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TABLE OF CONTENTS

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, high-level document that establishes expectations of our quality management system; specific subsystems are detailed in corresponding procedures.

1.2 Scope: This quality manual, and the corresponding quality management systems, aligns with ISO 17025 and applicable aspects of 40 CFR Part 160, and 21 CFR Parts 11, 58, 210/211, 820, and 1271.

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

1.3 Justification: POL0001 - Global Quality Policy is established, understood, implemented, and maintained. The quality manual expands upon the quality policy and gives details for high-level requirements and processes.

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 applicable portions of ISO 17025 and 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 adhere to the outlined expectations.

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3.0 DEFINITIONS

3.1 LIMS: Laboratory Information Management System

3.2 LMS: Learning Management System

3.3 QMS: Quality Management System

4.0 DOCUMENTATION REQUIREMENTS

4.1 General

4.1.1 General quality objectives are contained in this quality manual. Annual quality targets are created 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.

4.2 Distribution

4.2.1 The quality manual is maintained in electronic format and is available to all employees. All employees are required to document that they have read and understand the global quality policy outlined in POL0001. This manual may also be distributed to client and potential clients upon request.

4.3 Control of Documents

4.3.1 Requirements for the control of documents are outlined in procedures.

4.3.2 NL document control systems identify the current revision status of documents and ensure the following:

4.3.2.1 Documents are approved by authorized personnel

4.3.2.2 Documents are reviewed periodically

4.3.2.3 Changes and current revision status are identified

4.3.2.4 Relevant versions of documents are available to appropriate personnel at points of use through controlled distribution

4.3.2.5 Documents are uniquely identified

4.3.2.6 The unintended use of obsolete documents is prevented, and the documents are identified suitably.

4.4 Control of Records

4.4.1 Records associated with or in support of the quality management system are legible, retained, and archived according to procedure.

4.4.2 NL procedures outline controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, disposal of

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records, and availability. Records are maintained for a period outlined in procedure and consistent with contractual obligations. Access to all archived data is controlled to limit risk to loss and maintain confidentiality.

5.0 MANAGEMENT RESPONSIBILITIES

5.1 Management Commitment

5.1.1 Management is committed to all aspects of the quality management system described in this manual. Management communicates, by word and example, the importance of meeting regulations and customer needs to fulfill our mission of Safeguarding Global Health. Management inspires an attitude of quality through laboratory policies, actions, and leadership. 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.

5.2 Customer Focus

5.2.1 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, quality issues, and complaints.

5.2.2 To accomplish quality goals, NL management:

5.2.2.1 Maintains a commitment to hiring excellent quality staff and providing them with the tools and resources they need to do their job well.

5.2.2.2 Verifies the effectiveness of training through initial qualifications, ongoing proficiency testing, examination, evaluation, or other means of proving competency

5.2.2.3 Maintains state-of-the-art laboratory facilities

5.2.2.4 Maintains a sophisticated metrology laboratory with NIST-traceable standards

5.2.2.5 Provides easy document accessibility

5.2.2.6 Analyzes trends and critical systems to ensure continuous improvement

5.2.2.7 Sets goals for quality performance and quality improvement

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5.2.2.8 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

5.2.2.9 Requests client feedback via surveys, customer service and sales visits, on-site audits, and the NL website

5.2.2.10 Ensures the integrity of the management system when changes are made by the use of a formal change management system

5.2.2.11 May perform Kaizen (i.e., continuous improvement) events to continually refine and improve processes

5.2.3 The QMS 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.

5.2.4 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.

6.0 PLANNING

6.1 Quality Objectives

6.1.1 The quality objectives are outlined in this document and the quality policy. Specific, measurable quality goals are set annually and monitored throughout the year by management.

7.0 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

7.1 Management communicates responsibilities to employees via job descriptions. Authority is communicated directly and documented in the organizational chart.

7.2 Organizational Charts: Top management ensures that responsibilities and authority are defined and communicated. A copy of the organizational structure is maintained in an electronic HR system.

7.3 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.

7.4 Senior Leadership Team: The senior leadership team consists of the President, Vice President (VP) of Operations, Vice President of Human Resources, Vice President of Finance, Vice President of Quality, and Vice President of Sales. This group meets regularly with the President to advise on strategy, report on company

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performance, plan resources, and set company direction. These managers maintain an open-door policy to provide easy access for all staff members.

7.5 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.

7.6 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.

7.7 VP of Operations: The VP of Operations for each geolocation is responsible for supervising the directors of laboratory operations and other lab support functions, providing laboratory resources, managing routine scheduling of studies, assessing staffing needs, etc.

