**1. This working document is intended as a checklist for the assessor when conducting Testing and Calibration Laboratory and Sampling Organization Assessments according to ISO/IEC 17025:2017. This standard incorporates all elements of ISO 9001:2015 relevant to testing and calibration laboratories and Sampling Organizations. Organizations that already have ISO 9001:2015 for their scope of service similar to their accreditation scope will be held to the requirements as referenced in Clause 8, Option B which eliminates a full assessment to clauses 8.2-8.9. However, assessors should ensure that the laboratory has incorporated this standard in their quality system regardless of their ISO 9001:2015 certification.**

**1.a.) Clauses highlighted in blue are new changes/addtions not in previous versions of ISO/IEC 17025 and can be used for transition assessments.**
**1.b.) Clauses and notes highlighted in green are AOAC requirements.**

**2. Please make notes in the Comments column any deficiencies in the laboratory's management system identified during the assessment (see item #3). These observations may be useful when preparing the assessment report and indicate to the reviewer that a thorough assessment was conducted. It is also imperative to note evidence of compliance, making reference to procedures/work instructions, dates, and other specific observations. At a minimum should be 1 comment per major element of the checklist.**

**3. Do not recommend specific solutions to deficiencies, as this would constitute a conflict of interest.**

**4. Assess the system only to the relevant standard and to the requested scope of accreditation. Do not be concerned with system requirements stemming from: Company- or facility-imposed policies, Regulatory bodies, Subcontractors,Other sources**

**5. If additional questions arise during the assessment, indicate them (and the appropriate responses) either in the blank working document pages at the end of this document or in the empty rows included in some of the sections.**

**6. Please read the questions carefully, as the "preferred" answer in some cases may be "no" or "not applicable."**

**7. If, at any time, the assessment team requires assistance in the interpretation of the requirements of ISO/IEC 17025: 2017, contact the PJLA office immediately.**

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| 4 | **General Requirements** | | | |
| 4.1 | **Impartiality** | | | |
| 4.1.1 | Does the laboratory perform laboratory activities impartially and manage activities so as to safeguard impartiality? | | | |
| 4.1.2 | Is the laboratory management committed to impartiality? | | | |
| AOAC | Are conflict-of-interest agreements established along with appropriate conflict-of-interest training programs for personnel? | | | |
| AOAC | Does training for impartiality consist of initial and refresher training? | | | |
| AOAC | Has the laboratory defined a schedule for refresher training and renewal of conflict-of-interest agreements? | | | |
| 4.1.3 | Is the laboratory responsible for the impartiality of it's laboratory activities and does not allow commercial, financial or other pressures to compromise impartiality? | | | |
| 4.1.4 | Does the laboratory identify risks to it's impartiality on an on-going basis? Are those risks that arise from its activities, or from its relationships, or from the relationships of it's personnel identified? Such relationships do not necessarily present a laboratory with a risk to impartiality. | | | |
| Note | Note: A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc. | | | |
| 4.1.5 | If a risk to impartiality is identified, can the laboratory demonstrate how it eliminates or minimizes such risk? | | | |
| 4.2 | **Confidentiality** | | | |
| 4.2.1 | Is the laboratory responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities? | | | |
| 4.2.1 | Does the laboratory inform the customer, in advance, of the information it intends to place in the public domain? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **4.2.1** | Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), is all other information is considered proprietary information and regarded as confidential? | | | |
| **4.2.2** | When required by law or authorized by contractual arrangements to release confidential information,is the customer or individual concerned, unless prohibited by law, notified of the information provided? | | | |
| **4.2.3** | Is information about the customer obtained from sources other than the customer (e.g. complainant, regulators) kept confidential between the customer and the laboratory? | | | |
| **4.2.3** | Is the identity of the source of information kept confidential by the laboratory and not shared with the customer, unless agreed to by the source? | | | |
| **4.2.4** | Do all personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, maintain confidentiality of all information obtained or created during the performance of laboratory activities? | | | |
| **5** | **Structural Requirements** | | | |
| **5.1** | Is the laboratory a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities? | | | |
| **Note** | Note: For the purposes of this document, a governmental laboratory is deemed to be a legal entity on the basis of its governmental status. | | | |
| **5.2** | Has the laboratory identified management that has overall responsibility for the laboratory? | | | |
| **5.3** | Has the laboratory defined and documented the range of laboratory activities for which it conforms with this document? Is the claim of conformity with this document for this range of laboratory activities only? | | | |
| **5.4** | Are laboratory activities carried out in such a way as to meet the requirements of this document, the laboratory's customers, regulatory authorities and organizations providing recognition in all locations where those laboratory activities are performed? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **5.5** | Does the laboratory do the following laboratory required activities: | | | |
| **5.5** | a) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services; | | | |
| **5.5** | b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities; | | | |
| **5.5** | c) document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results? | | | |
| **5.6** | Does the laboratory have personnel who have the authority and resources needed to carry out their duties, including: | | | |
| **5.6** | a) implementation, maintenance and improvement of the management system; | | | |
| **5.6** | b) identification of deviations from the management system or from the procedures for performing laboratory activities; | | | |
| **5.6** | c) initiation of actions to prevent or minimize such deviations; | | | |
| **5.6** | d) reporting to laboratory management on the performance of the management system and any need for improvement; | | | |
| **5.6** | e) ensuring the effectiveness of laboratory activities? | | | |
| **5.7** | Does laboratory management ensure that: | | | |
| **5.7** | a) communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and other requirements; | | | |
| **5.7** | b) the integrity of the management system is maintained when changes to the management system are planned and implemented? | | | |
| **6** | **Resource Requirements** | | | |
| **6.1** | **General** | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **6.1** | Does the laboratory have available the personnel, facilities, equipment, systems, and suppport services necessary to manage and perform its laboratory activities? | | | |
| **6.2** | **Personnel** | | | |
| **6.2.1** | Are all laboratory personnel performing tasks that may influence laboratory activities competent, acting impartially and working in accordance with the management system? | | | |
| **6.2.2** | Are competence requirements documented for each function influencing the results of laboratory activities? Include requirements for education, qualification, training, technical knowledge, skills and experience | | | |
| **AOAC** | In cases in which staff is qualified on only a portion of a method, do the training records indicate those parts upon which they have been trained? | | | |
| **6.2.3** | How does the laboratory ensure that personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations? | | | |
| **AOAC** | For laboratories performing work with dietary supplements and/or pharmaceuticals: Do they have a qualified person reviewing complaints for possible failures and investigating where needed? | | | |
| **AOAC** | Does the laboratory define the qualifications of staff handling complaints? | | | |
| **6.2.4** | How does the management of the laboratory communicate to personnel their duties, responsibilities and authorities? | | | |
| **6.2.5** | Does the laboratory have procedure(s) and retain records for: | | | |
| **6.2.5** | a) determining the competence requirements? | | | |
| **6.2.5** | b) selection of personnel? | | | |
| **6.2.5** | c) training of personnel? | | | |
| **6.2.5** | d) supervision of personnel? | | | |
| **6.2.5** | e) authorization of personnel? | | | |
| **6.2.5** | f) monitoring competence of personnel? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| 6.2.6 | Does the laboratory authorize personnel to perform specific laboratory activities, including but not limited to | | | |
