

[organization name]

Appendix 2 – ISO/IEC 17025:2017 Internal Audit Checklist

| Clause | Requirement | YES | NO | Comments |
|------------|--|-----|----|---|
| 4.0 | GENERAL REQUIREMENTS | | | |
| 4.1.1 | [REDACTED] | X | | <i>e.g. Management has implemented a suitable program</i> |
| 4.1.2 | Is laboratory management committed to impartiality? | | | |
| 4.1.3 | Does the laboratory prevent [REDACTED] impartiality? | | | |
| 4.1.4 | Does the laboratory identify risks to its impartiality on an on- going basis? | | | |
| 4.1.5 | [REDACTED] | | | |
| 4.2.1 | Does the laboratory ensure the [REDACTED] results? | | | |
| 4.2.2 | Is the laboratory responsible, through legally enforceable [REDACTED] performance of its activities? | | | |
| 4.2.3 | When legally allowed, does the laboratory notify its customer of any release of confidential information? | | | |
| 4.2.4 | [REDACTED] | | | |
| 4.2.5 | Do all personnel, including [REDACTED] required by law? | | | |
| 5.0 | STRUCTURAL REQUIREMENTS | | | |
| 5.1 | Is the laboratory a legal entity or a defined part of a legal entity that is responsible for all its activities? | | | |

Commented [170251]: This checklist is to be used for the first internal audit to ensure that all the elements, clauses and issues of standard have been adequately covered during implementation.

1) Note 1: The term “documented information” means that the standard requires the organization to establish, document, implement and maintain a management system.

2) Note 2: To meet the requirements, the laboratory shall implement a QMS in accordance with Option A (8.1.2) or Option B (8.1.3). See also Annex B of standard.

3) Note 3: Documentation can be in any form and any type of medium.

Commented [170252]: These are the requirements of the ISO/IEC 17025:2017 standard; you should also insert the specific requirements from your own documentation.

Note that this is the complete set of requirements and can either be done at one time, several different times, or split throughout the year as per the “Internal Audit Plan.” The important thing is that the entire system be audited at least once annually.

Commented [170253]: To be filled in during the audit – fill in Yes or No depending on whether the company is compliant or not.

Commented [170254]: To be filled in during the audit – records, verbal statements, or auditor’s personal observations that confirm the finding.

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| 5.2 | Has the laboratory identified management who have overall responsibility for the laboratory? | | | |
| 5.3 | Does the laboratory carry out its activities at its permanent, temporary, mobile sites and temporary and mobile facilities or customer facilities? | | | |
| 5.4 | Has the laboratory defined and documented the range of laboratory activities for which it conforms to this ISO standard? | | | |
| 5.5 | Has the laboratory: a. Specified the responsibility, authority and competence of all personnel performing laboratory activities? | | | |
| | b. Specified the responsibility, authority and competence of all personnel performing laboratory activities? | | | |
| | c. Documented its results? | | | |
| 5.6 | Does the laboratory have a. Implementation, maintenance and improvement of the management system? | | | |

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| | b. Identification of deviations from the management system or from procedures for performing laboratory activities? | | | |
| | c. Initiation of actions to prevent or minimize such deviations? | | | |
| | d. Reporting to management of the effectiveness of the management system and its ability to improve? | | | |
| | e. Ensuring the required validity of laboratory activities? | | | |
| 5.7 | Does laboratory management ensure: | | | |
| | a. That the objectives of the management system are implemented? | | | |
| | b. That communication takes into account the requirements of the management system and the requirements of regulatory bodies and other requirements? | | | |
| 6.0 | RESOURCE REQUIREMENTS | | | |
| 6.1 | In general, does the laboratory activities? | | | |
| 6.2 | Personnel: | | | |
| 6.2.1 | Do all personnel, internal or external, that could influence system? | | | |
| 6.2.2 | Does the laboratory document requirements for education, | | | |

