Discontinuation: If a retest is needed but cannot be performed, the project may be discontinued and any valid results are reported.

15.2.2.2 Out of specification (OOS) results are tracked and trended by QA and presented to the quality committee.

15.3 Analysis of Data

15.3.1 Data are collected and presented as described in specific sections of this manual.

15.4 Continual Improvement

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15.4.1 NL is committed to continual improvement through the use of the quality policy, quality goals, audit results, trend analysis, corrective action, preventive action and other systems specified herein. In addition, Kaizen teams and other teams or initiatives may be designated to evaluate and improve company systems.

15.5 Corrective Action and Preventive Action

15.5.1 The NL corrective and preventive action (CAPA) system is designed to capture, track, and document specific non-compliances, response to adverse trends, and potential non-compliances.

15.5.2 Any employee may request a CAPA. CAPA events are documented, tracked and trended. Systems feeding into the CAPA system include: amended reports, deviations, out of specifications, re-analysis, internal and external audit observations, customer complaints, quality control processes, and supplier issues.

15.5.3 The CAPA system includes requirements for detailed root cause analysis. Appropriate containment actions, corrections, corrective and preventive actions are presented to the quality committee for approvals.

15.5.4 Corrective actions are monitored to verify that actions taken are effective.

15.5.5 The laboratory has written procedures for the retraction of analytical reports when any information is discovered which brings results into question.

16.0 OTHER

16.1 Confidentiality

16.1.1 NL treats the sponsor and sponsor-related information with the strictest confidence. Only persons identified by the sponsor in writing will receive laboratory reports. Specific confidentiality agreements will be written if requested by the sponsor.

16.1.2 NL's reports are also submitted to sponsors confidentially. It is requested that no reference to the work, to the results of the report, or to NL be made in the form of promotional material, advertisement, news release or other distribution without prior written authorization from NL. Copies of final reports may be distributed by sponsors provided the entire final report is duplicated.

16.1.3 Results from determinations relate only to the tested items. Any extrapolation of the test results to the properties of lots from which the samples were selected is outside the scope of the services provided by NL.

16.1.4 All employees are maintained under specifically written and signed confidentiality agreements. These agreements restrict all information about sponsors, their test results, information about their products, and the work environment.

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16.1.5 NL maintains a high level of security. Exterior security is monitored using at least one of the following: closed circuit TV (CCTV) monitors, gated access to the building, locking systems or on-site security personnel.

16.2 Data Recording and Control Procedures

16.2.1 All laboratory data recorded on paper media must be recorded in ink at the time the observations of data are made. Water soluble inks and pencils are unacceptable. Transcribing data without reference to original raw data is unacceptable.

16.2.2 All data entries or complete notebook pages must be dated and signed or initialed. When entering corrections to original data entries, the changes should be made with a strike-out which does not obliterate the original entry. Data changes must be dated and signed or initialed, and the reason for the change explained. Data books should be complete and permit reconstruction of the entire study. Explanatory notes and comments are appropriate.

16.2.3 Automated data recording systems are performed according to requirements established by predicate rules and in accordance to 21 CFR Part 11.

16.2.4 All dates should be in the following format:

DAY (XX) MONTH (XXX) YEAR (XXXX) (Example: 22 May 2017)

16.2.5 The analyst is responsible for properly recording data.

16.3 Housekeeping

16.3.1 Custodial and facility cleaning takes place according to procedures or is subcontracted to an external custodial company. These procedures detail cleaning procedures, materials, and processes, and include reports for cleaning tasks according to established intervals. In facilities that use a contracted custodial and facility service, local management monitors and provides standards to be followed by custodial contractors.

16.3.2 Noncontaminated and recycle waste are removed regularly. Infectious materials are handled only by trained personnel, contracted service and in accordance with procedures.

16.4 Legal Identity

16.4.1 NL is standalone business unit within Sotera Health, LLC. Sotera Health is a privately-held company.

16.5 Impartiality, Independence and Integrity

16.5.1 NL shareholders do not hold stock in any company for which analyses are performed. Employees are paid a wage or salary, based on job description, and as required by applicable state and federal laws. Outcome of laboratory analyses is not in any way related to compensation, bonuses, promotion, or longevity. NL does not have outside shareholder interests, business, or personal relationships which would compromise the impartiality, independence, or integrity of the reported results.