7.8 VP of Quality: The VP of Quality is responsible for all quality issues pertaining to laboratory operations. The VP of Quality has direct oversight over the QMS, the Quality Assurance (QA), and Document Control (DC) departments. Responsibilities include ensuring the quality system is implemented and is compliant with applicable regulations and ISO standards, regulations, and ISO 17025.

7.9 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.

7.10 Senior Lab Operations Managers (SLOMs): SLOMs manage specific laboratory departments. Their responsibilities include all phases of laboratory management for their specific department.

7.11 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.

7.12 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.

7.13 Management Representative: Appointed by Management with Executive Responsibility to ensure that quality system requirements are effectively established and maintained, and the performance of the quality system is reported to Management with Executive Responsibility. These representatives typically include site-specific or regional-specific quality and lab/operational leaders. The VP of Quality also acts as the Management Representative when reporting directly to the President.

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8.0 MANAGEMENT REVIEW

8.1 General

8.1.1 A defined group 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 formal review of company goal performance is conducted annually. Minutes of quality committee meetings are maintained for evidence of review and actions taken.

8.2 Review Input

8.2.1 Quality indicators, constraints, performance metrics, customer feedback, and other items are reviewed as directed by procedure.

8.3 Review Output

8.3.1 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.

9.0 RESOURCE MANAGEMENT

9.1 The senior leadership team meets regularly to determine, review, and discuss company strategy and the implementation thereof. Senior laboratory operations managers and functional 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. Resources are also reviewed as part of management review.

9.2 Provision of Resources

9.2.1 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.

9.3 Human Resources

9.3.1 General

9.3.1.1 Employees are hired with an appropriate combination of education, training, skills, and experience for their position.

9.3.2 Competence, Awareness, and Training

9.3.2.1 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.

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9.3.2.2 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.

9.3.3 Training Intervals

9.3.3.1 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.

9.3.4 Training System

9.3.4.1 Documentation is maintained for all training events. These records may be maintained electronically in the LMS.

9.3.4.2 NL's professional development department is responsible for overseeing 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.

10.0 INFRASTRUCTURE

10.1 Appropriate building, workspace, and associated facilities are provided. NL carries out analytical activities at its permanent facilities, except for certain tests being performed at the customer's site upon request (e.g., sterilization validation). 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.

10.2 Work Environment

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

10.3 Environmental Control

10.3.1 NL has a wide range of environmental control procedures and systems to ensure that environmental control is maintained.

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10.3.1.1 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 established 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.

10.3.2 Environmental Microbial Monitoring

10.3.2.1 NL performs extensive microbial monitoring. The environmental monitoring includes both fallout and surface contact plate monitoring throughout the applicable laboratory areas.

11.0 PRODUCT REALIZATION

11.1 The product produced by NL is a test result documented in the form of a final report or certificate of analysis.

11.2 Product Realization Planning

11.2.1 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.

11.2.2 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.

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

11.3 Customer-Related Processes

11.3.1 Determination and Review of Product Requirements

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

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11.3.1.2 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.

11.3.1.3 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.

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

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

11.3.1.6 Other contract reviews are performed as directed by the customer or NL needs. These include non-disclosure agreements, confidentiality agreements, consulting agreements, quality agreements, change agreements, and master service agreements.

11.3.2 Customer Communication

11.3.2.1 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 to provide the sponsor a written record of the procedural reference. Non-conformities or deviations that affect customers must be communicated to the customer.

11.4 Purchasing

11.4.1 Supplier Management

11.4.1.1 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.

11.4.1.2 Supplier level risk is designed to gather sufficient information about a supplier’s organization, management,

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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.

11.4.1.3 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.

11.4.1.4 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.

11.4.1.5 Tests may also be subcontracted to an acceptable facility after approval by the sponsor, (e.g., animal tests, packaging, and some analytical and calibration tests). Subcontractors are periodically assessed for qualification status.

11.4.2 Purchasing Information

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

11.4.3 Verification of Purchased Products

11.4.3.1 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.

11.4.3.2 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.

11.5 Production and Service Provision

11.5.1 Validation

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

11.5.2 Identification and Traceability

11.5.2.1 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.

11.5.2.2 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.

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

11.5.3 Customer Property

11.5.3.1 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.

11.5.4 Preservation of Product

11.5.4.1 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. NL reports are sent to the customer via a secure client server or other delivery methods, as requested.