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| | qualification, training, technical knowledge, skills and experience? | | | |
| 6.2.3 | Does the laboratory ensure that [redacted] significance of, and response to deviations in laboratory activities? | | | |
| 6.2.4 | Does the laboratory communicate [redacted] responsibilities and authorities? | | | |
| 6.2.5 | Does the laboratory have procedures and maintain records for: | | | |
| | a. [redacted] | | | |
| | b. Selection of personnel? | | | |
| | c. Training of personnel? | | | |
| | d. Supervision of personnel? | | | |
| | f. [redacted] | | | |
| 6.2.6 | Does the laboratory authorize personnel to: | | | |
| | a. [redacted] | | | |
| | b. [redacted] | | | |
| | c. Report results? | | | |
| 6.3 | Facilities and environmental conditions: | | | |
| 6.3.1 | Are the facilities and [redacted] validity of results? | | | |
| 6.3.2 | Are the requirements for facility [redacted] | | | |
| 6.3.3 | Does the laboratory monitor, [redacted] procedures or where they influence the validity of results? | | | |

Commented [170257]: Look for a procedure.

Commented [170258]: Look for records.

Commented [170259]: Look for a procedure.

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| 6.3.4 | Are measures to control facilities <small>implemented, maintained periodically reviewed, including when necessary</small> a. Access to and use of areas affecting laboratory activities? | | | |
| | b. <small>Availability of resources necessary to address changes in laboratory activities?</small> | | | |
| | c. Effective separation <small>of different types of work and incompatible activities</small> | | | |
| 6.3.5 | When the laboratory performs <small>activities in facilities subject to access control, are controls for the requirements relating to access and environmental conditions of the facilities</small> met? | | | |
| 6.4 | Equipment: | | | |
| 6.4.1 | Does the laboratory have access to <small>equipment required for the current activities of the laboratory</small> activities: a. Measurement instruments? | | | |
| | b. Software? | | | |
| | c. Measurement standards? | | | |
| | d. Reference materials? | | | |
| | e. Reference data? | | | |
| | f. <small>Measurement equipment</small> | | | |
| | g. Auxiliary apparatus? | | | |
| | h. <small>Measurement equipment</small> | | | |
| 6.4.2 | When the laboratory uses <small>measurement equipment subject to access control, are the requirements for equipment of the ISO standard are met?</small> | | | |
| 6.4.3 | Does the laboratory have a <small>procedure for handling, controlling, storage, use and disposal of measurement equipment</small> ensure proper functioning and in | | | |

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| | order to prevent contamination or deterioration? | | | |
| 6.4.4 | Does the laboratory verify that [blurred text] into service? | | | |
| 6.4.5 | Is the equipment used for [blurred text] to provide a valid result? | | | |
| 6.4.6 | When the measurement accuracy [blurred text] result, or metrological traceability is a requirement, is the measuring equipment calibrated? | | | |
| 6.4.7 | Did the laboratory establish a [blurred text] maintained? | | | |
| | Is the calibration program reviewed and adjusted as necessary in order to maintain confidence in the status of calibration? | | | |
| 6.4.8 | [blurred text] | | | |
| 6.4.9 | When equipment is subjected to [blurred text] out of service? | | | |
| | Is that equipment isolated to prevent its use and/or clearly labeled or marked as being out of service? | | | |
| | [blurred text] | | | |
| 6.4.10 | When intermediate checks are [blurred text] equipment, are these checks | | | |

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| | carried out according to a procedure? | | | |
| 6.4.11 | For calibration and reference implemented as appropriate, to meet specified requirements? | | | |
| 6.4.12 | Does the laboratory ensure results? | | | |
| 6.4.13 | Are records maintained for following: | | | |
| | a. The identity of equipment, including software? | | | |
| | b. | | | |
| | c. | | | |
| | d. The current locations, where appropriate? | | | |
| | e. Calibration dates, results of calibration frequency? | | | |
| | f. Dates, results and period of validity? | | | |
| | g. Maintenance plan and equipment? | | | |
| | h. Details of any damage, malfunction, modification or repair to the equipment? | | | |

Commented [1702510]: Look for a procedure.