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16.5.2 NL's policy of impartiality, independence, and integrity is taught to employees. NL has a formal code of conduct and code of ethics. Formal policies provide for investigation and termination for breach of these personal conduct codes.

16.5.3 The code of conduct includes violation of company drug policy, theft, unauthorized use or disclosure of confidential or proprietary information, falsification of documents or records, dishonesty, giving or taking of bribes, engaging in a competing business or in activities which create or constitute a conflict of interest, violation of any federal, state or local law or regulation, engaging in any illegal, unethical act.

16.5.4 NL does not certify products. Results are reported on samples submitted without embellishment or promotion. All laboratory data are reported as results of analyses.

16.6 Disclaimer

16.6.1 All reports, letters and protocols issued by NL are for the exclusive use of the client/customer/sponsor to whom they are addressed and for such other parties as client/customer/sponsor shall disclose in writing to NL. Reports may be distributed without permission if issued in their entirety. Quotations from reports or use of the corporate name is not permitted except as expressly authorized by NL in writing. The significance of any data is subject to the adequacy and representative character of the samples submitted for testing. NL warrants that all tests are performed in accordance with established laboratory procedures and standards. NL makes no other warranties of any kind, expressed or implied. NL expressly states that it makes no representation or warranty regarding the adequacy of the samples submitted for testing for any specific use or application, that determination being the sole responsibility of the sponsor. Liability for any loss or damage resulting from NL actions or failure to act shall not exceed the cost of test performed. Moreover, NL is not liable for any incidental or consequential damages.

16.6.2 Results that are reported in the final report only apply to the sample tested.

16.7 Cooperation

16.7.1 NL and staff provide full cooperation with clients to meet their needs, as stated in the quality policy, complaint handling system, and throughout this manual. NL maintains an open door policy for audits. Audits should be scheduled in advance. Client auditors are given access to all applicable areas and systems, within a confidential manner. Upon request, NL will prepare, package, and dispatch samples needed by the client to verify test performance. These same courtesies are afforded to accreditation bodies such as ISO/IEC 17025 registered bodies.

16.7.2 NL cooperates with standards organizations and other laboratories. We participate in cooperative studies (round-robin) and method development. We exchange non-confidential information regularly with colleagues. We maintain membership in many standards organizations in an effort to help

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develop and improve test methods. Where possible, we also participate in external certification and proficiency testing programs.

16.8 Duties Resulting From Accreditation

16.8.1 NL complies with the requirements of the standards and criteria prescribed by applicable accreditation bodies. NL claims accreditation only for those services for which it has been accredited. NL complies with all duties resulting from accreditation as set forth in ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories, and in all cases represents the most current accreditation status as prescribed. The current Scope of Accreditation to ISO/IEC 17025 for each facility is provided on the NL website.

16.9 Witnessing of Tests

16.9.1 Sponsors are permitted to witness any tests submitted. Sponsors are also notified that third party assessors (ISO, FDA, etc.) will be given rights to witness tests and review data. NL will cooperate fully with the notified bodies in all respects.

17.0 SUMMARY OF CHANGES

17.1 Justification/Reason for change

- 17.1.1 Regulatory is covered under the Quality Assurance group
- 17.1.2 PDS and SDS are now covered under the CSS process
- 17.1.3 Procedures and processes are still required but changes allow other approved procedures at the local level to be used for each process.
- 17.1.4 EU GMP certification is maintained and the quality objectives of NL are to comply with the EU GMPs
- 17.1.5 Values reflect the Sotera Health values which align with the previous values of NL
- 17.1.6 Titles and positions were updated for accuracy and to allow for the growth of the company.
- 17.1.7 Sterigenics International changed its name to Sotera Health.
- 17.1.8 SOP0165 – Greater than 90 Day Studies is retired.
- 17.1.9 AUX0040 – Supplier Annual Assessment Worksheet is being retired.
- 17.1.10 Changes were made to generalize quality manual. The requirements to have the discussed processes and procedures remain but this allows some flexibility at each location.
- 17.1.11 To provide information to customers on where to find the scope of accreditation for ISO/IEC 17025

