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3.0 Organization Information

Ion Labs is a leading contract manufacturer of dietary supplements, pet supplements, skin care products and OTC drugs in the US. Ion Lab has 30 years' experience in supplement manufacturing.

The organization has established their testing laboratory as an independent legal entity headquartered in Largo, FL. The lab was previously under the Parent company of Ion Labs providing testing results for the internal products. The lab then separated from Ion Labs to allow testing to be performed for external customers or internal customers to Ion Labs.

4.0 Lab Management System Scope and Non-Applicable Requirements

The organization's ISO 17025:2017 laboratory management system applies to testing services controlled by the operations at 8031 114th Ave, Suite 4000, Largo, FL 33773. Testing activities included in the ISO 17025:2017 accreditation are listed in the table below.

Method ID	Test Parameter
D-720	Caffeine, Theacrine, and Theobromine Determination using HPLC with UV/VIS Detection (Caffeine Only)
D-715	Microbial Limit Testing using the 3M Petri film System
D-715.0	Microbial Limit Testing using Agar Plates
D-729	Determination of Tributyrin by GC-FID
D-776	Cannabinoid Determination and Identification by HPLC
D-778	Limit of Citrinin by LC-MS
D-780	Determination of Quercetin by HPLC using UV-VIS Spectroscopy

The Ion Labs' Laboratory only claims conformity with ISO 17025 for this range of testing services, and this excludes externally provided activities that are subcontracted on a continuing basis.

All laboratory activities performed to address the testing services in the table above are carried out in a manner that conforms to the requirements of this manual, customer requirements, applicable regulatory authorities, laboratory accreditation agencies, the

established methods listed, detailed testing procedures maintained by the organization, and the requirements of ISO 17025.

All testing activities are performed in the Ion Labs' Laboratory within environments controlled by Lab personnel. Uncertainty budgets and testing procedures consider the effects of environmental conditions on testing results, and assurance of testing outcomes is provided by conforming with the requirements of the laboratory management system described in this manual.

All test activities are performed in accordance with methods developed by established by International standards organizations or recognized agencies, and where necessary, lab-developed methods which are validated in accordance with the D-103 Analytical Method Validation procedure.

The Lab performs testing services only. No calibration services are performed. Therefore, requirements specific to calibration activities identified in ISO 17025 are not addressed by the organization's operations or within this Laboratory Management System Manual.

5.0 Laboratory Management System Overview

The Laboratory Management System (LMS), like the documentation describing it, is structured around processes affecting the competence of our testing services and confidence in our testing results. The LMS has been established, documented, implemented, and is maintained to assure the quality of the laboratory results and to demonstrate consistent achievement of the requirements of ISO 17025, assuring the quality of testing results.

The management system can be viewed as a system of processes that fall into two categories: service provision processes, and support processes. The service provision processes involve testing service activities directly affecting the confidence and capability of the testing services provided to customers. Support processes are those necessary to support the successful operation and control of the service provision processes and the LMS as a whole.

The D-119 Sales-Laboratory Sample Submission procedure describes practices implemented to identify customer requirements, ensures the laboratory can satisfy requirements, and establishes effective arrangements to communicate with customers and obtain feedback regarding whether customers are satisfied with the service they have received.

The D-122 Lab Operations procedure describes how activities specific to testing are controlled, including control of nonconforming work, and how testing and reporting are performed. Activities performed to validate and when necessary, identify improvement opportunities are described in the D-118 Laboratory Qualities Assurance Activities Plan (Proficiency Testing) procedure. The process for determining and reporting measurement uncertainty is described in the Measurement Uncertainty procedure. The D-103 Analytical Method Validation procedure ensures lab-developed and non-standard methods are effectively validated when standard methods are not available.

The D-117 Laboratory Purchases and Receiving procedure ensures the products, services, outsourced processes, and subcontracted testing services the organization requires are obtained in a manner that safeguards the testing processes are consistent and reliable.

