Dexter Laboratories LLC / 7 Aug 2019

ISO/IEC 17025:2017 Checklist

Complete

Inspection score	Failed items	Created actions
99.28%	1	0

Laboratory/Site

Dexter Laboratories LLC

Conducted on

7th Aug, 2019 2:12 PM +08

Prepared by

Deirdre Smith, MHA

Location

133 S Hickory St
Dexter, MO 63841
United States
(36.79162942590022, -89.95177454143651)

Failed items

1 Failed

Internal Assessment / 6. Resource Requirements / 6.3 Facilities and Environmental Conditions

6.3.4 Measures to control facilities • to be implemented, monitored and periodically reviewed, including but not limited to a) access to and use of areas affecting laboratory activities b) prevention of contamination, interference or adverse influences on laboratory activities c) effective separation between areas with incompatible laboratory activities	Non-Compliant

— Notes

We had an issue on temperature control and discovered a monitoring gap that we cannot allow to continue. I contacted Minnie to address the gap in temperature control and monitoring.

4. General Requirements

4.1 Impatiality

4.1.1 Laboratory activities • shall be undertaken impartially and structured and safeguarded to ensure impartiality	Compliant
4.1.2 Laboratory management • shall be committed to impartiality	Compliant
4.1.3 Laboratory responsibility • commercial, financial or other pressures must not compromise impartiality with regard to laboratory activities	Compliant
4.1.4 Risk identification the laboratory to undertake this on an on-going basis and include those arising from: • its activities • its relationships • relationships of personnel	Compliant
4.1.5 Risk mitigation • the laboratory shall demonstrate how risk to impartiality is eliminated or minimized	Compliant

4.2 Confidentiality

4.2.1 Laboratory responsibility • through legally enforceable commitments, manage all information obtained or created during the performance of laboratory activities • inform the customer in advance of the information it intends to place in the public domain • maintain all customer information as confidential, except for that information the customer makes public or that agreed to be made public	Compliant

4.2.2 Release of customer information • must not occur unless - when required by law - authorized by contractual arrangements • customer to be notified of information provided (unless prohibited by law)	Compliant
4.2.3 Customer information from other sources • shall be confidential between the customer and laboratory • the source of this information shall remain confidential to the laboratory	Compliant
4.2.4 Confidentiality obligations of personnel • shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law	Compliant

5. Structural Requirements

5.1 Legal status • the laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities	Compliant
5.2 Laboratory management • identify management that has overall responsibility for the laboratory	Compliant
5.3 Scope of laboratory activities • the laboratory to define and document the range of activities which it claims conformity to the Standard • cannot include laboratory activities which are provided externally on an ongoing basis	Compliant
5.4 Conduct of laboratory activities and premises • to be performed to meet the requirements of - the ISO 17025:2017 standard - customer requirements - regulatory authorities • activities include those conducted at - permanent facilities - sites away from permanent facilities - temporary or mobile facilities - customer premises	Compliant

5.5 Structure, personnel and documentation a) define the laboratory's place in any parent organisation, the relationship between management, technical operations and support services b) specify the responsibilities, authorities and interrelationships of those who manage, perform or verify work affecting the results of laboratory activities c) document procedures to the extent necessary to ensure consistent conduct of laboratory activities and the validity of results	Compliant
5.6 Personnel authorities and resources a) available to implement, maintain and improve the management system b) able to identify deviations in the management system or laboratory activity procedures c) able to initiate actions to prevent or minimize deviations d) report to laboratory management the performance of the management system and needs for improvement e) ensure the effectiveness of laboratory activities	Compliant
5.7 Laboratory management responsibilities a) ensure communication on the effectiveness of the management system and meeting customers' and other requirements b) ensure integrity of the management system is maintained when changes are planned and implemented	Compliant

6. Resource Requirements

6.1 General

6.1 Available resources • laboratory to have available personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities	Compliant

6.2 Personnel

6.2.1 Competence and impartiality • all personnel (internal or external) associated with the laboratory that could influence the laboratory activities to be competent and act impartially in accordance with the management system	Compliant