Commented [1702511]: Look for records.

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| 6.5 | Metrological Traceability: | | | |
| 6.5.1 | Does the laboratory establish and maintain metrological traceability of the measurement results by means of a documented calibration chain of calibration with uncertainty, linking them to an appropriate reference? | | | |
| 6.5.2 | Does the laboratory ensure that | | | |
| | a. Calibration? | | | |
| | b. Certified values of certified reference materials with stated metrological traceability to the SI? | | | |
| | c. [unclear] | | | |
| 6.5.3 | When metrological traceability to appropriate reference such as: | | | |
| | a. [unclear] | | | |
| | b. Results of reference measurement procedures, [unclear] results fit for their intended use and ensured by suitable comparison? | | | |
| 6.6 | Externally Provided Products and Services: | | | |

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| 6.6.1 | Does the laboratory assure the | | | |
| | a. Are intended for incorporation into the laboratory's own activities? | | | |
| | b. Are provided, in part or in | | | |
| | from the external supplier? | | | |
| | c. | | | |
| 6.6.2 | Does the laboratory have a procedure and records for: | | | |
| | a. Defining, reviewing and | | | |
| | b. Defining the criteria for | | | |
| | c. Ensuring that externally | | | |
| | directly provided to the customer? | | | |
| | d. Taking any actions arising from evaluations, monitoring and re-evaluations? | | | |
| 6.6.3 | requirements for: | | | |
| | a. The products and services to be provided? | | | |
| | b. The acceptance criteria? | | | |

Commented [1702512]: Look for a procedure and records.

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| | c. Competence, including any required qualification of personal? | | | |
| | d. Activities that the [blurred text] premises? | | | |
| 7.0 | PROCESS REQUIREMENTS | | | |
| 7.1 | Review of Requests, Tenders and Contracts: | | | |
| 7.1.1.1 | Does the laboratory have a procedure for the review of requests, tenders and contracts? Does it contain: | | | |
| | a. [blurred text] understood? | | | |
| | b. Does the laboratory have [blurred text] used? | | | |
| | c. Does the laboratory use [blurred text] customer requirements? | | | |
| | Does the laboratory have a procedure to cover the activities of external providers? | | | |
| | Does the laboratory advise the [blurred text] provided laboratory activities? | | | |
| | Does the laboratory ensure that [blurred text] requirements of the standard? | | | |
| 7.1.1.2 | Does the laboratory inform the customer when the method requested by the customer is | | | |

Commented [1702513]: Look for a procedure.

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| | considered to be representative of use of test? | | | |
| 70228 | Are methods used for conformity to a specification or standard available to all users of test? | | | |
| 70229 | Are differences between requests and contracts resolved before laboratory activities begin to each contract accepted by both the customer and the laboratory? | | | |
| 70230 | Is the customer informed of any deviation from the contract? | | | |
| 70231 | Is the contract review repeated if the contract is amended after work has commenced? Are amendments communicated to all affected personnel? | | | |
| 70232 | Does the laboratory cooperate with customers in verifying the customer's request and in monitoring the laboratory's performance in relation to the work performed? <ol style="list-style-type: none"> a. Providing reasonable access to relevant areas of the laboratory? b. Preparation, packaging and shipment of items needed by the customer for verification purposes? | | | |
| 70233 | Are records of review, discussion resulting changes, maintained? | | | |
| 70234 | Selection, verification and validation of methods | | | |
| 70235 | Selection and verification of methods | | | |
| 70236 | Does the laboratory use appropriate methods and procedures for all laboratory activities? | | | |
| 70237 | Are all methods, procedures and supporting documentation used up to date? Does this include instructions, standards, manuals and reference data? | | | |
| 70238 | Are all deviations from methods and procedures documented and suitably verified, authorized and accepted by the customer? | | | |

Commented [1702515]: Look for procedures, work instructions, specifications or technique sheets for each test or calibration.