11.5.4.2 Final reports and associated raw data are archived on paper or optically scanned and maintained in a digital archive according to retention requirements outlined in procedure.

11.6 Control of Monitoring and Measuring Devices

11.6.1 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

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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.

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

11.6.3 NL maintains a 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 are verified by quality assurance.

12.0 MONITORING AND MEASUREMENT

12.1 Customer Satisfaction

12.1.1 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.

12.1.1.1 Internal audits are conducted according to a pre-determined schedule to evaluate the performance of applicable systems, functions to ensure compliance with applicable regulations and standards, procedures, and training requirements. The audit schedule may be modified to re-arrange the order of assessments if quality system monitors indicate a need.

12.1.2 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)

12.1.3 Monitoring and Measurement of Product

12.1.3.1 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 and GMP designated studies require a second person to review the

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record for accuracy, completeness, and compliance with established standards (QC review). Formats are governed by 21 CFR 58 (FDA GLP), 40 CFR 160 (EPA GLP), and ISO 17025 reporting requirements.

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

12.1.3.3 Test and inspection data are stored in an approved record retention location. The archive areas are only accessible by authorized personnel.

12.2 Control of Nonconforming Product

12.2.1 Purchased Supplies

12.2.1.1 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.

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

12.2.2 Out of Specification (OOS) Procedures

12.2.2.1 NL handles OOS using multiple systems.

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

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

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12.2.2.1.3 When controls or reference materials do not perform as expected, or when a protocol, procedure, 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.

12.3 Continual Improvement

12.3.1 NL is committed to continual improvement through 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.

12.4 Corrective Action and Preventive Action

12.4.1 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.

12.4.2 CAPA events are documented, tracked and trended.

12.4.3 The CAPA system includes requirements for assessing risk and detailing root cause analysis. Appropriate containment actions, corrections, corrective and preventive actions are implemented when necessary.

13.0 OTHER

13.1 Confidentiality

13.1.1 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.

13.1.2 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.

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13.1.3 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.

13.1.4 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.

13.1.5 NL maintains a high level of security to protect information as well as employees.

13.2 Data Recording and Control Procedures

13.2.1 All laboratory data is expected to follow the principles of ALCOA+, meaning that it is required to be attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring and available.

13.2.2 Automated data recording systems are established according to requirements outlined by predicate rules and in accordance to 21 CFR Part 11, Annex 11, and data integrity principles.

13.2.3 All dates should be in the following format:

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

13.3 Housekeeping

13.3.1 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 documentation of 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.

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

13.4 Legal Identity

13.4.1 NL is standalone business unit within Sotera Health, LLC. Sotera Health is a public company.

13.5 Impartiality, Independence and Integrity

13.5.1 Employees are paid a wage or salary, based on their role, 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 periodically assesses risk which would compromise the impartiality, independence, or integrity of the reported results.

13.5.2 NL's policy of impartiality, independence, and integrity is taught to employees. NL has a formal code of conduct and code of ethics.

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13.5.3 Results are reported on samples submitted without embellishment or promotion. All valid laboratory data are reported as results of analyses.

13.6 Disclaimer

13.6.1 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 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.

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

13.7 Cooperation

13.7.1 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 attempts to accommodate all requests for audits, but due to volume audits should be scheduled in advance. Client auditors are given access to all applicable areas and systems, within a confidential manner.

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

13.8 Duties Resulting from Accreditation

13.8.1 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 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.

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14.0 SUMMARY OF CHANGES

Section	Description of Change	Justification of Change
Update 0: Effective 27 Sep 2023		
1.1	Removed prior mission	New mission of Safeguarding Global Health was established with the formation of Sotera Health
1.3	Added reference to global quality policy, also removed reference to the old policy	POL0001 was created and is now referenced
7.0	Aligned roles and responsibilities to current titles	Updated to match the current organization. Requirements of responsibility are met with changes
Throughout	Simplification and generalization to apply to multiple locations and align with policy, manual, and procedure hierarchy	The manual still outlines high-level expectations. Specifics are details in applicable procedures
13.4	Added parent company and public company information	NL is no longer a private company
References	Removed AUX0039	Removed due to document archival
References	Removed MAN0006	MAN0006 archived and was replaced with Sotera Health Employee Guidebook
References	Removed SOP0096	SOP0096 archived and was replaced with WI0377
References	Removed SOP0145	SOP0145 archived and was replaced with WI0378
Update 1: Effective 28 Jun 2024		
1.2	Removed Mexico City from scope.	The Mexico City lab is no longer in scope of the NL QMS per CC01769.