| 6.2.6 | a) development, modification, verification and validation of methods; | | | |
| 6.2.6 | b) analysis of results, including statements of conformity or opinions and interpretations; | | | |
| 6.2.6 | c) report, review and authorization of results? | | | |
| 6.3 | **Facilities and Environmental Conditions** | | | |
| 6.3.1 | Are facilities and environmental conditions suitable for the laboratory activities to produce valid results? | | | |
| 6.3.2 | Are requirements for facilities and environmental conditions necessary for the performance of the laboratory activities documented? | | | |
| 6.3.3 | Does the laboratory monitor, control and record environmental conditions in accordance with relevant specifications, methods or procedures or where they influence the validity of the results? | | | |
| 6.3.4 | Are measures to control facilities implemented, monitored and periodically reviewed? Do they include, but are not limited to: | | | |
| 6.3.4 | a) access to and use of areas affecting laboratory activities? | | | |
| 6.3.4 | b) prevention of contamination, interference or adverse influences on laboratory activities? | | | |
| 6.3.4 | c) effective separation between areas with incompatible laboratory activities? | | | |
| AOAC | Does the separation between areas include any areas for reagent preparation or trace analysis instrumentation where separation is necessary to avoid system contamination? | | | |
| 6.3.5 | When the laboratory performs laboratory activities at sites or facilities outside its permanent control, does it ensure that the requirements related to facilities and environmental conditions of this document are met? | | | |
| 6.4 | **Equipment** | | | |
| AOAC | Are the minimum requirements for the calibration and verification of critical equipment being met as per Appendix A? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **6.4.1** | Does the laboratory have access to equipment including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus which is required for the correct performance of laboratory activities and which can influence the result? | | | |
| **6.4.2** | In those cases where the laboratory uses equipment outside its permanent control, does the laboratory ensure that the requirements for equipment of this document are met? | | | |
| **6.4.3** | Does the laboratory have a procedure for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning and to prevent contamination or deterioration? | | | |
| **AOAC** | Are reference materials handled and stored according to instructions provided by material supplier/ producer, unless valid reasons exist for not doing so? Are deviations from these storage instructions and justification for the deviation recorded? If deviations occur, is the ensured quality of reference materials demonstrated? Is documentation accompanying the reference material stored and available at all times? | | | |
| **6.4.4** | Does the laboratory verify that equipment conforms to specified requirements before being placed or returned into service? | | | |
| **AOAC** | Are reagents, reagent solutions, sample solutions, and internal reference materials [including certified reference materials (CRMs) used as internal reference materials] used prior to their expiration date? Are reagents used after their expiration date without recorded verification that they are still suitable for use? Are media and CRMs (which cannot be used beyond their expiration date) disposed of property after expiration? | | | |
| **AOAC** | Does the laboratory define the use of the water and ensure the water is fit for that use? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **6.4.5** | Is the equipment used for measurement capable of achieving the measurement accuracy or measurement uncertainty required to provide a valid result? | | | |
| **6.4.6** | Is measuring equipment calibrated when: | | | |
| **6.4.6** | — the measurement accuracy or measurement uncertainty affects the validity of the reported results? or | | | |
| **6.4.6** | — calibration of the equipment is required to establish the metrological traceability of the reported result? | | | |
| **Note** | Types of equipment having an effect on the validity of the reported results can include:<br>— those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement;<br><br>— those used to make corrections to the measured value, e.g. temperature measurements;<br>— those used to obtain a measurement result calculated from multiple quantities. | | | |
| **6.4.7** | Does the laboratory establish a calibration programme which is reviewed and adjusted as necessary in order to maintain confidence in the status of calibration? | | | |
| **6.4.8** | Does all equipment requiring calibration or which has a defined period of validity labelled, coded or otherwise identified to allow the user of the equipment to readily identify the status of calibration or period of validity? | | | |
| **AOAC** | Are all reference materials labeled using an identification scheme that allows the laboratory to trace the lot of reference material used in any analysis? Is each reference material labeled with the date received when the date is used for determining the expiration date? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **6.4.9** | Is equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, taken out of service?<br>Is It isolated to prevent its use or clearly labelled or marked as being out of service until it has been verified to perform correctly?<br>Does the laboratory examine the effect of the defect or deviation from specified requirements and initiate the management of nonconforming work procedure? (see 7.10) | | | |
| **6.4.10** | When intermediate checks are necessary to maintain confidence in the performance of the equipment, are these checks shall be carried out according to a procedure? | | | |
| **6.4.11** | When calibration and reference material data include reference values or correction factors, does the laboratory ensure the reference values and correction factors are updated and implemented, as appropriate, to meet specified requirements? | | | |
| **6.4.12** | Does the laboratory take practicable measures to prevent unintended adjustments of equipment from invalidating results? | | | |
| **6.4.13** | Records shall be retained for equipment which can influence laboratory activities? Do laboratory records include the following, where applicable: | | | |
| **6.4.13** | a) the identity of equipment, including software and firmware version? | | | |
| **6.4.13** | b) the manufacturer's name, type identification, and serial number or other unique identification? | | | |
| **6.4.13** | c) evidence of verification that equipment conforms with specified requirements? | | | |
| **6.4.13** | d) the current location? | | | |
| **6.4.13** | e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **6.4.13** | f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity? | | | |
| **6.4.13** | g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment? | | | |
| **6.4.13** | h) details of any damage, malfunction, modification to, or repair of, the equipment? | | | |
| **6.5** | **Metrological Traceability** | | | |
| **6.5.1** | Does the laboratory 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? | | | |
| **Note 1** | In ISO/IEC Guide 99, metrological traceability is defined as the "property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty". | | | |
| **Note 2** | See Annex A for additional information on metrological traceability. | | | |
| **6.5.2** | Does the laboratory ensure that measurement results are traceable to the International System of Units (SI) through one of the following: | | | |
| **6.5.2** | a) calibration provided by a competent laboratory;? | | | |
| **Note 1** | Laboratories fulfilling the requirements of this document are considered to be competent. | | | |
| **6.5.2** | b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI? | | | |
| **Note 2** | Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent. | | | |
| **6.5.2** | c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards? | | | |
| **Note 3** | Details of practical realization of the definitions of some important units are given in the SI brochure? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| 6.5.3 | When metrological traceability to the SI units is not technically possible, does the laboratory demonstrate metrological traceability to an appropriate reference ? Is the reference assocated with: | | | |
| 6.5.3 | a) certified values of certified reference materials provided by a competent producer? | | | |
| 6.5.3 | b) results of reference measurement procedures, specified methods or consensus standards that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison? | | | |
| **6.6** | **Externally Provided Products and Services** | | | |
| 6.6.1 | Does the laboratory ensure that only suitable externally provided products and services that affect laboratory activities are used when such products and services: | | | |
| 6.6.1 | a) are intended for incorporation into the laboratory's own activities? | | | |
| 6.6.1 | b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider? | | | |
| 6.6.1 | c) are used to support the operation of the laboratory? | | | |
| Note | Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services. | | | |
| 6.6.2 | Does the laboratory have a procedure and retain records for: | | | |