Support processes operate in parallel with the above realization processes. The C-501 Document Control procedure, D-123 Control of Laboratory Electronic Documentation procedure, and C-502 Record Storage, Retention, and Destruction procedure ensures control over process documents and records; the A-113 Training procedure and A-117 Personnel Qualifications procedure ensures personnel performing work affecting the accuracy and precision of the Lab are competent; the G-208 Analytical Calibration and Equipment Control procedure ensures calibrated lab equipment used to perform tests are suitable for their measurements, operates properly, and is traceable to national and international units of measure, and non-measuring lab equipment is maintained to ensure it operates properly. The H-101 Internal Audits procedure monitors all management system processes to ensure their effectiveness and promote improvement. The D-118 Lab Operations, D-118 Laboratory Qualities Assurance Activities Plan (Proficiency Testing) and QS-112 Core Quality Systems and Quality Events, QS-101 Complaints, D-105 Out of Specification Test Results Investigation, and QS-108 Corrective and Preventive Action procedures ensures actions are taken to control nonconforming outputs and detected problems do not recur. The D-121 Management -Laboratory procedure ensures top management reviews the LMS as a whole periodically to ensure its continuing suitability, adequacy, and effectiveness.

A documented procedure has been established, implemented, and maintained for each LMS process, including both service realization and support processes. Each procedure identifies the

inputs to and outputs of the process and describes how inputs are transformed into outputs under controlled conditions. Each procedure also identifies responsibilities and authorities of personnel performing the process, as well as those responsible for measuring or monitoring process performance against established objectives, and for reacting appropriately to provide confidence in the service and to promote improvement.

6.0 Laboratory Management System Processes

6.1 Organization

6.1.1 The organization provides testing services to meet the requirements of ISO 17025 and to satisfy the needs of customers. The LMS applies to work carried out at the Ion Lab's facility.

6.1.2 Management ensures all personnel are free from any undue internal or external commercial, financial, or other pressures and influences that may adversely affect the confidence in the work they are assigned to perform. This is accomplished through training and through investigations of nonconforming work and complaints.

6.1.3 All personnel have the authority and resources needed to carry out their assigned duties, and to identify needed resources. As described in the LMS procedures, personnel are responsible for, and authorized to, implement, maintain, and improve the management system, and to identify departures from procedures or methods and to initiate corrective action, as appropriate, to prevent or minimize such problems.

6.1.4 The organization implements policies and procedures regarding involvement in any activities that would diminish confidence in its competence, impartiality, judgment, or operational integrity, as applicable. Documented operating procedures specify how activities associated with testing services are conducted to provide confidence in the organization's competence, impartiality, judgment, operational integrity, and ensure the consistent application of its activities and the validity of testing results. Adherence to the documented procedures assures

consistent application of testing activities, leading to valid and repeatable results.

6.1.5 The Lab Director is responsible for ensuring the LMS is implemented and always followed. The Lab Director has direct access to top management, who makes decisions regarding policies and resources. The Lab Director is responsible for establishing, implementing, and maintaining the LMS, for reporting and reviewing performance information and improvement opportunities during Management Review, for promoting awareness of customer requirements throughout the organization, and for ensuring that all personnel in the scope of ISO 17025 accreditation are aware of the relevance and importance of their activities and how they contribute to the achievement of objectives. (This is accomplished via a combination of orientation training, and objective/performance reporting communicated appropriately in the organization). Management has responsibility for the technical operations and the provision of resources needed to ensure the Lab can achieve the accuracy and precision necessary.

6.1.6 Though responsibilities and authorities ultimately reside with top management, they are delegated to competent personnel as necessary. All personnel who perform, manage, and/or verify work are responsible for the services provided by the organization. All employees are responsible for complying with documented procedures and the direction of management. All employees are authorized to identify and record problems relating to services, processes, and the management system as a whole, and to provide suggestions for improvement or recommendations for solving problems by initiating corrective actions according to the QS-112 Core Quality Systems and Quality Events, D-105 Out of Specification Test Results Investigation, QS-108 Corrective and Preventive Action procedures. All employees are also responsible for cooperating fully with internal audits, customer audits, and assessments conducted by accreditation bodies.

6.1.7 Personnel are responsible for ensuring control over their activities and to complete work in a safe and responsible manner. All employees are responsible for maintaining work areas in a state of order, cleanliness, and repair consistent with service and processing needs. They are also responsible for identifying nonconforming work, stopping processing as necessary, and controlling further processing until management has been promptly notified and the problem has been corrected. A general description of responsibilities and authorities associated with each position are controlled as described in the A-113 Training, A-117 Personnel Qualifications, and D-120 Laboratory Management Structure and Position Requirements procedure and in specific LMS process procedures.

6.2 Confidentiality

6.2.1 Management ensures responsibilities and authorities are defined and communicated to all employees. Management is ultimately responsible for the quality of the organization's services and processes.