Commented [1702516]: Look for procedures and supporting documentation.

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| 70224 | Does the laboratory use methods that meet customer requirements? | | | |
| 70225 | Does the laboratory ensure that it is using the latest edition of a method? | | | |
| 70226 | When the customer does not specify a method, does the laboratory select an appropriate method and inform the customer of the method used? | | | |
| 70227 | Does the laboratory verify that it can properly perform a method before introducing it? | | | |
| 70228 | When method development is required, is it conducted solely by qualified personnel equipped with adequate resources? Is method development proceeds on their periodic review to verify that the needs of the customer are being met? | | | |
| 70229 | Validation of Methods | | | |
| 70230 | Does the laboratory verify that standard methods, laboratory developed methods and modified methods used outside their intended scope? Is the validation or verification of methods to meet requirements for the customer needs recorded? | | | |
| 70231 | When changes are made to customer methods, are the changes documented and a new validation performed? | | | |
| 70232 | Are the range and accuracy of when obtained from validated methods assessed to ensure they are relevant to customer requirements? | | | |
| 70233 | Does the laboratory retain the following as evidence of validation: a. The validation procedure used? b. Specification of the requirements? c. Determination of the performance? | | | |

Commented [1702517]: Look for a record for each validation.

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| | <p>Documentation of the method?</p> <p>a. Results obtained?</p> <p>b. Verification that the requirements can be fulfilled by using the method?</p> <p>c. Assessment of the ability of the method, including its fitness for the intended use?</p> | | | |
| 7.2 | <p>Sampling</p> <p>To there is sampling procedure?</p> <p>Does it address factors to be considered to ensure the validity of subsequent testing or calibration results?</p> <p>To there is sampling plan and procedure for sampling when carried out for calibration, maintenance or products for subsequent testing or calibration?</p> <p>To the sampling plan is defined outside of the site where sampling is undertaken?</p> <p>Are sampling plans, where necessary, based on appropriate statistical methods?</p> | | | |
| 7.3 | <p>Do sampling methods describe the selection of samples or sites, sampling plan, withdrawal and preparation of a sample from the source?</p> <p>To there is process in place when the sample reaches the laboratory?</p> | | | |
| 7.4 | <p>Does the laboratory keep relevant sampling data that forms part of the testing or calibration that is undertaken?</p> <p>Do these records include:</p> <p>a. The reference to the sampling procedure?</p> <p>b. Date and where sampled, site of sampling?</p> <p>c. Relevant data to identify and describe the sample?</p> | | | |

Commented [1702518]: If sampling is not done, mark this section as N/A (not applicable).

Commented [1702519]: Look for procedures if sampling is perform in or by a laboratory.

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| | 1. Identification of the sample? | | | |
| | 2. If relevant, environmental conditions? | | | |
| | 3. Diagram or other equivalent means to identify the sampling location when appropriate? | | | |
| 7.12 | Handling of Test or Calibration Items | | | |
| 7.12.1 | Is there a procedure for the transportation, receipt, handling, protection, storage, retention and disposal under return of test or calibration items to protect the interests of the laboratory and the customer? Is special care taken to avoid loss or damage during transport? Are handling instructions provided with the item returned? | | | |
| 7.12.2 | Does the laboratory have a system for identifying test and/or calibration items? | | | |
| 7.12.3 | Does the laboratory have a system to identify and trace decomposition or destruction from specific conditions? | | | |
| 7.12.4 | When items have to be stored under specified environmental conditions, are these conditions monitored, controlled and recorded? | | | |
| 7.13 | Technical Records | | | |
| 7.13.1 | Does the laboratory ensure that technical records for each laboratory activity contain the report of results, a possible identification of factors affecting the measurement uncertainty? Do technical records include the date and identity of personnel responsible for each laboratory activity and for checking data and results? | | | |

Commented [1702520]: Look for a procedure.

Commented [1702521]: Look for a record.

Commented [1702522]: Look at the records.