17.2 Summary of changes:

- 17.2.1 Update 0: Effective 08 Jun 2018

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- 17.2.1.1 Regulatory was removed from the definitions section and all references to RA or Regulatory Affairs were changed to Quality Assurance.
- 17.2.1.2 References to SDS and PDS were removed.
- 17.2.1.3 Removed references to specific procedures and processes.
- 17.2.1.4 Added EU GMPs to quality objectives and references.
- 17.2.1.5 Updated values section to align with new values.
- 17.2.1.6 Titles and positions were updated to reflect the current state.
- 17.2.1.7 Changed Sterigenics to Sotera Health.
- 17.2.1.8 Removed SOP0165 from references and monitoring and measurement sections.
- 17.2.1.9 Removed AUX0040 from section 13.5.1.2 and references section
- 17.2.1.10 Removed prefixes from referenced documents
- 17.2.1.11 Included other changes to simplify procedure
- 17.2.1.12 Added a reference the scope of accreditation that is maintained on the NL website
- 17.2.2 Update 1: Effective 07 Dec 2020
 - 17.2.2.1 References section was moved in order to align with current practices.
 - 17.2.2.2 Updated footer to align with current formatting
- 17.2.3 Update 2: Effective 02 Nov 2021
 - 17.2.3.1 SOP0096 and SOP0145 have archived and were removed from the references section.

REFERENCES FOR MAN0001 REV 16

Note: Not all referenced documents are applicable for all sites. Other approved documents may be used at some sites as applicable.

1.0 EXTERNAL REFERENCES

- 1.1 ISO/IEC 17025. *General Requirements for the Competence of Testing and Calibration Laboratories*. International Organization for Standardization, Geneva, Switzerland. (CRD006)
- 1.2 21 CFR Part 58. *Good Laboratory Practice for Nonclinical Laboratory Studies. Subpart E, Testing Facilities Operation*. Federal Register, National Archives and Records Administration, Washington, D.C. (CRD002)
- 1.3 21 CFR Part 210. *Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs*. Federal Register, National Archives and Records Administration, Washington, D.C. (CRD079)
- 1.4 21 CFR Part 211. *Current Good Manufacturing Practice for Finished Pharmaceuticals. Federal Register, National Archives and Records Administration, Washington, D.C.* (CRD001)
- 1.5 21 CFR Part 820. *Quality System Regulation*. Federal Register, National Archives and Records Administration, Washington, D.C. (CRD003)
- 1.6 40 CFR Part 160. *Good Laboratory Practice Standards*. Federal Register, National Archives and Records Administration, Washington, D.C. (CRD004)
- 1.7 21 CFR Part 1271. *Current Good Tissue Practices for Human Cells, Tissues, and Cellular and Tissue-Based Products*. Federal Register, National Archives and Records Administration, Washington, D.C. (CRD232)
- 1.8 21 CFR Part 11. *Electronic Records, Electronic Signatures*. Federal Register, National Archives and Records Administration, Washington, D.C. (CRD007)
- 1.9 *Australian Code of Good Manufacturing Practice for human blood and blood components, human tissues and human cellular therapy products*. Therapeutic Goods Administration, Symonston, Australia. (CRD450)
- 1.10 EudraLex - *The Rules Governing Medicinal Products in the European Union Volume 4. EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use*. European Commission, Brussels, Belgium. (CRD521)
- 1.11 *PE009, the PIC/S guide to GMP for medicinal products TGA interpretation and expectations for demonstrating compliance*. 2020. Therapeutic Goods Administration (TGA), Symonston, Australia (CRD789)

2.0 INTERNAL REFERENCES

- 2.1 AUX0039 – Qualified Supplier List
- 2.2 MAN0002 – Custodial Manual
- 2.3 MAN0003 – Statistical Control Manual
- 2.4 MAN0004 – Chemical Hygiene Plan and Safety Manual
- 2.5 MAN0005 – Biosafety Manual
- 2.6 MAN0006 – Policy and Procedures Manual
- 2.7 MAN0007 – Validation Master Plan