| 6.6.2 | a) defining, reviewing and approving the laboratory's requirements for externally provided products and services? | | | |
| 6.6.2 | b) defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **6.6.2** | c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer? | | | |
| **6.6.2** | d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers? | | | |
| **6.6.3** | Does the laboratory communicate its requirements to external providers for: | | | |
| **6.6.3** | a) the products and services to be provided; | | | |
| **6.6.3** | b) the acceptance criteria; | | | |
| **6.6.3** | c) competence, including any required qualification of personnel; | | | |
| **6.6.3** | d) activities that the laboratory, or its customer, intends to perform at the external provider's premises? | | | |
| **7** | **Process Requirements** | | | |
| **7.1** | **Review of Requests, Tenders and Contracts** | | | |
| **7.1.1** | Does the laboratory have a procedure for the review of requests, tenders and contracts that ensures that: | | | |
| **7.1.1** | a) the requirements are adequately defined, documented and understood; | | | |
| **7.1.1** | b) the laboratory has the capability and resources to meet the requirements; | | | |
| **7.1.1** | c) where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval; | | | |
| **Note 1** | It is recognized that externally provided laboratory activities can occur when:<br>— the laboratory has the resources and competence to perform the activities, however, for unforeseen reasons is unable to undertake these in part or full;<br>— the laboratory does not have the resources or competence to perform the activities. | | | |
| **7.1.1** | d) the appropriate methods or procedures are selected and are capable of meeting the customers' requirements. | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **Note 2** | For internal or routine customers, reviews of requests, tenders and contracts can be performed in a simplified way. | | | |
| **7.1.2** | Does the laboratory inform the customer when the method requested by the customer is considered to be inappropriate or out of date? | | | |
| **7.1.3** | When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance) has the decision rule been clearly defined? Unless inherent in the requested specification or standard, is the decision rule selected communicated to, and agreed with, the customer? | | | |
| **Note** | For further guidance on statements of conformity, see ISO/IEC Guide 98-4. | | | |
| **7.1.4** | Are differences between the request or tender and the contract resolved before laboratory activities commence? Is each contract acceptable both to the laboratory and the customer? Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results. | | | |
| **7.1.5** | Is the customer informed of any deviation from the contract? | | | |
| **7.1.6** | If a contract is amended after work has commenced, is the contract review repeated and any amendments communicated to all affected personnel? | | | |
| **7.1.7** | Does the laboratory cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed? | | | |
| **Note** | Such cooperation can include:<br>a) providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities;<br>b) preparation, packaging, and dispatch of items needed by the customer for verification purposes. | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| 7.1.8 | Are records of reviews, including any significant changes, retained? Are records also retained of pertinent discussions with a customer relating to the customer's requirements or the results of the laboratory activities? | | | |
| 7.2 | **Selection, Verification and Validation of Methods** | | | |
| 7.2.1 | **Selection and Verification of Methods** | | | |
| 7.2.1.1 | Does the laboratory use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data? | | | |
| Note | "Method" as used in this document can be considered synonymous with the term "measurement procedure" as defined in ISO/IEC Guide 99. | | | |
| AOAC | Have methods of analysis that are specified in law or regulation been followed in accordance with those requirements? | | | |
| 7.2.1.2 | Are all methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, kept up to date and made readily available to personnel (see 8.3)? | | | |
| 7.2.1.3 | Does the laboratory ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so? When necessary, is the application of the method supplemented with additional details to ensure consistent application? | | | |
| Note | International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a laboratory. It can be necessary to provide additional documentation for optional steps in the method or additional details. | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **7.2.1.4** | When the customer does not specify the method to be used, does the laboratory select an appropriate method and inform the customer of the method chosen? Does the laboratory use recommended methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment? Laboratory-developed or modified methods can also be used. | | | |
| **7.2.1.5** | Does the laboratory verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance? Are records of the verification retained? If the method is revised by the issuing body, is verification repeated to the extent necessary? | | | |
| **AOAC** | Does the laboratory method verification confirm that the laboratory has defined and can obtain the required performance for its purpose (e.g., matrix applicability, LOD, and precision)? | | | |
| **7.2.1.6** | When method development is required, is it a planned activity and assigned to competent personnel equipped with adequate resources? | | | |
| **7.2.1.6** | As method development proceeds, is a review carried out to confirm that the needs of the customer are still being fulfilled? | | | |
| **7.2.1.6** | Have any modifications to the development plan been approved and authorized? | | | |
| **7.2.1.7** | If deviations from methods for laboratory activities occur, has the deviation been documented, technically justified, authorized, and accepted by the customer? | | | |
| **Note** | Customer acceptance of deviations can be agreed in advance in the contract. | | | |
| **7.2.2** | **Validation of Methods** | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **7.2.2.1** | Does the laboratory conduct sufficeintly extensive validation of non-standard methods, laboratory-developed methods and/or standard methods used outside their intended scope to meet the needs of the given application or field of application? | | | |
| **Note 1** | Validation can include procedures for sampling, handling and transportation of test or calibration items. | | | |
| **Note 2** | The techniques used for method validation can be one of, or a combination of, the following:<br>a) calibration or evaluation of bias and precision using reference standards or reference materials;<br>b) systematic assessment of the factors influencing the result;<br>c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;<br>d) comparison of results achieved with other validated methods;<br>e) interlaboratory comparisons;<br>f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method. | | | |
| **7.2.2.2** | When changes are made to a validated method, is the influence of such changes determined and a new method validation performed when necessary? | | | |
| **7.2.2.3** | Are the performance characteristics of validated methods as assessed for the intended use, relevant to the customers' needs and consistent with specified requirements? | | | |
| **Note** | Performance characteristics can include, but are not limited to, the measurement range, accuracy, the measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias. | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **7.2.2.4** | Does the laboratory retain the following records of validation: | | | |
| **7.2.2.4** | a) the validation procedure used; | | | |
| **7.2.2.4** | b) specification of the requirements; | | | |
| **7.2.2.4** | c) determination of the performance characteristics of the method; | | | |
| **7.2.2.4** | d) results obtained; | | | |
| **7.2.2.4** | e) a statement on the validity of the method, detailing its fitness for the intended use? | | | |
| **AOAC** | Does the laboratory record the laboratory representative who authorized adoption of the method and the date this authorization was granted? | | | |
| **7.3** | **Sampling** | | | |
| **7.3.1** | Does the laboratory have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration? | | | |
| **7.3.1** | Does the sampling method address the factors to be controlled to ensure the validity of subsequent testing or calibration results? | | | |
| **7.3.1** | Are the sampling plan and method available at the site where sampling is undertaken? | | | |
| **7.3.1** | Are sampling plans, whenever reasonable, based on appropriate statistical methods? | | | |
| **AOAC** | For laboratories that do not collect sample materials outside the laboratory: When the laboratory has not been responsible for the initial sampling stage, when appropriate do they state in the report that the samples were analyzed as received? | | | |