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| | Are original observations, data and calculations recorded at the time they are made? | | | |
| 17022 | Does the laboratory ensure procedures to protect records can be traced back to either previous versions and to original observations for the file kept? | | | |
| 170 | Evaluation of Measurement Uncertainty | | | |
| 17023 | If the laboratory is performing calibrations, including of its own equipment, does it evaluate the measurement uncertainty for all of its calibrations? | | | |
| 17024 | If the laboratory is performing sampling or testing activities, does the laboratory identify all the contributors to measurement uncertainty? Does it make a reasonable estimation of their magnitude? | | | |
| 17025 | When evaluating the measurement uncertainty, are all components of significance identified and taken into account using the appropriate methods of analysis? | | | |
| 171 | Ensuring the Validity of Results | | | |
| 17121 | Does the laboratory have a procedure for regularly monitoring the validity of laboratory activities and the quality of the laboratory output? | | | |
| | In this monitoring does the laboratory use a procedure that needs an observable? | | | |
| | In this monitoring observed and measured and include where appropriate, but not limited to: | | | |
| | 1. Regular use of reference materials of quality control material. | | | |
| | 2. Regular use of alternative measurement that has been calibrated to provide traceable results. | | | |
| | 3. Functional check of measuring and test equipment. | | | |

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| | <ol style="list-style-type: none"> a. Use of tests or testing methods with control charts where applicable b. Periodic recalibration checks on measuring equipment c. Replicate tests or calibrations using the same or different methods d. Monitoring or recalculation of control limits e. Investigation of results for different characteristics of an item f. Review of reported data by competent persons g. Inter-laboratory comparison h. Short run | | | |
| 7722 | Does the laboratory monitor the quality of the laboratory's performance by comparing with control or other laboratories? (Proficiency Testing is the monitoring preferred and required) | | | |
| 7723 | Is data from monitoring activities analyzed and used to both control and improve the laboratory's activities? | | | |
| 772 | Reporting the Results | | | |
| 77221 | Are the results provided accurately, clearly, intelligently and objectively to a report? Do they contain all the information agreed with the customer? Are report reports maintained in accordance with? | | | |
| 772 | Report: Customer Requirements | | | |
| 77221 | Does each report include the following information? | | | |
| | <ol style="list-style-type: none"> a. Title b. The name and address of the laboratory c. The location where the tests/calibrations were performed | | | |

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| | a. A unique identification number for the report | | | |
| | b. The name and contact information of the auditor | | | |
| | c. Identification of the method used | | | |
| | d. A description, including a description and when necessary, the condition of the site | | | |
| | e. The date of receipt of the test data and the date of sampling | | | |
| | f. The date of the test or collection | | | |
| | g. The date the report was issued | | | |
| | h. Reference to sampling plans if relevant | | | |
| | i. A statement to the effect that the results relate only to the items tested or collected | | | |
| | ii. The test or collection results and where appropriate the units of measurement | | | |
| | iii. Identification of the person authoring the report | | | |
| | iv. Their identification when the results are those of external providers | | | |
| TABLE 2 | Does the laboratory take responsibility for all information provided in the test or collection report or collection certificate? | | | |
| TABLE 3 | Specific requirements for test reports | | | |
| TABLE 4 | Where necessary, do test reports contain the following: | | | |
| | a. Specific test conditions (such as environmental) | | | |
| | b. A statement of conformity? | | | |
| | c. Measurement uncertainty? | | | |
| | d. Reference to the relevant standard? | | | |