6.2.2 Management is responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of the Lab's activities. Although it typically does not occur, the Lab Director will notify the customer in advance, o the information the Lab intends to place in the public domain.

6.2.3 Except for information that the customer makes publicly available, or when agreed between Ion Labs and the customer (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and is regarded as confidential.

6.2.4 When the Lab is required by law or authorized by contractual arrangements to release confidential information, the customer or individual concerned will, unless prohibited by law, be notified of the information provided. Records of the notifications will be retained.

6.2.5 Information about the customer obtained from sources other than the customer (e.g. complainant, regulators) is kept confidential between the customer and the Lab. The source of this information is also kept confidential to the Lab and is not shared with the customer, unless agreed by the source.

6.3 Management Responsibility

6.3.1 Management is committed to maintaining and improving the management system to continually satisfy customers by providing them with services that meet their requirements. Management ensures customer requirements are determined and met along with providing accurate testing services. This commitment is demonstrated by the development and implementation of the laboratory management system, by establishing policies, and by establishing measurable objectives against which management system performance is evaluated and acted upon in an effort to improve processing and the resulting services. Management ensures employees understand the importance of meeting requirements and providing accurate and precise testing services.

6.3.2 Management also demonstrates a commitment the performance of the Lab by conducting periodic management reviews of the LMS and its processes. Based on factual information regarding performance and other feedback from customers, and in consideration of future customer needs, management allocates resources as necessary to ensure conformity of service, to improve the management system, its processes, and resulting service.

6.3.3 As established in previous sections of this manual, the Lab has established, implemented, and continues to maintain a LMS appropriate to the scope of our testing activities. Policies, procedures, testing methods, equipment operating instructions, etc. have been documented to the extent necessary to assure confidence in testing results. Management system documentation is communicated to, understood by, and available to appropriate personnel, who process work accordingly.

6.3.4 Management reviews its policies and objectives periodically during management review to ensure its continuing suitability, ensuring it remains appropriate for the organization, that it includes a commitment to comply with requirements and to continually improve the management system, and that it provides a foundation for measurable objectives against which performance can be evaluated. Top management also ensures employees understand the policies, how they apply to their work, how their performance relates to the achievement of the policy objectives, and the importance of meeting customer requirements and the requirements of ISO 17025.

6.3.5 Management has established measurable objectives for management system performance. Such objectives serve as a foundation for reviewing performance at both the process and system level, to both the management system processes and to the system of processes in aggregate.

6.3.6 Key objectives and measurements are addressed during management review meetings, along with an indication of a timeframe for their achievement. Objectives, associated targets, and relative performance information is communicated to affected personnel.

6.3.7 Monitoring and measurement methods to evaluate performance against established objectives have been identified, where suitable and applicable to improve performance. The Metrics worksheet of the LMS Planning Tool describes each objective, the monitoring and/or measurement(s) applied, and the frequency of measurement analysis. Management provides details regarding responsibilities and authorities for reviewing the resulting performance information, for analyzing it, for reacting appropriately, and for reporting management system performance to employees.

6.3.8 Planning at the process level focuses on processing a customer order for testing services to ensure conformity of the service to applicable requirements according to the original equipment manufacturer specifications and if required, customer specifications. This planning is to establish processes and information

specific to the service, and to identify service-specific resource requirements. This level of planning results in resource allocation and identification of processing steps, records demonstrating conformity and reporting testing results, and methods for reacting if planned arrangements are not achieved.

6.3.9 Planning at the system level involves establishing the LMS processes and infrastructure necessary to meet general requirements of performing accredited testing focusing on the ability of the system to meet these requirements effectively and efficiently. Such planning results in system-level processes and procedures that represent the planned arrangements described by management system documentation.

6.3.10 Where changes to the LMS are planned, due to changes in the volume of work, technology or in the accredited testing offered to customers, changes caused by suppliers, changes to processes, procedures, or service requirements, introduction of new processes or services, etc., Management will ensure the integrity of the LMS is maintained to ensure conformity of service to requirements. The full impact of changes will be determined, as appropriate. Changes will be verified and validated to ensure conformity to customer requirements before implementation. Management system planning and change management is conducted during management review, or more frequently as circumstances dictate. See the D-121 Management - Laboratory procedure.

6.3.11 Management ensures resource requirements are determined and met where they are needed to effectively operate and control management system processes, to maintain and improve the management system, and to provide testing services that demonstrate accuracy and precision.