| **AOAC** | For laboratories that conduct field sampling of products: Do they comply with established procedures for those programs (e g , the Meat Importers Council of America North America Guidelines for the Settlement of Fat Claims, GOOD Samples: Guidance on Obtaining Defensible Samples) and these requirements? Is there a procedure for routinely used sampling methods? | | | |
| **7.3.2** | Does the sampling method describe: | | | |
| **7.3.2** | a) the selection of samples or sites; | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **7.3.2** | b) the sampling plan; | | | |
| **7.3.2** | c) preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration? | | | |
| **Note** | When received into the laboratory, further handling can be required as specified in 7.4. | | | |
| **7.3.3** | Does the laboratory retain records of sampling data that forms part of the testing or calibration that is undertaken? These records shall include, where relevant: | | | |
| **7.3.3** | a) reference to the sampling method used; | | | |
| **7.3.3** | b) date and time of sampling; | | | |
| **7.3.3** | c) data to identify and describe the sample (e.g. number, amount, name); | | | |
| **7.3.3** | d) identification of the personnel performing sampling; | | | |
| **7.3.3** | e) identification of the equipment used; | | | |
| **7.3.3** | f) environmental or transport conditions; | | | |
| **7.3.3** | g) diagrams or other equivalent means to identify the sampling location when appropriate; | | | |
| **7.3.3** | h) deviations, additions to or exclusions from the sampling method and sampling plan? | | | |
| **7.4** | **Handling of Test or Calibration Items** | | | |
| **7.4.1** | Does the laboratory have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items? | | | |
| **7.4.1** | Does the procedure include all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer? | | | |
| **7.4.1** | Have precautions been taken to avoid deterioration, contamination, loss or damage to the item during handling, transporting, storing/waiting, and preparation for, testing or calibration? | | | |
| **7.4.1** | Are handling instructions provided with the item followed? | | | |
| **AOAC** | When not specified by the customer or regulations, are minimum sample retention periods communicated to customers so that all parties are aware of how long the sample will be available for retesting or retrieval? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **AOAC** | Many laboratories do not test the entire sample as received, but instead perform testing on a subdivision of a sample (i.e., subsample, portion, aliquot, etc.). Is this portion identified in such a way that it is unmistakably associated to the original sample? | | | |
| **AOAC** | Does the laboratory have documented procedures for subdividing, compositing, and/or homogenizing to ensure that a representative test portion is used for analysis? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **7.4.2** | Does the laboratory have a system for the unambiguous identification of test or calibration items? | | | |
| **7.4.2** | Is the identification retained while the item is under the responsibility of the laboratory? | | | |
| **7.4.2** | Does the system ensure that items will not be confused physically or when referred to in records or other documents? | | | |
| **7.4.2** | Does the system, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items? | | | |
| **7.4.3** | Upon receipt of the test or calibration item, are deviations from specified conditions recorded? | | | |
| **7.4.3** | When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, does the laboratory consult the customer for further instructions before proceeding? | | | |
| **7.4.3** | Is there a record for the results of this consultation? | | | |
| **7.4.3** | When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, does the laboratory include a disclaimer in the report indicating which results may be affected by the deviation? | | | |
| **7.4.4** | When items need to be stored or conditioned under specified environmental conditions, are those conditions maintained, monitored and recorded? | | | |
| **7.5** | **Technical Records** | | | |
| **7.5.1** | Does the laboratory ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate identification of factors affecting the measurement result and its associated measurement uncertainty? | | | |
| **7.5.1** | Is there sufficient information to enable the repetition of the laboratory activity under conditions as close as possible to the original? | | | |
| **7.5.1** | Do technical records include the date and the identity of personnel responsible for each laboratory activity and for checking data and results? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **7.5.1** | Are original observations, data and calculations recorded at the time they are made and identifiable with the specific task? | | | |
| **AOAC** | Does an audit trail in laboratory records include the following: | | | |
| **AOAC** | [a] Analyst | | | |
| **AOAC** | [b] Analyst training → with traceability to Reference Materials (RMs) and proficiency checks | | | |
| **AOAC** | [c] Calibration records → with traceability to suitable RMs | | | |
| **AOAC** | [d] Column lot number | | | |
| **AOAC** | [e] Equipment performance → (e.g., using CRMs, proficiency checks, and daily checks) | | | |
| **AOAC** | [f] Equipment qualification and maintenance | | | |
| **AOAC** | [g] Equipment used | | | |
| **AOAC** | [h] Media/Reagent identity | | | |
| **AOAC** | [i] Media/Reagent open date when open date impacts expiration date | | | |
| **AOAC** | [j] Media/Reagent/Reference material expiration date | | | |
| **AOAC** | [k] Media/Reagent/Reference material laboratory assigned identification | | | |
| **AOAC** | [l] Media/Reagent/Reference material lot number | | | |
| **AOAC** | [m] Media/Reagent/Reference material received date | | | |
| **AOAC** | [n] Prepared media/reagent preparation date | | | |
| **AOAC** | [o] Prepared media/reagent preparer | | | |
| **AOAC** | [p] Prepared reagent components | | | |
| **AOAC** | [q] Prepared reagent special instruction, hazards, or use restrictions | | | |
| **AOAC** | [r] Reagent concentration/purity | | | |
| **AOAC** | [s] Reports (mailed or electronic) | | | |
| **AOAC** | [t] Results | | | |
| **AOAC** | [u] Review of electronic transmissions [e g , Laboratory Information Management Systems (LIMS) acquisitions)] | | | |
| **AOAC** | [v] Reviews | | | |
| **AOAC** | [w] Sample analysis (raw data including chromatograms, standard curves, etc ) | | | |
| **AOAC** | [x] Sample handling and storage | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **AOAC** | [y] Sample preparation | | | |
| **AOAC** | [z] Sample receipt (log-in/check-in) | | | |
| **AOAC** | If a method allows multiple testing options, does the laboratory record document which option was followed? | | | |
| **AOAC** | Where strict chain of custody is requested by the customer (e g , samples used in litigation or otherwise required by law), does the laboratory have a policy and procedure for it? | | | |
| **7.5.2** | Does the laboratory ensure that amendments to technical records can be tracked to previous versions or to original observations? Are the original and amended data and files retainted, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations? | | | |
| **7.6** | **Evaluation of Measurement Uncertainty** | | | |
| **7.6.1** | Does the laboratory identify the contributions to measurement uncertainty? When evaluating measurement uncertainty, are all significant contributions, including those arising from sampling, shall be taken into account using appropriate methods of analysis? | | | |
| **7.6.2** | Does a laboratory performing calibrations, including of its own equipment, evaluate the measurement uncertainty for all calibrations? | | | |
| **7.6.3** | Does the laboratory performing testing evaluate measurement uncertainty? | | | |
| **7.6.3** | Where the test method precludes rigorous evaluation of measurement uncertainty, is an estimation made based on an understanding of the theoretical principles or practical experience of the performance of the method? | | | |
| **Note 1** | In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions. | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| Note 2 | For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control. | | | |
| Note 3 | For further information, see ISO/IEC Guide 98-3, ISO 21748 and the ISO 5725 series. | | | |
| 7.7 | **Ensuring the Validity of Results** | | | |
| 7.7.1 | Does the laboratory have a procedure for monitoring the validity of results? | | | |
| 7.7.1 | Is the resulting data recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to review the results? | | | |
| 7.7.1 | Is the monitoring planned and reviewed and include, where appropriate, but not be limited to: | | | |
| 7.7.1 | a) use of reference materials or quality control materials; | | | |
| 7.7.1 | b) use of alternative instrumentation that has been calibrated to provide traceable results; | | | |
| 7.7.1 | c) functional check(s) of measuring and testing equipment; | | | |
| 7.7.1 | d) use of check or working standards with control charts, where applicable; | | | |
| 7.7.1 | e) intermediate checks on measuring equipment; | | | |
| 7.7.1 | f) replicate tests or calibrations using the same or different methods; | | | |
| 7.7.1 | g) retesting or recalibration of retained items; | | | |
| 7.7.1 | h) correlation of results for different characteristics of an item; | | | |