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| | a. Additional required information? | | | |
| TABLE 2 | Do sampling records or test reports meet the requirements listed in Table 1? | | | |
| TABLE 3 | Specific requirements for calibration certificates | | | |
| TABLE 3a | In addition to the requirements listed in Table 1, do calibration certificates include the following: | | | |
| | a. Measurement uncertainty? | | | |
| | b. Environmental conditions? | | | |
| | c. Statement of Metrological Traceability? | | | |
| | d. Results before and after adjustment? | | | |
| TABLE 4 | Sampling Sampling | | | |
| | When the laboratory is responsible for the sampling stage, do the results contain the following: | | | |
| | a. The date of sampling? | | | |
| | b. Identification of the items sampled? | | | |
| | c. Location of the sampling site? | | | |
| | d. Reference to the sampling plan? | | | |
| | e. Details of environmental conditions during sampling? | | | |
| | f. Information required to include measurement uncertainty for subsequent testing or calibration? | | | |
| TABLE 5 | Statements of conformity | | | |
| TABLE 5a | When a statement of conformity is issued, does the laboratory take into account the level of risk associated with statements of conformity? | | | |
| TABLE 5b | Does the statement of conformity state clearly: | | | |
| | a. To which results the statement applies? | | | |
| | b. Which specification, standard or other formal document is referred to in the test? | | | |
| | c. The decision rule applied? | | | |

[organization name]

| Item | Description | Yes | No | Not Applicable |
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| 17021 | Reporting Agreements and Interpretations | | | |
| 17021A | Are agreements and interpretations based on the results obtained from tested or collected items and clearly marked as such? | | | |
| 17021B | Does the organization ensure that only approved personnel are responsible for agreements and interpretations, outside the statement? | | | |
| 17021C | Does the organization document the basis upon which the agreed and/or interpretation is made? | | | |
| 17021D | Does the organization communicate directly with the customer about agreements and interpretations to them as a result of the communication? | | | |
| 17022 | Agreements to Report | | | |
| 17022A | When a report needs to be changed, is the changed information clearly identified? | | | |
| 17022B | Are agreements made only in the form of a written and identified document? | | | |
| 17022C | Does it contain the title "Agreements to Report"? | | | |
| 17022D | When new reports are issued, do they contain references to the original that it replaces? | | | |
| 17023 | Complaints | | | |
| 17023A | Does the organization have a documented process for receiving, analyzing and making decisions of complaints? | | | |
| 17023B | Is a description of the handling process available to any interested party on request? | | | |
| 17023C | Does the organization confirm that the complaint relates to identified activities? | | | |
| 17023D | Does the organization take responsibility for the complaint process? | | | |

Commented [1702525]: Look for a document.

Commented [1702526]: Look for the procedure.

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| 7.1.1 | Does the compliance handling process include: a. A description of the monitoring, auditing and investigating of the compliance? b. Tracking and recording of the compliance? c. Ensuring that any appropriate action is taken? | | | |
| 7.1.2 | Does the information gather and verify all necessary information to address the compliance? | | | |
| 7.1.3 | Does the information acknowledge receipt of the compliance and provide progress reports and the status? | | | |
| 7.1.4 | Are compliance incidents and approved by individuals not involved in the original compliance activities? | | | |
| 7.1.5 | Does the information give final notice at the end of the compliance handling? | | | |
| 7.1.6 | Nonconforming Work | | | |
| 7.1.6.1 | Does the information have a procedure that covers the report of compliance activities that results in nonconforming work? Does the procedure ensure that: a. Responsibilities and authorities for the management of nonconforming work are defined? b. All actions are based upon the facts established by the laboratory? c. An evaluation is made of the significance of the nonconforming work, including an impact analysis on product quality? d. A decision is taken on the acceptability of the nonconforming work? | | | |

Commented [1702527]: Look for a procedure.