6.2.2 Documentation of competency requirements • to include education, qualification, training, technical knowledge, skills and experience for each role which influence the laboratory activities	Compliant
6.2.3 Competency • ensure personnel are competent to perform laboratory activities for which they are responsible and to evaluate the significance of deviations	Compliant
6.2.4 Duties, responsibilities and authorities • ensure these are communicated	Compliant
6.2.5 Procedures and records a) for the determination of the competence requirements b) for the selection of personnel c) for training d) for supervision e) for authorisations f) for the monitoring of competence	Compliant
6.2.6 Authorisations to perform specific activities a) develop, modify, verify and validate methods b) analyse results, including statements of conformity or opinions and interpretations c) report, review and authorise results	Compliant

6.3 Facilities and Environmental Conditions 1 Failed

6.3.1 Suitability of facilities and environmental conditions • appropriate and not adversely affect the validity of results	Compliant
6.3.2 Document • the requirements for facilities and environmental conditions to perform laboratory activities	Compliant
6.3.3 Monitor, control and record • the environmental conditions in accordance with the relevant specifications, methods and procedures or when they influence the validity of results	Compliant

6.3.4 Measures to control facilities • to be implemented, monitored and periodically reviewed, including but not limited to a) access to and use of areas affecting laboratory activities b) prevention of contamination, interference or adverse influences on laboratory activities c) effective separation between areas with incompatible laboratory activities	Non-Compliant
— Notes We had an issue on temperature control and discovered a monitoring gap that we cannot allow to continue. I contacted Minnie to address the gap in temperature control and monitoring.	
6.3.5 Sites outside laboratory's permanent control • ensure facilities and environmental conditions comply with requirements of the Standard	Compliant

6.4 Equipment

6.4.1 Availability of equipment • laboratory has access to equipment for correct performance of laboratory activities	Compliant
6.4.2 Equipment outside control of laboratory • the requirements of the Standard are met	Compliant
6.4.3 Procedure • is available for handling, storage, use and planned maintenance to ensure proper functions and to prevent contamination or deterioration	Compliant
6.4.4 Verification • ensure equipment conforms to specified requirements before being placed or returned into service	Compliant
6.4.5 Accuracy and/or measurement uncertainty (MU) • to provide a valid result, equipment must be capable of achieving the required - measurement accuracy; and/or - MU	Compliant

6.4.6 Calibration • equipment shall be calibrated when • measurement accuracy or MU affects the validity of the results; and/or • the equipment is necessary to establish metrological traceability of the results	Compliant
6.4.7 Calibration program • shall be established and reviewed and adjusted as necessary in order to maintain confidence in the status of calibration	Compliant
6.4.8 Labelling • all equipment which requires calibration or has a defined period of validity shall be labeled, coded or otherwise identified	Compliant
6.4.9 Out-of-service • overloaded, mishandled or poorly functioning equipment shall be isolated and not reused until verified that it performs correctly • the effect of such defective equipment shall be investigated and the management of non-conforming work initiated	Compliant
6.4.10 Intermediate checks • shall be carried out when necessary to confirm performance of the equipment • in accordance with a procedure	Compliant
6.4.11 Correction factors • when calibration and reference material data include reference values or correction factors, these are to be updated and implemented, as appropriate, to meet specified requirements	Compliant
6.4.12 Unintended adjustments • practicable measures are taken to prevent these from occurring and invalidating results	Compliant

6.4.13 Records • shall be retained for equipment which can influence laboratory activities, including: - identity, including software/firmware version - manufacturer's name, type and serial number or other identification - evidence of verification - location - calibration dates and results, results of adjustments, acceptance criteria, due date of next calibration or interval - documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity - maintenance plan and maintenance performed; - details of damage, malfunction, modifications or repair	Compliant

6.5 Metrological Traceability

6.5.1 Establish metrological traceability • the laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference	Compliant
6.5.2 Measurement results traceable to SI units • to be established through a) calibration provided by a competent laboratory; or b) certified values of CRMs from a competent producer with stated traceability to SI units; or c) direct realization of the SI units ensured by comparison with national or international standards	Compliant
6.5.3 Traceability to SI not technically possible • where this occurs, metrological traceability to an appropriate reference shall be demonstrated, for example a) certified values of CRMs provided by a competent producer to non SI values b) results of reference measurement procedures, specified methods or consensus standards that are accepted as providing measurement results fit for their intended use and ensured by suitable comparison	Compliant