| 7.7.1 | i) review of reported results; | | | |
| 7.7.1 | j) intralaboratory comparisons; | | | |
| 7.7.1 | k) testing of blind sample(s)? | | | |
| AOAC | Are there quality control procedures that include the use of quality control materials defined for both quantitative and qualitative methods in order to demonstrate that the test worked properly? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **AOAC** | Are quality control procedures defined for both quantitative and qualitative methods? Do these procedures include the use of quality control materials? Does the use of thee materials demonstrate that the test worked properly? If a CRM or RM cannot be found, did the laboratory do its best to obtain a material with a consensus value and consensus accuracy? Has the laboratory justified the suitability of the quality control material? | | | |
| **AOAC** | Has a quality control material been used with each batch of analyzed samples? Has the laboratory defined and justified what constitutes a batch of samples? | | | |
| **AOAC** | Has method precions been periodically evaluated? | | | |
| **7.7.2** | Does the laboratory monitor its performance by comparison with results of other laboratories, where available and appropriate? | | | |
| **7.7.2** | Is this monitoring planned and reviewed and include, but is not be limited to, either or both of the following: | | | |
| **7.7.2** | a) participation in proficiency testing; | | | |
| **Note** | ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent. | | | |
| **7.7.2** | b) participation in interlaboratory comparisons other than proficiency testing. | | | |
| **AOAC** | For pre-accreditation: Does the laboratory have successful proficiency testing or interlaboratory comparison results to qualify each test method for which the laboratory wants to become accredited? | | | |
| **AOAC** | For ongoing accreditation: Does the laboratory demonstrate competence through the participation in proficiency testing based upon the scope they have: | | | |
| **AOAC** | [1] Biological Scope - Does the laboratory participate in one proficiency testing event each year for each method on the scope? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **AOAC** | [2] Chemical Scope - Does the laboratory participate in one proficiency testing event each year for each method on the scope or can it provide evidence in the form of additional justification showing the similarity of process between each of these methods? | | | |
| **AOAC** | [3] Does the laboratory have a documented proficiency testing (PT) plan that includes the following: | | | |
| **AOAC** | [3a] Does the laboratory document how it will cover its entire scope annually including commercial and alternate programs? | | | |
| **AOAC** | [3b] Chemical Scope - If the laboratory included any justifaction for similarity of tests, do they state how they accomplish thin in it's PT plan? | | | |
| **AOAC** | [3c] Does the laboratory have a PT schedule for the next 4 years? | | | |
| **AOAC** | [4] When a relevant and appropriate PT program is not available, does the laboratory document its planned participation in interlaboratory comparisons other than proficiency testing, where available and appropriate? -or- When no PT or interlaboratory comparison is available, does the laboratory develop and justify an alternative plan for monitoring data? | | | |
| **AOAC** | [5] Are proficiency test samples analyzed following the normal working practices operated in the laboratory? If more than one qualified analyst exists, are they rotated among qualified analysts? | | | |
| **7.7.3** | Is the data from monitoring activities analysed, used to control and, if applicable, improve the laboratory's activities?<br>If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, is appropriate action taken to prevent incorrect results from being reported? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| AOAC | Does the laboratory have procedures that define quality control material acceptance criteria and what constitutes a trend in the SPC data? When quality control material data do not meet acceptance criteria or indicates a trend, does the laboratory initiate its procedures for processing nonconforming work? Does the laboratory have a procedure for the evaluation of data associated with a quality control material that fails and how to address it? | | | |
| AOAC | Does the laboratory avoid unproductive corrective actions for statistically random events? The laboratory's criteria may take into consideration the fact that for some multianalyte methods, some analytes behave better than others (i e , exhibiting less variance and/or higher mean recovery) and that an analyte's variance may increase as the concentration of the analyte decreases. Does the laboratory take actions to set limits that take into account the probability of an out-of-control result in multianalyte methods? | | | |
| AOAC Note | Note: Assign the analytes to groups that have similar analytical characteristics or chemical structure An example of this is low-molecular-weight ketones that tend to be lost in the sample preparation process or organic acids that may be poor performers in certain extraction processes Then the quality control and control charting procedure can be designed to track a representative analyte of each of these groups<br>Note: Set limits that take into the account the probability that an out-of-control result will be encountered, such as the approach set forth for environmental testing laboratories in the TNI (The NELAC Institute) 'Management and Technical Requirements for Laboratories Performing Environmental Analysis (2016) " | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| AOAC | Does the laboratory evaluate PT results when they are received? Does the laboratory use criteria that are at least as stringent as the PT provider's? If the PT provider does not issue acceptability criteria or the laboratory is performing proficiency testing by alternative means as described above, do they have procedures that define the acceptability of the results? | | | |
| AOAC | Is the the assigned value established by one of the following four options: | | | |
| AOAC | [1] The SPC ranges for blinded LCSs | | | |
| AOAC | [2] Fortification value of prepared samples | | | |
| AOAC | [3] Assigned result from a previous round (set) | | | |
| AOAC | [4] Results obtained from a group of two or more accredited laboratories for that analyte that have demonstrated proficiency in the past | | | |
| 7.8 | **Reporting of Results** | | | |
| 7.8.1 | **General** | | | |
| 7.8.1.1 | Are the results reviewed and authorized prior to release? | | | |
| 7.8.1.2 | Are the results provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling) and include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used? Are all issued reports retained as technical records? | | | |
| Note 1 | For the purposes of this document, test reports and calibration certificates are sometimes referred to as test certificates and calibration reports, respectively. | | | |
| Note 2 | Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met | | | |
| 7.8.1.3 | When agreed with the customer, the results may be reported in a simplified way. Is any information listed in 7.8.2 to 7.8.7 and not reported to the customer, readily available? | | | |
| 7.8.2 | **Common Requirements for Reports (Test, Calibration or Sampling)** | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **7.8.2.1** | Does each report include at least the following information, unless the laboratory has valid reasons for not doing so, thereby minimizing any possibility of misunderstanding or misuse? | | | |
| **7.8.2.1** | a) a title (e.g. “Test Report”, “Calibration Certificate” or “Report of Sampling”); | | | |
| **7.8.2.1** | b) the name and address of the laboratory; | | | |
| **7.8.2.1** | c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory’s permanent facilities, or in associated temporary or mobile facilities; | | | |
| **7.8.2.1** | d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end; | | | |
| **7.8.2.1** | e) the name and contact information of the customer; | | | |
| **7.8.2.1** | f) identification of the method used; | | | |
| **7.8.2.1** | g) a description, unambiguous identification, and, when necessary, the condition of the item ; | | | |
| **7.8.2.1** | h) the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results; | | | |
| **7.8.2.1** | i) the date(s) of performance of the laboratory activity; | | | |
| **7.8.2.1** | j) the date of issue of the report; | | | |
| **7.8.2.1** | k) reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results; | | | |
| **7.8.2.1** | l) a statement to the effect that the results relate only to the items tested, calibrated or sampled; | | | |
| **7.8.2.1** | m) the results with, where appropriate, the units of measurement; | | | |
| **7.8.2.1** | n) additions to, deviations, or exclusions from the method; | | | |
| **7.8.2.1** | o) identification of the person(s) authorizing the report; | | | |
| **7.8.2.1** | p) clear identification when results are from external providers? | | | |
| **Note** | The laboratory should include a statement specifying that the report shall not be reproduced except in full, without approval of the laboratory. | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **7.8.2.2** | Is the laboratory responsible for all the information provided in the report, except when information is provided by the customer? | | | |