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| | <ul style="list-style-type: none"> a. When necessary, the customer is notified and work is notified b. The responsibility for addressing the investigation of work is defined | | | |
| 7.1.1.1 | Does the laboratory have records of the work conforming work and control? | | | |
| 7.1.1.2 | When evaluation indicates that nonconforming work could have or have about compliance in laboratory operations, does the laboratory implement corrective action? | | | |
| 7.1.2 | Control of Data - Information Management | | | |
| 7.1.2.1 | Does the laboratory have controls for data and information needed to provide laboratory activities? | | | |
| 7.1.2.2 | Does the current management information system utilized by the laboratory reflect being controlled? | | | |
| 7.1.2.3 | Are changes to the IIS authorized, documented and validated before implementation? | | | |
| 7.1.2.4 | Does the laboratory IIS: <ul style="list-style-type: none"> a. Protect from unauthorized access? b. Safeguard against tampering or loss? c. Operate in an environment of compliance with specifications? d. Maintain in a manner that ensures integrity of data and information? e. A recording system for backup and the corrective action? | | | |
| 7.1.2.5 | Is all data management of the IIS managed and data in compliance with the requirements of the ISO 17025 standard? | | | |
| 7.1.2.6 | Does the laboratory ensure that instructions, methods and reference data are relevant to the | | | |

[organization name]

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| 7.1.1 | Are all records available to personnel? | | | |
| 7.1.2 | Are all records and data transfered when an appropriate check has previously been? | | | |
| 8.1 | Management System Documentation | | | |
| 8.1.1 | Management System Documentation | | | |
| 8.1.1.1 | Do the laboratory establish documented and maintained policies and objectives for fulfillment of the ISO 17025 standard? | | | |
| 8.1.1.2 | Do the policies and objectives acknowledge and implement all of them? | | | |
| 8.1.1.3 | Do the policies and objectives address competence, impartiality and consistent operation of the laboratory? | | | |
| 8.1.1.4 | Does laboratory management provide evidence of commitment to the development and implementation of the SMS and its continuous improvement effectiveness? | | | |
| 8.1.1.5 | Are all documentation, processes, systems and records related to the fulfillment of the ISO 17025 standard and referenced or linked to the SMS? | | | |
| 8.1.1.6 | Do all personnel involved in laboratory activities have access to the parts of the SMS documentation and related information that are applicable to their responsibilities? | | | |
| 8.1.2 | Control of Management System Documents | | | |
| 8.1.2.1 | Does the laboratory control all documents, internal and external, that relate to the management system and ISO standard? | | | |
| 8.1.2.2 | Does the laboratory ensure: <ul style="list-style-type: none"> a. Documents are approved prior to issue? b. Documents are periodically reviewed and updated? | | | |

Commented [1702528]: Option 'B' Laboratories are usually part of a larger organization that complies to ISO 9001. The following audit items may have been part of the ISO 9001 internal audit. Indicate each section with a note stating the date of that audit.

[organization name]

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| | <ul style="list-style-type: none"> 1. Storage and control records index is identified? | | | |
| | <ul style="list-style-type: none"> 2. Records are available at point where they are to be reviewed and distributed is controlled? | | | |
| | <ul style="list-style-type: none"> 3. All documents are uniquely identified? | | | |
| | <ul style="list-style-type: none"> 4. Use of obsolete documents is prevented? | | | |
| 6.2 | Control of Records | | | |
| 6.2.1 | Does the laboratory establish and maintain regular records to demonstrate compliance to the ISO 17025 standard? | | | |
| 6.2.2 | <ul style="list-style-type: none"> 1. Do the laboratory implement controls for the identification, storage, protection, back up, retention time and disposal of its records? 2. Access to these records consistent with confidentiality arrangements? | | | |
| 6.3 | Actions to Address Risks and Opportunities | | | |
| 6.3.1 | <ul style="list-style-type: none"> 1. Does the laboratory consider risks and opportunities associated with laboratory activities in order to: <ul style="list-style-type: none"> a. Risk assessment that the management system can address its intended result? b. Enhance opportunities to address the purpose and objectives of the laboratory? c. Prevent or reduce customer impacts and potential failures in the laboratory activities? d. Address improvement? | | | |
| 6.3.2 | <ul style="list-style-type: none"> 1. Does the laboratory planning <ul style="list-style-type: none"> a. Address to address these risks and opportunities? b. How to <ul style="list-style-type: none"> 1. Identify and implement actions that | | | |

[organization name]