6.6 EXTERNALLY PROVIDED PRODUCTS AND SERVICES

6.6.1 Use of externally provided products and services • Only suitable products and services are used when a) incorporated into the laboratory's own activities b) provided directly to the customer by the laboratory as received from the external provider c) used to support the operation of the laboratory	Compliant
6.6.2 Procedure and records for a) defining, reviewing and approving the laboratory's requirements for externally provided products and services b) defining criteria for evaluation, selection, monitoring of performance and re- evaluation of external providers c) ensuring that prior to laboratory use or supply to customers, the products and services conform to the laboratory's requirements or where relevant to the Standard d) actions to take arising from evaluations, monitoring or re-evaluations of external providers	Compliant
6.6.3 Communication of requirements to external providers • These include a) the products and services to be provided b) the acceptance criteria c) competence, including any required qualification of personnel d) activities that the laboratory, or its customer, intends to perform at the external provider's premises	Compliant

7. Process Requirements

7.1 Review of Requests, Tenders, and Contracts

7.1.1 Procedure Shall ensure a) requirements are defined, documented and understood b) laboratory has the capability and resources to meet the requirements c) where external providers are used, the customer is advised and approves; d) appropriate methods or procedures are selected	Compliant
7.1.2 Inappropriate method requested • customer is informed, including if method is out-of-date	Compliant

7.1.3 Statement of conformity requested • specification or standard and the decision rule are clearly defined • unless inherent in the specification or standard, the decision rule is agreed with the customer	Compliant
7.1.4 Differences between requests and contract • are resolved prior to laboratory activities commencing • contract to be acceptable to both the laboratory and customer • deviations requested do not impact on the laboratory's integrity or the validity of results	Compliant
7.1.5 Deviations from the contract • customer is informed	Compliant
7.1.6 Amendments to contracts • contract review is repeated after work commences and amendments communicated to all affected personnel	Compliant
7.1.7 Cooperation with customers • laboratory to clarify requests and to allow the customer to monitor its performance	Compliant
7.1.8 Records of reviews • are retained, including changes to contracts and discussions had with the customer	Compliant

7.2 Selection, Verification, and Validation of Methods

7.2.1 Selection and Verification of Methods

7.2.1.1 Methods and procedures • to be appropriate for all laboratory activities, including where necessary, for evaluation of measurement uncertainty and statistical techniques for data analysis	Compliant
7.2.1.2 Currency of methods and procedures • to be kept up-to-date and made available to personnel	Compliant
7.2.1.3 Method version • latest valid versions to be used unless it is not appropriate or possible • where necessary, supplemented with additional details for consistent application	Compliant

7.2.1.4 Method selection • the laboratory to select an appropriate method and inform the customer when the customer has not specified the method	Compliant
7.2.1.5 Method verification • before introducing methods, the laboratory must verify that it can achieve the required performance • records of verification must be kept • verification to be repeated when changes to the methods are made by the issuing body/ies	Compliant
7.2.1.6 Method development • as proceeds, periodic review to occur to confirm the needs of the customer are still satisfied • changes to the development plan to be approved and authorized	Compliant
7.2.1.7 Deviations from methods • shall only occur if the deviation is technically justified, documented, authorized and accepted by the customer	Compliant

7.2.2 Validation of Methods

7.2.2.1 Validation • non-standard methods, laboratory-developed methods and standard methods used outside their scope or modified shall be validated	Compliant
7.2.2.2 Changes made to validated method • the influence of such changes shall be determined and if they affect the original validation, then the method must be revalidated	Compliant
7.2.2.3 Method performance characteristics • satisfy the customers' needs and specified requirements	Compliant
7.2.2.4 Validation records a) the validation procedure used b) specification of the requirements c) performance characteristics of the method d) results obtained e) a statement on the validity of the method, detailing its fitness for the intended use	Compliant

7.3 Sampling

7.3.1 Sampling plan and method • method addresses factors to be controlled to ensure validity of subsequent testing or calibration • plan and method available at sampling site • sampling plans based on statistical methods whenever reasonable	Compliant
7.3.2 Method • describes a) selection of samples or sites b) sampling plan c) preparation and treatment of samples from a substance, material or product	Compliant
7.3.3 Records of sampling data • include a) reference to the sampling method b) date and time of sampling c) data to identify and describe the sample d) identification of the personnel e) identification of the equipment used f) environmental or transport conditions g) diagrams or other means to identify the sampling location when appropriate h) deviations, additions or exclusions from the method or sampling plan	Compliant