6.3.12 Resource requirements include human resources (including personnel and training resources), infrastructure resources (including buildings, workspace, process equipment, operating supplies, documentation, and supporting services and utilities), and work environment resources (including human/physical

aspects of work being performed where necessary to provide confidence in testing results).

6.3.13 Resource needs may be identified within any management system process, or they may arise in connection with management reviews, corrective actions, internal audits, employee observations, etc. These needs are fulfilled according to the D-117 Laboratory Purchases and Receiving procedure and human resources are fulfilled according to the A-113 Training, A-117 Personnel Qualifications, and D-120 Laboratory Management Structure and Position Requirements procedures.

6.4 Document Control

6.4.1 The C-501 Document Control and C-502 Record Storage, Retention, and Destruction supports all LMS processes. The process assures control over all documents comprising the management system, whether generated internally or externally, including standards, manuals, forms, testing methods, specifications, instructions, etc.

6.4.2 As a support process, the objective of document control is to ensure legible, approved documentation is available when and where it is needed in order to perform laboratory activities. Management system documents are uniquely identified, including (as appropriate) document number, title, and revision date. The procedure also describes how documentation is initially approved and how it is re-approved after being updated. Revision histories are retained for management system documents to identify new or changed contents. The control of documents originating externally is also described to ensure current revisions are known and used.

6.4.3 Document control ensures documentation is approved by relevant authorities and that current, controlled documentation is used, and obsolete documentation is removed from use and suitably marked or disposed of to prevent unintended use.

6.5 Sales-Laboratory Sample Submission

6.5.1 Relationships with customers and potential customers are established as described in the D-119 Sales-Laboratory Sample Submission procedure. Policies are in place to ensure customers are aware of the accredited testing services available. Accredited testing service references, such as use of the accreditation body's logo (indicating "accredited"), are strictly controlled to ensure customers are not misled regarding accredited vs. non-accredited testing activities.

6.5.2 The D-119 Sales-Laboratory Sample Submission procedure also describes service agreements and/or non-disclosure or confidentiality agreements that are executed with customers.

6.5.3 Requirements for testing services are expressed in Test sheets submitted Sales or Lab personnel on the customers' behalf. Each Test Request is reviewed to ensure the requirements and activities are clear and that it can be fulfilled within the requested service delivery date. See D-119 Sales-Laboratory Sample Submission procedure.

6.5.4 When customers initiate changes to requirements, the same review process described above is repeated. All accepted changes are communicated to appropriate personnel. When deviations from quote requirements occur due to unexpected variations which may affect testing results, customers are notified. Records of communications are maintained in accordance with the D-119 Sales-Laboratory Sample Submission procedure.

6.5.5 Feedback indicating customers' perception of the organization's performance (both positive and negative) is actively collected and assessed to determine customer perception of the organization's performance. Records of customer feedback are maintained in the Customer Feedback Log. The organization reacts appropriately to customer feedback and complaints, initiating corrective action as appropriate, per the D-122 Laboratory Operations and QS-112 Core Quality Systems and Quality Events, QS-101 Complaints, and QS-108

Corrective and Preventive Action procedures and the Customer Complaint Policy.

6.5.6 The organization is willing to cooperate with customers or their representatives in clarifying and monitoring performance in relation to work performed. This cooperation may include providing the customer or the customer's representative reasonable access to relevant areas of the facility for demonstration of testing services, and/or provision of information regarding testing processes, observations, and results.

6.6 Purchasing and Receiving

6.6.1 Consumables, equipment, measurement equipment, calibration services, maintenance services, consulting services, and internal audit services are obtained through the process described in the D-117 Laboratory Purchases and Receiving, E-601 Vendor Qualification, and D-202 Outsourced Testing procedures. These procedures also describe the process for evaluating, approving, and re-evaluating external providers and outsourced service providers.

6.6.2 The procedure also establishes controls for identifying approved suppliers, ensuring requirements are known for critical materials, and for tracking the performance of subcontracted testing service providers. The controls also provide records of received items where lot identification and/or lot traceability are required.

7.0 Test Services

7.1 Personnel

7.1.1 The A-113 Training and A-117 Personnel Qualifications and D-120 Laboratory Management Structure and Position Requirements procedure describes how the Lab determines and provides personnel with the competence required to operate specific equipment, perform testing activities, record/evaluate results, and manage organizational activities. Training records have been developed to

identify competence requirements for each position affecting the outputs of the activities performed, based on appropriate education, training, experience and/or demonstrated skills. Although staff undergoing training to perform tests, trainees operate under the direct supervision of experienced personnel and/or management until deemed competent.