REFERENCES FOR MAN0001 REV 16

- 2.8 SOP0001 – Management of Controlled Procedures and Forms
- 2.9 SOP0006 – Customer Specification Sheets
- 2.10 SOP0019 – Temperature and Environmental Measurement and Control
- 2.11 SOP0020 – In-House Environmental Monitoring
- 2.12 SOP0024 – Waste Disposal
- 2.13 SOP0027 – Water System
- 2.14 SOP0029 – Emergency Circumstances
- 2.15 SOP0030 – Pest Control Procedure
- 2.16 SOP0033 – Emergency Power Generator
- 2.17 SOP0035 – Contracts & Confidentiality
- 2.18 SOP0039 – Change Management
- 2.19 SOP0048 – Workstation User Responsibilities
- 2.20 SOP0062 – Hood and HEPA Filter Certification
- 2.21 SOP0063 – Flowmeter Calibration
- 2.22 SOP0064 – Timer Calibration
- 2.23 SOP0065 – General Temperature & Thermometer Calibration
- 2.24 SOP0067 – General Calibration And Maintenance
- 2.25 SOP0068 – Non-Routine Repairs
- 2.26 SOP0069 – Equipment Receiving
- 2.27 SOP0071 – Sponsor And Vendor Equipment
- 2.28 SOP0076 – Requisition and Purchasing Process
- 2.29 SOP0077 – Incoming Receiving and Inspection
- 2.30 SOP0079 – Log-In
- 2.31 SOP0080 – Identification, Handling, and Disposition of Test Samples
- 2.32 SOP0081 – Data Recording and Correction
- 2.33 SOP0082 – Quality Records and Archives
- 2.34 SOP0085 – Final Reports
- 2.35 SOP0089 – Management Responsibilities
- 2.36 SOP0090 – Study Director Responsibilities
- 2.37 SOP0092 – GLP Study Procedures
- 2.38 SOP0093 – Customer Feedback Handling
- 2.39 SOP0094 – Responsibilities, Deputies, and Organizational Structure
- 2.40 SOP0095 – Auditing of Logbooks and Binders
- 2.41 SOP0098 – Training System
- 2.42 SOP0099 – Quality Committee and Management Review Procedures

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- 2.43 SOP0101 – Final Report Retraction
 - 2.44 SOP0102 – Design, Installation, Operational, And Performance Qualification of Equipment, Facilities, Systems, And Software
 - 2.45 SOP0103 – Internal Audits
 - 2.46 SOP0106 – Supplier Management
 - 2.47 SOP0115 – Test Method Validation
 - 2.48 SOP0116 – Expression of Uncertainty
 - 2.49 SOP0117 – Proficiency and Competency Testing Program
 - 2.50 SOP0118 – Spreadsheet Control
 - 2.51 SOP0119 – Control Charts and Duplicate Analyses
 - 2.52 SOP0136 – Quality Events, Investigations, Retests, and Study Discontinuations
 - 2.53 SOP0137 – Sample Discrepancy
 - 2.54 SOP0140 – Document Imaging
 - 2.55 SOP0144 – Pricing Policies and Procedures
 - 2.56 SOP0154 – Quality Assurance Unit Responsibilities
 - 2.57 SOP0157 – Rees Environmental Monitoring System
 - 2.58 SOP0159 – On-Site Supplier/Subcontractor Audit Process
 - 2.59 SOP0164 – Nonconforming Supplies and Services
 - 2.60 SOP0167 – Quality Assessment of Incoming Supplies
- 3.0 RECORDS
- 3.1 There are no records generated from this manual.
- 4.0 REFERENCE CHANGE HISTORY
- 4.1 Update 1: Effective 07 Dec 2020
 - 4.1.1. Inserted CRD789
 - 4.1.2. References section was moved in order to align with current practices.
 - 4.2 Update 2: Effective 02 Nov 2021
 - 4.2.1. Removed SOP0096 and SOP0145 due to archival