7.4 Handling of Test or Calibration Items

7.4.1 Procedure • ensures the protection of integrity of the item and the interests of the laboratory and customer and covers - transportation - receipt - handling - protection - storage - retention and/or disposal • precautions taken to avoid deterioration, contamination, loss or damage • handling instructions provided with the item to be followed	Compliant
7.4.2 Identification • system is in place for the unambiguous identification of items, including, if relevant, the subdivision and transfer of items	Compliant

7.4.3 Item deviations • upon receipt, deviations from specified conditions are recorded • if there is doubt about suitability of item, or it does not conform to description provided, ensure that the customer is consulted and that the instructions are recorded • when deviation is acknowledged and customer instructs to proceed with testing or calibration, the laboratory is to include a disclaimer in the report indicating that the results may be affected	Compliant
7.4.4 Storage conditions • to be maintained, monitored and recorded	Compliant

7.5 Technical Records

7.5.1 Records • for each laboratory activity include - results - report - factors affecting the results and its measurement uncertainty - date - identify of personnel conducting the laboratory activity and checking data and results • allow repetition of the laboratory activity • original observations, data and calculations to be recorded at the time they made and be identifiable with the specific task	Compliant
7.5.2 Amendments • can be traced to original observations or previous version of records • original and amended data - to be retained - include the date - an indication of the altered aspects - the personnel responsible	Compliant

7.6 Evaluation of Measurement Uncertainty (MU)

7.6.1 Contributions of MU • shall be identified • significant contributions taken into account when evaluating MU, including those from sampling	Compliant
7.6.2 Calibration • MU for all calibrations performed shall be evaluated	Compliant

7.6.3 Testing • where the test method precludes rigorous evaluation, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method	Compliant

7.7 Ensuring Validity of Results

7.7.1 Procedure • for monitoring validity of results is in place • data from monitoring activities are recorded in a manner which allows the detection of trends with statistical methods applied, where possible, for review of the results • monitoring is to be planned and reviewed and include, where appropriate a) use of reference materials or quality control materials b) use of alternative calibrated instrumentation providing traceable results c) functional checks of measuring and testing equipment; d) use of check or working standards with control charts e) intermediate checks on measuring equipment f) replicate tests or calibrations g) retesting or recalibration of retained items h) correlation of results for different characteristics of an item i) review of reported results j) intra-laboratory comparisons k) testing of blind sample(s)	Compliant
7.7.2 Comparison of results with other laboratories • shall be used to monitor the laboratory's performance • monitoring shall be planned and reviewed and include participation in either or both a) proficiency testing b) inter-laboratory comparisons	Compliant
7.7.3 Analysis of monitoring data • used to control and improve, where applicable, laboratory activities • appropriate action is taken to prevent incorrect results from being reported when monitoring data is found to be outside of pre-defined criteria	Compliant

— Notes

We have recently used this Analytics of iAuditor and it gives us a quick overview of our monitoring activities and allows us to do a deep dive of frequently missed items. We will use the data to improve our refresher trainings and reinforce best practices in the lab.

7.8 Reporting of Results

7.8.1 General

7.8.1.1 Review and authorization of results • shall occur prior to release	Compliant
7.8.1.2 Reports • results are provided accurately, clearly, unambiguously and objectively • include all the information agreed with the customer and necessary for the interpretation of the results • issued reports are retained as technical records	Compliant
7.8.1.3 Simplified reports • when agreed with the customer • all information not reported to customer and covered by 7.8.2 to 7.8.7 must be readily available	Compliant

7.8.2 Common Requirements for Reports (Test, Calibration or Sampling)

7.8.2.1 Report content a) title b) name and address of the laboratory c) location where the laboratory activities were performed d) unique identification that all components are recognised as a portion of a complete report and a clear identification of the end e) name and contact information of the customer f) method used g) a description, unambiguous identification, and if necessary, the condition of the item h) date of receipt of the item or date of sampling of the item where critical to the validity and application of the results i) date(s) of the performance of the laboratory activity j) date of the issue of the report k) reference to the sampling plan and sampling method if relevant to the validity and application of the results l) statement to the effect that results only relate to the item tested, calibrated or sampled m) the results with the units of measurement, where appropriate n) additions, deviations or exclusions from the method o) identification of the person authorising the report p) clear identification when the results are from external providers	Compliant