7.2 Facilities and Environmental Conditions

7.2.1 All testing activities are performed in the controlled environment in the Ion Labs' Laboratory. This ensures any variation or impact on the accuracy of the testing activities performed is minimized.

7.2.2 Uncertainty budgets and testing procedures consider the effects of environmental conditions on testing results, and assurance of testing outcomes is provided by conforming with the requirements of the laboratory management system described in this manual. Controls described in testing methods protect testing results from conditions which would adversely affect testing outcomes.

7.2.3 Access to the organization's facilities by personnel who are not members of organizational staff (including customers or their representative witnessing testing) is controlled to ensure confidentiality and security are maintained.

7.3 Equipment

7.3.1 Management furnishes all equipment and measuring instruments needed for the correct performance of testing activities within the defined laboratory scope.

7.3.2 All calibrated equipment is uniquely identified. Before measurement equipment is released for use, it is calibrated or verified, and its software confirmed (where applicable) to be capable of achieving the accuracy required and complies with specifications relevant to the activities for which it is intended. Measurement equipment is calibrated periodically and/or prior to use as described in the G-208 Analytical Calibration and Equipment Control procedure.

7.3.3 Measurement equipment is identified with calibration labels, wherever practical, displaying the date of previous calibration and the due date for the next calibration.

7.3.4 Equipment records contain information regarding equipment used in testing activities. Equipment maintenance records and records of any malfunctions are maintained for all equipment used to perform accredited tests. All records for equipment and measurement equipment are retained in accordance with the C-502 Record Storage, Retention, and Destruction.

7.3.5 Equipment that has been subjected to overloading or mishandling, provides suspect results, or has been shown to be defective is taken out of service and is marked clearly so it is not used.

7.4 Measurement Traceability

7.4.1 All measurement equipment which can affect the accuracy or validity of testing results is calibrated before being released for use in accordance with the G-208 Analytical Calibration and Equipment Control procedure. The process ensures suitable, accurate measuring equipment is used. The process also ensures measuring devices are selected and used in a manner consistent with testing requirements, and devices are calibrated or verified periodically (or before use) to ensure their continuing fitness for use, in order to impart confidence that the devices are suitable in their precision and the resulting measurements are accurate.

7.4.2 The G-208 Analytical Calibration and Equipment Control procedure also ensures calibration results are traceable to international or national standards. The procedure ensures devices are appropriately identified, handled, stored, and safeguarded to prevent damage and deterioration. Monitoring or measurement software is treated as a calibrated device and will be confirmed and reconfirmed as necessary to ensure its continuing suitability.

7.4.3 When a measuring device is found to be out of calibration, the Lab Director will investigate the impact of potentially errant measurements on calibrations previously performed with the device to ensure the impact is known, it is corrected or otherwise resolved, and all affected parties including customers, are notified, as appropriate. Unsuitable devices are withdrawn from use, or their use is limited to be appropriate for the measurements being carried out.

7.5 Testing Methods

7.5.1 Lab personnel use appropriate methods and procedures for all testing within the accredited scope of laboratory operations. The D-122 Lab Operations procedure and applicable testing instructions provide controls for handling, transport, storage, and preparation of equipment used during the testing process. Instructions for operating and using testing equipment are available to Lab personnel, as appropriate. All instructions, standards, manuals, and reference data is controlled and made available according to the C-501 Document Control and C-502 Record Storage, Retention, and Destruction procedures and the D-122 Lab Operations procedure.

7.5.2 The Lab may have the need to establish lab-developed testing methods. It is not likely that non-standard methods will be required. When lab-developed methods are necessary, the method will be validated in accordance with the D-103 Analytical Method Validation procedure. This ensures that all tests are performed using established testing methods that meet original equipment manufacturer needs are adequately supplemented and are appropriate for the equipment being calibrated. Unless otherwise specified, the latest valid edition of any published testing method is used, or the latest lab-developed method is used.

7.5.3 Computers or automated equipment used for performing testing or acquiring testing data are validated before being placed in use or after changes to the function of the equipment are made. Provisions for protecting data, including the integrity and confidentiality of data entry or collection, data storage, data

transmission, and data processing appear in the C-501 Document Control and C-502 Record Storage, Retention, and Destruction procedures.