| **7.8.2.2** | Is data provided by a customer clearly identified? In addition, is a disclaimer put on the report when the information is supplied by the customer and can affect the validity of results? | | | |
| **7.8.2.2** | Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), does the laboratory state in the report that the results apply to the sample as received? | | | |
| **7.8.3** | **Specific Requirements For Test Reports** | | | |
| **7.8.3.1** | In addition to the requirements listed in 7.8.2, do the test reports , where necessary for the interpretation of the test results, include the following: | | | |
| **7.8.3.1** | a) information on specific test conditions, such as environmental conditions; | | | |
| **7.8.3.1** | b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6); | | | |
| **7.8.3.1** | c) where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when: | | | |
| **7.8.3.1** | — it is relevant to the validity or application of the test results; | | | |
| **7.8.3.1** | — a customer's instruction so requires, or | | | |
| **7.8.3.1** | — the measurement uncertainty affects conformity to a specification limit; | | | |
| **7.8.3.1** | d) where appropriate, opinions and interpretations (see 7.8.7); | | | |
| **7.8.3.1** | e) additional information which may be required by specific methods, authorities, customers or groups of customers? | | | |
| **7.8.3.2** | Where the laboratory is responsible for the sampling activity, do test reports meet the requirements listed in 7.8.5 where necessary for the interpretation of test results? | | | |
| **7.8.4** | **Specific Requirements for Calibration Certificates** | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **7.8.4.1** | In addition to the requirements listed in 7.8.2, do the calibration certificates include the following: | | | |
| **7.8.4.1** | a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent); | | | |
| **Note** | According to JCGM 200:2012, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty. | | | |
| **7.8.4.1** | b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results; | | | |
| **7.8.4.1** | c) a statement identifying how the measurements are metrologically traceable (see Annex A); | | | |
| **7.8.4.1** | d) the results before and after any adjustment or repair, if available; | | | |
| **7.8.4.1** | e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6); | | | |
| **7.8.4.1** | f) where appropriate, opinions and interpretations (see 7.8.7)? | | | |
| **7.8.4.2** | Where the laboratory is responsible for the sampling activity, do the calibration certificates meet the requirements listed in 7.8.5 where necessary for the interpretation of test results? | | | |
| **7.8.4.3** | Does the calibration certificate or calibration label lack any recommendation on the calibration interval except where this has been agreed with the customer? | | | |
| **7.8.5** | **Reporting Sampling – Specific Requirements** | | | |
| **7.8.5.1** | Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, do reports include the following, where necessary for the interpretation of results: | | | |
| **7.8.5.1** | a) the date of sampling; | | | |
| **7.8.5.1** | b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate); | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| 7.8.5.1 | c) the location of sampling, including any diagrams, sketches or photographs; | | | |
| 7.8.5.1 | d) a reference to the sampling plan and sampling method; | | | |
| 7.8.5.1 | e) details of any environmental conditions during sampling that affect the interpretation of the test results; | | | |
| 7.8.5.1 | f) information required to evaluate measurement uncertainty for subsequent testing or calibration? | | | |
| 7.8.6 | **Reporting Statements of Conformity** | | | |
| 7.8.6.1 | When a statement of conformity to a specification or standard is provided, does the laboratory document the decision rule employed? | | | |
| 7.8.6.1 | Do they take into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed and apply the decision rule? | | | |
| Note | Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary. | | | |
| 7.8.6.2 | Does the laboratory report on the statement of conformity, such that the statement clearly identifies: | | | |
| 7.8.6.2 | a) to which results the statement of conformity applies; | | | |
| 7.8.6.2 | b) which specifications, standards or parts thereof are met or not met; | | | |
| 7.8.6.2 | c) the decision rule applied (unless it is inherent in the requested specification or standard)? | | | |
| Note | For further information, see ISO/IEC Guide 98-4. | | | |
| 7.8.7 | **Reporting Opinions and Interpretations** | | | |
| 7.8.7.1 | When opinions and interpretations are expressed, does the laboratory ensure that only personnel authorized for the expression of opinions and interpretations releases the respective statement? Does the laboratory document the basis upon which the opinions and interpretations have been made? | | | |
| Note | It is important to distinguish opinions and interpretations from statements of inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC 17065, and from statements of conformity as referred to in 7.8.6. | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **7.8.7.2** | Are the opinions and interpretations expressed in reports based on the results obtained from the tested or calibrated item and shall be clearly identified as such. | | | |
| **7.8.7.3** | When opinions and interpretations are directly communicated by dialogue with the customer, is a record of the dialogue be retained? | | | |
| **7.8.8** | **Amendments to Reports** | | | |
| **7.8.8.1** | When an issued report needs to be changed, amended or re-issued, are any changes of information clearly identified and, where appropriate, the reason for the change included in the report? | | | |
| **7.8.8.2** | Are amendments to a report after issue made only in the form of a further document, or data transfer, and do they include the statement “Amendment to Report, serial number... [or as otherwise identified]”, or an equivalent form of wording? | | | |
| **Note** | Such amendments shall meet all the requirements of this document. | | | |
| **7.8.8.3** | When a complete new report is issued, is it uniquely identified and does it contain a reference to the original that it replaces? | | | |
| **7.9** | **Complaints** | | | |
| **7.9.1** | Does the laboratory have a documented process to receive, evaluate and make decisions on complaints? | | | |
| **7.9.2** | Is the handling process for complaints available to any interested party on request? Upon receipt of a complaint, does the laboratory confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, deal with it? Does the laboratory take responsibility for all decisions at all levels of the handling process for complaints? | | | |
| **7.9.3** | Does the process for handling complaints include at least the following elements and methods: | | | |
| **7.9.3** | a) description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it; | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **7.9.3** | b) tracking and recording complaints, including actions undertaken to resolve them; | | | |
| **7.9.3** | c) ensuring that any appropriate action is taken? | | | |
| **7.9.3** | Does the laboratory receiving the complaint take responsibility for gathering and verifying all necessary information to validate the complaint? | | | |
| **7.9.5** | Whenever possible, does the laboratory acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome? | | | |
| **7.9.6** | Are outcomes communicated to the complainant made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question? | | | |
| **Note** | This can be performed by external personnel. | | | |
| **7.9.7** | Whenever possible, does the laboratory give formal notice of the end of the complaint handling to the complainant? | | | |
| **7.10** | **Nonconforming Work** | | | |
| **7.10.1** | Is there a procedure implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria)? Does the procedure ensure that: | | | |
| **7.10.1** | a) the responsibilities and authorities for the management of nonconforming work are defined; | | | |
| **7.10.1** | b) actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory; | | | |
| **7.10.1** | c) an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results; | | | |
| **7.10.1** | d) a decision is taken on the acceptability of the nonconforming work; | | | |
| **7.10.1** | e) where necessary, the customer is notified and work is recalled; | | | |
| **7.10.1** | f) the responsibility for authorizing the resumption of work is defined? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **7.10.2** | Does the laboratory retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f)? | | | |
| **7.10.3** | Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own management system, does the laboratory implement corrective action? | | | |
| **7.11** | **Control of Data and Information Management** | | | |
| **7.11.1** | Does the laboratory have access to the data and information needed to perform laboratory activities? | | | |
| **7.11.2** | Has the laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data been validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction? | | | |