7.8.2.2 Laboratory responsibility • for all information provided in the report except when provided by the customer - customer information to be clearly identified and a disclaimer included when information supplied can affect the validity of results • when customer is responsible for sampling, the report is to state that the results apply to the sample as received (also refer to 7.4.3)	Compliant

7.8.3 Specific Requirements for Test Reports

7.8.3.1 Additional information • for the interpretation of the test results, in addition to 7.8.2, reports to include where necessary a) information on specific test conditions, such as environmental conditions b) where relevant, a statement of conformity with requirements or specifications c) where applicable, the MU in the same units as the measurand or in a term relative to the measurand when - relevant to the validity or application of the results - customer's instruction - MU affects conformity to a specification limit d) where appropriate, opinions and interpretations; e) additional information which may be required by specific methods, authorities, customers or groups of customers	Compliant
7.8.3.2 Sampling • when the laboratory is responsible for sampling, test reports shall meet the requirements of 7.8.5 where necessary	Compliant

7.8.4 Specific Requirements for Calibration Certificates

7.8.4.1 Additional information • in addition to 7.8.2, calibration certificates to include a) the MU of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand b) the conditions under which the calibrations were made that have an influence on the measurement results c) a statement to indicate how the measurements are metrologically traceable d) results before and after any adjustments or repair e) where relevant, a statement of conformity with requirements or specifications f) where appropriate, opinions and interpretation	Compliant

7.8.4.2 Sampling • when the laboratory is responsible for sampling, calibration certificates shall meet the requirements of 7.8.5 where necessary	Compliant
7.8.4.3 Calibration certificates or labels • shall not include any recommendation on calibration intervals, unless agreed with the customer	Compliant

7.8.5 Reporting Sampling - Specific Requirements

7.8.5 Additional information • when the laboratory is responsible for the sampling, in addition to 7.8.2, reports to include a) date of sampling b) unique identification of the item or material sampled c) location of sampling, including any diagrams, sketches or photographs d) reference to the sampling plan and sampling method e) details of any environmental conditions that affect the interpretation of the results f) information required to evaluate MU for subsequent testing or calibration	Compliant

7.8.6 Reporting Statements of Conformity

7.8.6.1 Decision rule • to be documented and applied, taking into account the associated risk, when a statement of conformity is provided to a customer	Compliant
7.8.6.2 Statement of conformity • includes a) which results the statement of conformity applies to b) which specifications, standards or parts thereof are met or not met c) the decision rule applied (unless it is inherent in the requested specification or standard)	Compliant

7.8.7 Reporting Opinions and Interpretations

7.8.7.1 Authorized personnel • opinions and interpretations are only made by authorized personnel and the basis upon which they have been made shall be documented	Compliant

7.8.7.2 Based on results • opinions and interpretations are based on the results obtained and clearly identified as such in reports	Compliant
7.8.7.3 Direct verbal communication • when opinions and interpretations are verbally communicated to the client, a record is retained	Compliant

7.8.8 Amendments to Reports

7.8.8.1 Amendments to reports • are clearly identified	Compliant
7.8.8.2 Amendments to reports • where appropriate, the reason for the change is included in the report	Compliant
7.8.8.3 Amendments to reports • a further report is issued and referenced as amended, is uniquely identified and makes reference to the original report it replaces	Compliant

7.9 Complaints

7.9.1 Documented process • is available for receiving, evaluating and making decisions on complaints	Compliant
7.9.2 Availability of documented process and responsibility • is available to any interested party • when a complaint is received, the laboratory is to confirm whether it relates to laboratory activities it is responsible for and action it • laboratory is responsible for all decisions relating to complaints handling	Compliant
7.9.3 Content of complaints process a) a description of the process for receiving, validating, investigating and deciding what actions are to be taken in response to it b) tracking and recording complaints, including actions taken c) ensuring that any appropriate action is taken	Compliant
7.9.4 Gathering and verifying information • the laboratory is responsible in order to validate the complaint	Compliant