7.6 Measurement Uncertainty

7.6.1 Estimates of measurement uncertainty are determined to ensure the capability of the Lab's measurement equipment and other factors that can influence the results of the testing are known. Testing results are reported in accordance with established testing methods and include measurement uncertainty values where relevant. The estimate of measurement uncertainty for each accredited testing is determined in accordance with the D-108 Estimation of Uncertainty procedure.

7.7 Assuring the Quality of Testing Results

7.7.1 Personnel monitor testing processes while they are being performed to ensure conformity to established testing methods. Data generated during testing are reviewed by personnel prior to issuing testing certificates. When data suggests a processing problem, the testing may be repeated or the process for controlling nonconforming service as described in the D-122 Lab Operations procedure is followed.

7.7.2 The Lab Director plans for and ensures additional measures are taken to assure the quality of testing results. In accordance with the D-118 Laboratory Qualities Assurance Activities Plan (Proficiency Testing) procedure, one of several methods identified in the procedure is used on an ongoing basis. The methods include retesting of retained items. use of check or working standards correlation of results for different characteristics of an item, and participation in Intralaboratory exercises, interlaboratory comparison or third-party proficiency testing programs. Data obtained from the quality assurance activity is analyzed and if found to be outside pre-defined criteria, correction and corrective actions are taken to mediate the problem and to prevent incorrect results from being reported. The results are also reported during management review. See the D-118 Laboratory Qualities Assurance Activities Plan (Proficiency Testing) and D-121 Management -Laboratory procedures.

7.8 Reporting Testing Results

7.8.1 Lab personnel performing the testing service is ultimately responsible for ensuring the results of each testing is reported accurately, clearly, unambiguously, and objectively, and in accordance with any specific instruction specified by the customer and established testing method. Requirements for reporting results are described in the D-122 Lab Operations procedure.

7.8.2 Test Reports are formatted using appropriate templates and undergo reviews and checks before release. These controls ensure the accuracy and integrity of the data upon release. The procedures that are followed and relevant controls in place ensure consistency and reliability and ensure conformance with established testing requirements.

7.8.3 Certificate of Analysis (CoA) or Test Reports are typically provided in hard copy and electronic copy per the customer requirements. Electronically transferred data is protected in accordance with the C-501 Document Control and C-502 Record Storage, Retention, and Destruction procedures.

7.8.4 If amendments are necessary for test reports after issue, the supplemental documents are identified and associated to the original certificate in accordance with the D-122 Lab Operations procedure. When it is necessary to issue a complete, new test report, the new report is uniquely identified and contains clear reference to the original test report it replaces.

7.9 Reporting Statements of Conformity

7.9.1 Lab personnel indicate conformity against the specifications through the test reports or CoA. The test report or CoA indicate to which results the statements of conformity apply, when specifications, standards, or parts thereof are met or not met, and the decision rule applied. The decision rule is stated on the Test Reports or CoA.

7.10 Reporting Opinions and Interpretations

7.10.1 Opinions and interpretations may be included on Test Reports or CoA provided to customers.

7.10.2 Opinions and interpretations are provided to customers upon Management discretion. Only Lab personnel authorized to provide the information do so.

7.11 Control of Nonconforming Work

7.11.1 The D-122 Lab Operations and QS-112 Core Quality Systems and Quality Events, D-105 Out of Specification Test Results Investigation, QS-108 Corrective and Preventive Action procedures describes the process when work does not conform to methods, procedures, or to the agreed requirements of the customer. If nonconformities are discovered (during or after testing):

7.11.1.1 Testing is stopped immediately if feasible. A designated authority determines if the nonconformity work impacts testing results and evaluates the significance of the nonconforming work. Reports and certificates are withheld until the issue has been resolved. A record is initiated as described in D-122 Lab Operations and QS-112 Core Quality Systems and Quality Events, D-105 Out of Specification Test Results Investigation, QS-108 Corrective and Preventive Action procedures.

7.11.1.2 A disposition is made for the testing activities and testing reports affected.

7.11.1.3 Corrective action is initiated when a systemic problem is suspected that would allow the nonconformity to recur, or when compliance to policies and procedures is in doubt the D-122 Lab Operations and QS-112 Core Quality Systems and Quality Events, D-105 Out of Specification Test Results Investigation, QS-108 Corrective and Preventive Action procedures.

7.11.1.4 Personnel correct the problem immediately, if possible. Testing activity will not resume until the problem has been corrected and the correction has been verified to be effective.

7.11.1.5 When appropriate, customers are contacted to inform them of the problem, and actions taken as agreed with the customer. Records of correspondence are maintained.