| **7.11.2** | Are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, authorized, documented and validated before implementation? | | | |
| **Note 1** | In this document "laboratory information management system(s)" includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems. | | | |
| **Note 2** | Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated. | | | |
| **AOAC** | Have procedures been established to prevent release of unauthorized reports, including the use of handwritten and electronic signatures? For dietary supplement and pharmaceutical laboratories, do electronic records and signatures meet the requirements of FDA Code of Federal Regulations Title 21, Part 11 Electronic Records; Electronic Signatures? | | | |
| **7.11.3** | Does the laboratory information management system(s): | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **7.11.3** | a) be protected from unauthorized access; | | | |
| **7.11.3** | b) be safeguarded against tampering and loss; | | | |
| **7.11.3** | c) be operated in an environment that complies with supplier or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription; | | | |
| **7.11.3** | d) be maintained in a manner that ensures the integrity of the data and information; | | | |
| **7.11.3** | e) include recording system failures and the appropriate immediate and corrective actions? | | | |
| **7.11.4** | When a laboratory information management system is managed and maintained off-site or through an external provider, does the laboratory ensure that the provider or operator of the system complies with all applicable requirements of this document? | | | |
| **7.11.5** | Does the laboratory ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel? | | | |
| **7.11.6** | Are calculations and data transfers checked in an appropriate and systematic manner? | | | |
| **8** | **Management System Requirements** | | | |
| **8.1.1** | **General** | | | |
| **8.1.1.1** | Did the laboratory establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results? In addition to meeting the requirements of Clauses 4 to 7, did the laboratory implement a management system in accordance with Option A or Option B? | | | |
| **Note** | See Annex B for more information. | | | |
| **8.1.2** | **Option A** | | | |
| **8.1.2** | As a minimum, does the management system of the laboratory address the following: | | | |
| **8.1.2** | — management system documentation (see 8.2); | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **8.1.2** | — control of management system documents (see 8.3); | | | |
| **8.1.2** | — control of records (see 8.4); | | | |
| **8.1.2** | — actions to address risks and opportunities (see 8.5); | | | |
| **8.1.2** | — improvement (see 8.6); | | | |
| **8.1.2** | — corrective action (see 8.7); | | | |
| **8.1.2** | — internal audits (see 8.8); | | | |
| **8.1.2** | — management reviews (see 8.9)? | | | |
| **8.1.3** | **Option B** | | | |
| **8.1.3** | A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9. | | | |
| **8.2** | **Management System Documentation (Option A)** | | | |
| **8.2.1** | Does laboratory management establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document? | | | |
| **8.2.1** | Does laboratory management ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization? | | | |
| **AOAC** | Are specific sections pertaining to special needs for various analytes and/or techniques easily identifiable? | | | |
| **8.2.2** | Do policies and objectives address the competence, impartiality and consistent operation of the laboratory? | | | |
| **8.2.3** | Does the laboratory management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness? | | | |
| **8.2.4** | Are all the documentation, processes, systems, records, related to the fulfilment of the requirements of this document included in, referenced from, or linked to the management system? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| 8.2.5 | Do all personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities? | | | |
| 8.3 | **Control of Management System Documents (Option A)** | | | |
| 8.3.1 | Does the laboratory control the documents (internal and external) that relate to the fulfilment of this document? | | | |
| Note | In this context, “document” can be policy statements, procedures, specifications, manufacturer’s instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital. | | | |
| 8.3.2 | Does the laboratory ensure following? | | | |
| 8.3.2 | a) documents are approved for adequacy prior to issue by authorized personnel; | | | |
| 8.3.2 | b) documents are periodically reviewed, and updated as necessary; | | | |
| 8.3.2 | c) changes and the current revision status of documents are identified; | | | |
| 8.3.2 | d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled; | | | |
| 8.3.2 | e) documents are uniquely identified; | | | |
| 8.3.2 | f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose. | | | |
| 8.4 | **Control of Records (Option A)** | | | |
| 8.4.1 | Does the laboratory establish and retain legible records to demonstrate fulfilment of the requirements in this document? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| 8.4.2 | Does the laboratory implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records? Does the laboratory retain records for a period consistent with its contractual obligations? Are access to these records consistent with the confidentiality commitments and are records readily available? | | | |
| Note | Additional requirements regarding technical records are given in 7.5. | | | |
| AOAC | Are method validation and verification records retained, at a minimum, for as long as the method is in use by the laboratory and do they adhere to the laboratory's policy on document retention? | | | |
| AOAC | Does the laboratory have a procedure to periodically confirm access to backup records? | | | |
| AOAC | Is there a record of these periodic confirmations? | | | |
| AOAC | Are the backup records stored in a separate location from the original records? | | | |
| 8.5 | **Actions to address risks and opportunities (Option A)** | | | |
| 8.5.1 | Does the laboratory consider the risks and opportunities associated with the laboratory activities in order to: | | | |
| 8.5.1 | a) give assurance that the management system achieves its intended results; | | | |
| 8.5.1 | b) enhance opportunities to achieve the purpose and objectives of the laboratory; | | | |
| 8.5.1 | c) prevent, or reduce, undesired impacts and potential failures in the laboratory activities; | | | |
| 8.5.1 | d) achieve improvement? | | | |
| 8.5.2 | Does the laboratory plan: | | | |
| 8.5.2 | a) actions to address these risks and opportunities; | | | |
| 8.5.2 | b) how to: | | | |
| 8.5.2 | — integrate and implement the actions into its management system; | | | |
| 8.5.2 | — evaluate the effectiveness of these actions? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| Note | Although this document specifies that the organization plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards. | | | |
| 8.5.3 | Are actions taken to address risks and opportunities proportional to the potential impact on the validity of laboratory results? | | | |
| Note 1 | Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision. | | | |
| Note 2 | Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs. | | | |
| 8.6 | **Improvement (Option A)** | | | |
| 8.6.1 | Does the laboratory identify and select opportunities for improvement and implement any necessary actions? | | | |
| Note | Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results. | | | |
| 8.6.2 | Does the laboratory seek feedback, both positive and negative, from its customers? Is the feedback analysed and used to improve the management system, laboratory activities and customer service? | | | |
| Note | Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers. | | | |
| 8.7 | **Corrective Action (Option A)** | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **8.7.1** | When a nonconformity occurs, does the laboratory: | | | |
| **8.7.1** | a) react to the nonconformity and, as applicable: | | | |
| **8.7.1** | — take action to control and correct it; | | | |
| **8.7.1** | — address the consequences; | | | |
| **8.7.1** | b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: | | | |
| **8.7.1** | — reviewing and analysing the nonconformity; | | | |
| **8.7.1** | — determining the causes of the nonconformity; | | | |
| **8.7.1** | — determining if similar nonconformities exist, or could potentially occur; | | | |
| **8.7.1** | c) implement any action needed; | | | |
| **8.7.1** | d) review the effectiveness of any corrective action taken; | | | |
| **8.7.1** | e) update risks and opportunities determined during planning, if necessary; | | | |
| **8.7.1** | f) make changes to the management system, if necessary? | | | |
| **AOAC** | [1] To identify possible causal factors, did they consider the following: | | | |
| **AOAC** | [1a] Physical causes – Did tangible, material items fail in some way? | | | |
| **AOAC** | [1b] Human causes – Did people do something wrong, or not do something that was needed? | | | |
| **AOAC** | [1c] Organizational causes – Is a system, process, or policy that people use to make decisions or do their work faulty? | | | |
| **AOAC** | [2] Did you ask why, repeatedly, until the cause was identified? | | | |