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REFERENCES FOR MAN0001 REV 17

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.* Therapeutic Goods Administration (TGA), Symonston, Australia (CRD789)

2.0 INTERNAL REFERENCES

2.1 MAN0002 – Custodial Manual

2.2 MAN0003 – Statistical Control Manual

2.3 MAN0004 – Chemical Hygiene Plan and Safety Manual

2.4 MAN0005 – Biosafety Manual

2.5 MAN0007 – Validation Master Plan

2.6 SOP0001 – Management of Controlled Documents

2.7 SOP0006 – Customer Specification Sheets

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REFERENCES FOR MAN0001 REV 17

2.8 SOP0019 – Temperature and Environmental Measurement and Control
2.9 SOP0020 – In-House Environmental Monitoring
2.10 SOP0024 – Waste Disposal
2.11 SOP0027 – Water System
2.12 SOP0029 – Emergency Circumstances
2.13 SOP0030 – Pest Control Procedure
2.14 SOP0033 – Emergency Power Generator
2.15 SOP0035 – Contracts & Confidentiality
2.16 SOP0039 – Change Management
2.17 SOP0048 – Workstation User Responsibilities
2.18 SOP0062 – Hood and HEPA Filter Certification
2.19 SOP0063 – Flowmeter Calibration
2.20 SOP0064 – Timer Calibration
2.21 SOP0065 – General Temperature and Thermometer Calibration
2.22 SOP0067 – General Calibration and Maintenance
2.23 SOP0068 – Non-Routine Repairs
2.24 SOP0069 – Equipment Receiving
2.25 SOP0071 – Sponsor, Vendor, and Off-Site Equipment
2.26 SOP0076 – Requisition and Purchasing Process
2.27 SOP0077 – Incoming Receiving and Inspection of Supplies
2.28 SOP0079 – Log-In
2.29 SOP0080 – Identification, Handling, and Disposition of Test Samples
2.30 SOP0081 – Data Recording and Correction
2.31 SOP0082 – Quality Records and Archives
2.32 SOP0085 – Final Reports
2.33 SOP0089 – Management Responsibilities
2.34 SOP0090 – Study Director Responsibilities
2.35 SOP0092 – GLP Study Procedures
2.36 SOP0093 – Customer Feedback Handling
2.37 SOP0094 – Responsibilities, Deputies, and Organizational Structure
2.38 SOP0095 – Auditing of Logbooks and Binders
2.39 SOP0098 – Training System
2.40 SOP0099 – Quality Committee and Management Review Procedures
2.41 SOP0101 – Final Report Retraction
2.42 SOP0102 – DQ, IQ, OQ, and PQ of EFS and Software

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REFERENCES FOR MAN0001 REV 17

2.43 SOP0103 – Internal Audits

2.44 SOP0106 – Supplier Management

2.45 SOP0115 – Test Method Validation

2.46 SOP0116 – Expression of Uncertainty

2.47 SOP0117 – Proficiency and Competency Testing Program

2.48 SOP0118 – Spreadsheet Control

2.49 SOP0119 – Control Charts and Duplicate Analyses

2.50 SOP0136 – Corrective & Preventive Action (CAPA) System: Quality Events (QE), including Deviations, Out of Specifications (OOS), Sponsor Complaints, and Action Assignment (AA)

2.51 SOP0137 – Sample Discrepancy

2.52 SOP0140 – Document Imaging

2.53 SOP0144 – Pricing Policies and Procedures

2.54 SOP0154 – Quality Assurance Unit Responsibilities

2.55 SOP0157 – Rees Environmental Monitoring System

2.56 SOP0159 – On-Site Supplier/Subcontractor Audit Process

2.57 SOP0167 – Quality Assessment of Incoming Supplies

2.58 Sotera Health Employee Guidebook

2.59 POL0001 - Global Quality Policy

2.60 WI0377 - QE: Escalated Events

2.61 WI0378 - QE: Complaints

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Signature Manifest

Document Number: NEL-MAN-0001 **Revision:** 17
Title: Nelson Laboratories Quality Manual
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All dates and times are in Mountain Time .

Quick Approval

Approve Now

Name/Signature	Title	Date	Meaning/Reason
Crysta Foight (CFOIGHT)	Document Specialist II	13 Sep 2023, 07:55:06 AM	Approved

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Name/Signature	Title	Date	Meaning/Reason
Cecily Munro (CMUNRO)	Document Control Specialist II	28 Jun 2024, 10:38:51 AM	Approved