7.11.1.6 If it is determined additional tests have been affected by the situation, including test reports that have been published and made available to customers, the Lab Director determines if retests are required. The decision is recorded and actions to recall reports taken as necessary.

8.0 Laboratory Management System Foundations

8.1 Requirements Addressed

8.1.1 The LMS has been established, documented, implemented, and is maintained to promote accuracy, precision, and improvement, and to support and demonstrate consistent achievement of the requirements of ISO 17025 and assuring the quality of testing results. The documented LMS defines the management system to plan and demonstrate the consistent fulfillment of the Lab's requirements. The Lab's management system addresses Option A of ISO 17025. The requirements of Option A are as follows, supported by the documented management system procedure listed:

Requirement	Applicable Procedure(s)
Management system documentation	C-501 Document Control C-502 Record Storage, Retention, and Destruction D-121 Management-Laboratory
Control of management system documents	C-501 Document Control C-502 Record Storage, Retention, and Destruction
Control of records	C-501 Document Control C-502 Record Storage, Retention, and Destruction
Actions to address risks and opportunities	D-121 Management-Laboratory
Improvement	D-121 Management-Laboratory D-122 Lab Operations QS-112 Core Quality Systems and Quality Events D-105 Out of Specification Test Results Investigation QS-108 Corrective and Preventive Action procedures D-119 Sales -Laboratory Sample Submission
Corrective actions	D-122 Lab Operations QS-112 Core Quality Systems and Quality Events D-105 Out of Specification Test Results Investigation QS-108 Corrective and Preventive Action procedures
Internal audits	H-101 Internal Audits
Management reviews	D-121 Management-Laboratory

8.2 Improvement

8.2.1 Improvement is achieved anytime an increased ability to fulfill requirements is demonstrated by measurable results or quantifiable benefits (or estimates thereof). The Lab continually improves the effectiveness of the LMS through use of its policies, objectives, audit results, analysis of data, corrective actions, and management review. (See the H-101 Internal Audit, D-121 Management-Laboratory, D-122 Lab Operations and QS-112 Core Quality Systems and Quality Events, D-105 Out of Specification Test Results Investigation, QS-108 Corrective and Preventive Action procedures.)

8.3 Actions to Address Risks and Opportunities

8.3.1 While planning and controlling laboratory activities, Management considers the risks and opportunities present in the LMS, facility, equipment, personnel

competency, and other aspects of the operation. Risks and opportunities are addressed to give assurance the management system achieves its intended results, prevents, or reduces undesired impacts and potential failures in laboratory activities, and achieve improvement. Opportunities will be enhanced to achieve the purpose and objectives of the laboratory. The process for addressing risks and opportunities is described in the D-121 Management-Laboratory procedure.

8.4 Nonconformity and Corrective Action

8.4.1 The nonconformity and corrective action process supports all LMS processes and improvement activities. As a support process, the objective of the nonconformity and corrective action process is to identify systemic or process-related problems or undesirable situations, to determine their causes, and to take actions to eliminate those causes so they do not recur. Corrective actions are taken appropriate to the magnitude of problems and risks involved. Error-proofing methods, including those to prevent human error, are employed wherever applicable.

8.4.2 Corrective actions are taken in response to audit results, customer feedback or complaints, supplier performance data, testing performance information regarding nonconforming work, process monitoring and measurement results, etc. Actions also arise in connection with improvement efforts associated with any management system process. Requests for corrective action are processed as described in the D-122 Lab Operations and QS-112 Core Quality Systems and Quality Events, D-105 Out of Specification Test Results Investigation, QS-108 Corrective and Preventive Action procedures.

8.4.3 According to the procedure, the following steps are taken for each corrective action initiated: the problem is reviewed, and its root cause(s) determined using appropriate problem-solving methods; possible actions to eliminate its root cause to prevent its recurrence are evaluated and an appropriate action is

selected and implemented; records of the completed action are maintained; the effectiveness of the action taken is verified and recorded.

8.4.4 When serious issues, risks, or problems cast doubt on compliance with policies or procedures, or our compliance with ISO 17025, the Lab Director ensures appropriate problem areas are addressed as soon as possible.

8.4.5 Once closed, corrective action records provide evidence of actions taken and verification of their effectiveness. Documentation revisions required as the result of actions are done according to the C-501 Document Control and C-502 Record Storage, Retention and Destruction procedure.