7.9.5 Acknowledging receipt • whenever possible, the laboratory does this and provides the complainant with progress reports and the outcome	Compliant
7.9.6 Communication of outcomes • to be made by, or reviewed and approved by, an individual(s) not involved in the original laboratory activities in question.	Compliant
7.9.7 Formal notice of end of complaint • whenever possible, the laboratory to advise the complainant	Compliant

7.10 Nonconforming Work

7.10.1 Procedure • is available and implemented when any aspect of the laboratories activities does not conform to its own procedures or the agreed requirements of the customer a) defines the responsibilities and authorizations for the management of non-conforming work b) actions are based upon the risk levels established by the laboratory c) an evaluation is made of the significance of the non-conforming work, including an impact analysis on previous results d) a decision is taken on the acceptability of the non-conforming work e) where necessary, the client is notified and work is recalled f) defines the responsibility for authorizing the resumption of work	Compliant
7.10.2 Records • are retained of non-conforming work and the actions taken	Compliant
7.10.3 Implementation of corrective action • shall be taken when the non-conforming work could recur, or there is doubt with the laboratory's operations with its own management system	Compliant

7.11 Control Of Data and Information Management

7.11.1 Access to data and information • data and information needed to perform laboratory activities is available	Compliant

7.11.2 Laboratory information management system • the system for collecting, processing, recording, reporting, storing and retrieving data is validated, including interfacing with other laboratory systems before being used • changes to the system are authorized, documented and validated before used	Compliant
7.11.3 Protection, safeguard and maintenance • the information system a) is protected from unauthorized access b) is safeguarded against tampering and loss c) is operated in an environment that complies with supplier or laboratory specifications or, for non-computerised systems, provides conditions which safeguard the accuracy of manual recording and transcription d) is maintained in a manner which ensures the integrity of the data and information e) includes the recording of system failures and the appropriate immediate and corrective actions	Compliant
7.11.4 Off-site systems • laboratory ensures that the provider or operator complies with all applicable requirements of the Standard	Compliant
7.11.5 Instructions, manuals and reference data • are readily available to personnel	Compliant
7.11.6 Calculations and data transfers • are checked in an appropriate and systematic manner	Compliant

8. Management System Requirements

8.1 Options

8.1.1 Management system • supports and demonstrates the consistent achievement of the requirements of the Standard • assures the quality of the laboratory results • allows the requirements of clauses 4 to 7 to be met • is in accordance with either Option A or Option B	Compliant

8.1.2 OPTION A, As a minimum, the laboratory management system shall address the clauses 8.2 to 8.9 8.1.3 OPTION B, Laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001:2015 and that is capable of supporting and demonstrating the consistent fulfillment of the requirements of clauses 4 to 7, also fulfills at least the intent of the management system requirements specified in clauses 8.2 to 8.9	Option B

If Option B, the following documentation is required

1) evidence the management system is certified by a certification body, or by another signatory to the International Accreditation Forum (IAF) Multilateral Recognition Agreement (MLA). 2) evidence that the certification body's accreditation covers ISO/IEC 17021-3 i.e. the certification body can certify management systems to ISO 9001:2015. 3) copies of the most recent certification audit report(s) issued by the certification body covering the laboratory's management system in full. 4) confirmation from the certification body of the closeout of any non-conformities raised during certification audits. 5) evidence the certification of the management system covers the laboratory activities covered by its scope of accreditation. 6) supports the facility fulfilling consistently the requirements of ISO/IEC 17025:2017 to assure the quality of results.	Docs Available

— Notes

We are at an advantage because we already are certified for ISO 9001. It was during our efforts to get certified for 9001 did we discover the auditing app.