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| | <p>is management system?</p> <p>2. Evaluate the effectiveness of these system?</p> | | | |
| 4.1.2 | <p>Are actions taken to address risk and opportunities proportional to the potential impact on the ability of laboratory results?</p> | | | |
| 4.1.3 | <p>Improvement</p> <p>4.1.3.1 Are the laboratory identified and selected opportunities for improvement and implemented necessary actions?</p> <p>4.1.3.2 Have the laboratory used feedback both positive and negative from its customers?</p> <p>Is the feedback analyzed and used to improve the management system, laboratory activities and customer service?</p> | | | |
| 4.2 | <p>Competence Action</p> <p>4.2.1 When necessary, does the laboratory:</p> <ol style="list-style-type: none"> a. Assess the competency and <ol style="list-style-type: none"> 1. Take action to address and correct it? 2. Deal with the consequences? b. Evaluate the need for action to eliminate the cause in order that it does not recur or is kept at a minimum by <ol style="list-style-type: none"> 1. Monitoring and analyzing the competency? 2. Determining the cause of the competency? 3. Determining if viable corrective action is available? <p>4.2.2 Is personnel who will be used?</p> <p>4.2.3 Review the effectiveness of the corrective action?</p> | | | |

[organization name]

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| | <ul style="list-style-type: none">1. Update risk and opportunities identified during planning?2. Make changes to the IIR process? | | | |
| 4712 | Are corrective actions appropriate to the effects of nonconformities identified? | | | |
| 4713 | Does the organization have evidence of: <ul style="list-style-type: none">1. The nature of the nonconformity, cause and subsequent action?2. The results of any corrective action? | | | |
| 481 | Internal Audit | | | |
| 4811 | Does the organization conduct internal audits at planned intervals to provide information on whether the management system: <ul style="list-style-type: none">1. conforms to:<ul style="list-style-type: none">a. The organization's own requirements for the management system, including objectives and plans?b. The requirements of the ISO 9001 standard?2. is effectively implemented and maintained? | | | |
| 4812 | Does the organization: <ul style="list-style-type: none">1. Plan, establish, implement and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which takes into consideration the importance of the identified activities concerned, change affecting the objectives and the results of previous audits? | | | |

Commented [1702529]: Look for records.

[organization name]

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| | 1. Define the audit scope and scope for each audit? | | | |
| | 2. Review the results of the audits are reported to relevant management? | | | |
| | 3. Implement appropriate corrective and preventive actions without undue delay? | | | |
| | 4. Review records as evidence of the implementation of the audit program and the audit results? | | | |
| 6.0 | Management Review | | | |
| 6.01 | Does internal management review the management system at planned intervals in order to ensure its continuing suitability, adequacy and effectiveness, including the control policies and procedures related to compliance with the ISO 13485 standard? | | | |
| 6.02 | Are reports to management timely, accurate and include information related to the following: | | | |
| | 1. Changes in internal and external issues that are relevant to the organization? | | | |
| | 2. Fulfillment of objectives? | | | |
| | 3. Suitability of policies and procedures? | | | |
| | 4. Status of actions from previous management review? | | | |
| | 5. Results of recent internal audits? | | | |
| | 6. Corrective actions? | | | |
| | 7. Measurements by external bodies? | | | |
| | 8. Changes in the nature and type of the work or in the range of activities provided? | | | |
| | 9. Customer feedback? | | | |
| | 10. Complaints? | | | |
| | 11. Effectiveness of risk management implementation? | | | |

[organization name]

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| | 1. Adequacy of resources? | | | |
| | 2. Results of top management? | | | |
| | 3. Adequacy of the structure of quality control? | | | |
| | 4. Other relevant factors, such as monitoring activities and training? | | | |
| 4.2.2 | Do the records from management review record all decisions and actions taken to: 1. The effectiveness of the management system and its processes? 2. Improvement of identified activities related to the fulfillment of requirements of the ISO 17025 standard? 3. Review of required resources? 4. The need for change? | | | |

[job title]

[name]

[signature]

Commented [1702530]: This is only necessary if the document is in paper form.