8.4.6 If corrective action proves ineffective, alternative solutions will be evaluated and applied until the issue is resolved.

8.5 Control of Records

8.5.1 C-501 Document Control and C-502 Record Storage, Retention and Destruction procedures supports all management system processes. As a support process, the purpose of records control is to ensure records of testing service activities, general lab activities, and management system activities are maintained for the required retention period. Records demonstrate the effective operation of the management system and conformity to applicable requirements.

8.5.2 Records control ensures LMS records are stored and protected from damage and deterioration, they are readily identifiable and retrievable when needed, and they are disposed of properly once their retention period has expired. All records are held secure and in confidence. The Records Retention Matrix specifies responsibilities for maintaining records, their storage and protection, their retrieval or filing method, their retention periods, and their method of disposal. The C-501 Document Control and C-502 Record Storage, Retention and Destruction procedures describes actions for protecting and backing-up electronic records.

8.5.3 Technical records include original observations, which are recorded in the appropriate hard or soft copy media and reports to document testing results. Observations, data, and calculations are recorded at the time they are made and are identifiable to the specific customer and order.

8.5.4 Records of original observations, derived data, calculations, etc., are sufficient to establish an audit trail along with equipment calibration records, training records, and a copy of each calibration certificate issued. Records contain sufficient information to facilitate, if possible, identification of factors affecting uncertainty and to enable the testing activity to be repeated under conditions as close as possible to the original.

8.6 Internal Audits

8.6.1 Internal audits support all LMS processes. As a support process, the objective of internal audits is to monitor processing activities at planned intervals to ensure their effective implementation, and to ensure they comply with the planned arrangements described by management system documentation and confirm continuing conformity with ISO 17025.

8.6.2 Internal audits are conducted, reported and the results acted upon according to the H-101 Internal Audit procedure. Internal audits verify working practice is conducted in accordance with the Lab's policies and objectives, procedures, and provisions in this manual, ensuring issues regarding conformity are resolved. All LMS processes are audited at least annually.

8.6.3 Internal Audits are scheduled according to the status and importance of the activities being audited, and changes affecting the Lab and/or its activities. Audits are conducted by trained, impartial internal auditors or contracted auditors, according to the instructions, scope, criteria, and any specific methods appearing on internal audit schedules and plans.

8.6.4 Where working practice fails to conform to planned arrangements, or when problems or opportunities for improvement are discovered, auditors generate findings, which become corrective actions as necessary.

8.6.5 Upon completion of an audit, auditors summarize their findings and conclusions on an internal audit report, and submit the report and findings to management, who take timely action.

8.6.6 When audit findings cast doubt on the effectiveness of operations or the correctness or validity of the testing results, the Lab Director ensures corrective action is taken in a timely manner and will notify customers in writing when necessary.

8.6.7 Corrective actions arising from audits will be followed-up according to the QS-112 Core Quality Systems and Quality Events, D-105 Out of Specification Test Results Investigation, QS-108 Corrective and Preventive Action procedures to verify actions taken demonstrate effectiveness and were completed in a timely manner.

8.7 Management Review

8.7.1 The D-121 Management-Laboratory procedure describes how performance data from various sources is analyzed and acted upon, including information relating to process or service performance trends suggesting need for improvement or corrective action, and supplier performance. Measurements are analyzed and acted upon in an effort to improve performance.

8.7.2 Inputs to management review meetings include corrective action data, actions decided during previous management reviews, supplier performance information, internal performance information regarding service conformity and process monitoring and measurement (including internal performance data and internal audit results), external performance information (including external assessments, feedback, any benchmarking data, etc.), any identified improvement opportunities or recommendations, and any identified internal or

external changes, including changes in the volume of work, that could impact the LMS.

8.7.3 Top management periodically reviews the management system as a whole to determine its effectiveness in meeting objectives and applicable requirements, including those of our customers and those of ISO 17025. Top management also determines whether the LMS, the quality policy, procedures, and objectives are suitable and adequate for the organization. The Management Review Meeting Minutes form is the control that identifies the agenda and when complete, stands as the record of the completed review. Actions are initiated and documented and are processed according to the D-121 Management-Laboratory procedure.

8.7.4 Once performance levels are analyzed and management system effectiveness has been determined, performance information and updated objectives/targets are communicated to staff, so they understand how their performance affects the achievement of established objectives. Communication occurs through verbal reporting during staff meetings, via email, or on an individual basis.

9.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	12/06/21	New procedure.	N/A	J. Sassman