8.2 Management System Documentation

8.2.1 Policies and objectives • are established, documented for the fulfillment of the Standard • are acknowledged and implemented at all levels of the laboratory	Compliant
8.2.2 Competence, impartiality consistent operations • are addressed by the polices and objectives	Compliant
8.2.3 Laboratory management • provides evidence of commitment to the development of the management system • continually improves the management system's effectiveness	Compliant

8.2.4 Reference to the management system • of all documentation, processes, systems and records	Compliant
8.2.5 Access to parts of the management system • is available to personnel	Compliant

8.3 Control of Management System Documents

8.3.1 Control of documents • both internal and external documents relating to the fulfillment of the requirements of the Standard	Compliant
8.3.2 Document control process a) documents are approved by authorized personnel prior to issue b) documents are periodically reviewed and updated as necessary c) changes and current revision status of documents are identified d) relevant versions of documents are available and their distribution controlled as necessary e) documents are uniquely identified f) unintended use of obsolete documents is prevented	Compliant

8.4 Control of Records

8.4.1 Records retention • to demonstrate fulfillment of the requirements of the Standard	Compliant
8.4.2 Controls • are implemented for - identification - storage - protection - back-up - archive - retrieval - retention times - disposal • are established for - retention periods to satisfy contractual obligations - confidentiality commitments - access and availability	Compliant

8.5 Actions to Address Risks and Opportunities

8.5.1 Risks and opportunities are considered a) to assure the management system achieves its intended goals b) to achieve the laboratory objectives c) to prevent (or minimize) undesired impacts and potential failures d) to achieve improvement	Compliant
8.5.2 Plan a) actions to address risks and opportunities b) how to - implement actions into the management system - evaluate the effectiveness of actions	Compliant
8.5.3 Actions to address risks and opportunities • are proportional to the potential impact on the validity of the laboratory results	Compliant

8.7 Corrective Actions

8.7.1 Nonconformities • when occur, the laboratory shall a) react and, as applicable, take action, correct the issue and address the consequences b) evaluate the need for action to eliminate the cause so that it does not recur c) implement any action necessary d) review the effectiveness of any corrective action e) update any risk and opportunities f) makes any necessary changes to the management system	Compliant
8.7.2 Corrective action taken • is appropriate to the effects of the nonconformity	Compliant
8.7.3 Records retained a) of the nature of the nonconformity, cause(s) and any action(s) taken b) of the outcomes of corrective action	Compliant

8.8 Internal Audits

8.8.1 Conducted at planned intervals • to establish whether the management system a) conforms to - the laboratory's requirements, including laboratory activities - the requirements of the Standard b) is effectively implemented and maintained	Compliant
8.8.2 Audit requirements a) is planned and implemented, including frequency, defined responsibilities and reporting, taking into account - the importance of the laboratory activities concerned - changes affecting the laboratory - the results of previous audits b) audit criteria and the scope of each audit are defined c) audit results are reported to relevant management d) corrective actions, where necessary, are implemented promptly e) records of the audit program, including outcomes, are retained	Compliant

8.9 Management Reviews

8.9.1 Review of management system • is conducted at planned intervals by laboratory management to ensure - continued suitability, adequacy and effectiveness - covers the stated policies and objectives related to the fulfilment of the Standard	Compliant
8.9.2 Records of inputs • including information related to a) changes in internal and external issues b) fulfillment of objectives c) suitability of policies and procedures d) status of actions from previous reviews e) outcomes of recent internal audits f) corrective actions g) assessment by external bodies h) changes in volume, type and range of laboratory activities i) customer and personnel feedback j) complaints k) effectiveness of any implemented improvements l) adequacy of resources m) results of risk identification n) outcomes of the assurance of validity of results o) any other relevant factors	Compliant

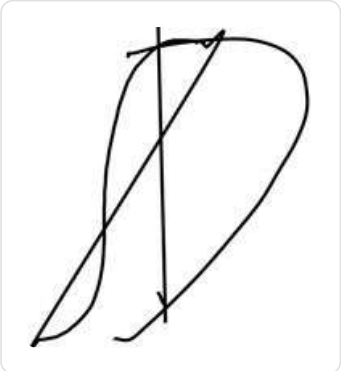
8.9.3 Records of outputs • include all decisions and actions relating to a) effectiveness of the management system b) improvement of the laboratory activities relating to satisfying the requirements of the Standard c) provision of required resources d) any need for change(s)	Compliant

Completion

Comments/Recommendations

We caught an issue with temperature control and monitoring and we are committed to fixing the issue within this week. We are continuously monitoring our lab activities and we're using the analyzed data collected to improve the competency of our lab and staff. We are almost ready for our third-party audit but until we fix the stability of temperature control, we will not be able to proceed.

Conducted by: Name and Signature



Deirdre York, MHA

7th Aug, 2019 2:19 PM +08