| **AOAC** | [3] Once a cause has been identified, did they take corrective action: | | | |
| **AOAC** | [3a] Did they decide what can be done to prevent the problem from happening again? | | | |
| **AOAC** | [3b] Did they determine how the solution will be implemented? | | | |
| **AOAC** | [3c] Did they define who will be responsible for implementation? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| AOAC | [3d] Did they evaluate the risks of implementing the solution? | | | |
| AOAC | [4] Did they verify the effectiveness of the corrective action. | | | |
| 8.7.2 | Are corrective actions appropriate to the effects of the nonconformities encountered? | | | |
| 8.7.3 | Does the laboratory retain records as evidence of: | | | |
| | a) the nature of the nonconformities, cause(s) and any subsequent actions taken; | | | |
| | b) the results of any corrective action. | | | |
| 8.8 | **Internal Audits (Option A)** | | | |
| 8.8.1 | Does the laboratory conduct internal audits at planned intervals to provide information on whether the management system: | | | |
| 8.8.1 | a) conforms to: | | | |
| 8.8.1 | — the laboratory's own requirements for its management system, including the laboratory activities; | | | |
| 8.8.1 | — the requirements of ISO/IEC 17025:2017; | | | |
| 8.8.1 | b) is effectively implemented and maintained? | | | |
| AOAC | Are internal audits of laboratory information management systems conducted at least once per accreditation cycle? | | | |
| AOAC | For Pre-Accreditation: Are internal audits completed for all parts of the quality system for which the laboratory wants to become accredited? | | | |
| 8.8.2 | Does the laboratory : | | | |
| 8.8.2 | a) plan, establish, implement and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting, | | | |
| 8.8.2 | Does the laboratory take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits? | | | |
| AOAC | Are the schedule and scope of the audit determined based on a risk-based assessment? | | | |
| 8.8.2 | b) define the audit criteria and scope for each audit; | | | |
| 8.8.2 | c) ensure that the results of the audits are reported to relevant management; | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **8.8.2** | d) implement appropriate correction and corrective actions without undue delay; | | | |
| **8.8.2** | e) retain records as evidence of the implementation of the audit program and the audit results? | | | |
| **Note** | ISO 19011 provides guidance for internal audits. | | | |
| **8.9** | **Management reviews (Option A)** | | | |
| **8.9.1** | Does the laboratory management review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of ISO/IEC 17025:2017? | | | |
| **AOAC** | Does management review include a review of nonconforming work for trends? | | | |
| **AOAC** | Are customer and personnel feedback and complaints reviewed for trends? | | | |
| **8.9.2** | Are the inputs to management review recorded?<br>Do they include information related to the following: | | | |
| **8.9.2** | a) changes in internal and external issues that are relevant to the laboratory; | | | |
| **8.9.2** | b) fulfilment of objectives; | | | |
| **8.9.2** | c) suitability of policies and procedures; | | | |
| **8.9.2** | d) status of actions from previous management reviews; | | | |
| **8.9.2** | e) outcome of recent internal audits; | | | |
| **8.9.2** | f) corrective actions; | | | |
| **8.9.2** | g) assessments by external bodies; | | | |
| **8.9.2** | h) changes in the volume and type of the work or in the range of laboratory activities; | | | |
| **8.9.2** | i) customer and personnel feedback; | | | |
| **8.9.2** | j) complaints; | | | |
| **8.9.2** | k) effectiveness of any implemented improvements; | | | |
| **8.9.2** | l) adequacy of resources; | | | |
| **8.9.2** | m) results of risk identification; | | | |
| **8.9.2** | n) outcomes of the assurance of the validity of results; and | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| **AOAC** | Does this review include a review of proficiency test results? | | | |
| **8.9.2** | o) other relevant factors, such as monitoring activities and training? | | | |
| **8.9.3** | Do the outputs from the management review record all decisions and actions related to at least: | | | |
| **8.9.3** | a) the effectiveness of the management system and its processes; | | | |
| **8.9.3** | b) improvement of the laboratory activities related to the fulfilment of the requirements of this document; | | | |
| **8.9.3** | c) provision of required resources; | | | |
| **8.9.3** | d) any need for change? | | | |
| **Additional Requirements (Required for surveillance and re-accreditation assessments)** | | | | |
| ***Objective Evidence of Laboratory's utilization of PJLA's accreditation symbol must be included in the package.** | | | | |
| **This includes but is not limited to (Website, letterhead, test or calibration report including subcontracted results and calibration labels)*** | | | | |
| ***If any of the requirements of SOP-3 are not followed a nonconformance must be written*** | | | | |
| **SOP-3 Use of the Symbol** | | | | |
| | **For applicant laboratories:** | | | |
| | Note: Applicant laboratories are not permitted to use the PJLA logo until official accreditation is granted by executive committee approval. | | | |
| | Does the applicant laboratory use the PJLA Logo? | | | |
| | **For accredited laboratories:** | | | |
| | Is the accredited laboratory utilizing the correct symbol (i.e. testing and/or calibration)? | | | |
| | Is the symbol reproduced in a size that is clearly distinguishable? | | | |
| | Is the symbol reproduced in a single-color (black or a single color belonging to the house-style of the accredited lab)? | | | |
| | Is the symbol identifiable? | | | |
| | Is the accredited laboratory properly stating their accreditation status?<br>"Accredited to ISO/IEC 17025:2005" or utilizing the ILAC criteria listed in the SOP-3 Procedure? (ILAC guidance not mandatory) | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| | Is the accredited laboratory properly using the symbol on: | | | |
| | a) promotional material and business stationary? | | | |
| | b) test or calibration certificates or labels? (See note 1) | | | |
| | c) website? | | | |
| | d) technical literature? | | | |
| | e) business reports? | | | |
| | f) quotations or proposals for work? (symbols may only be listed for accredited laboratories) | | | |
| | Note 1-Where statements of opinion and interpretation are outside the scope of the accreditation, the laboratory shall include a disclaimer in the report or certificate close to the accreditation symbol such as " the opinions/interpretations expressed on this report are outside the scope of this laboratory's accreditation." | | | |
| | Is the accredited laboratory appropriately using the symbol by not placing the symbol on: | | | |
| | a) legal documents (i.e. contracts or checks)? | | | |
| | b) on test/calibration certificates or any other material referencing work or items not covered by scope of accreditation?b) on test/calibration certificates or any other material referencing work or items not covered by scope of accreditation? | | | |
| | c) any documentation of sites that are not accredited by PJLA? | | | |
| | d) on subcontractor's certificates or documentation? | | | |
| | e) on products or items which laboratory has tested or calibrated (except calibration labels)? | | | |
| | Where tests or calibrations outside the scope of the accreditation are included on reports, certificates or enclosed letters with results, has the laboratory clearly defined "This laboratory is not accredited for the tests or calibrations marked"? | | | |
| | If the accredited laboratory included the results of subcontracted tests or calibrations on reports or certificates can they demonstrate that they have: | | | |
| | a) obtained approval from the subcontracted laboratory? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| | b) obtained approval from the subcontractor to report excerpts from the subcontractor's report on the certificate? | | | |
| | c) objective evidence that the subcontractor itself is accredited for the specific tests or calibrations concerned and results have been included in the subcontractor's endorsed report or certificate? | | | |
| | Does the laboratory use any oversight or recognition body logo or symbol on their certificates, reports or any other material? | | | |
| | If yes, which body's logo or symbol are they using? | | | |
| **PL-1 Proficiency Testing Requirements** | | | | |
| | **For applicant laboratories:**<br>Is there objective evidence for PT activity for each item to be included within proposed scope of accreditation? | | | |
| | Are the results meaningful i.e. demonstrating the laboratory's competence in performing specified tests or calibrations? | | | |
| | **For accredited laboratories:**<br>Is there a documented proficiency testing plan or schedule? | | | |
| | Does this plan or schedule include all items included on the scope of accreditation to be tested within a four year period? | | | |
| | Has the laboratory completed at least one proficiency test each year? | | | |
| | Has the proficiency plan or schedule been approved by PJLA? | | | |
| | For any unfavorable results gathered during proficiency testing, was appropriate corrective action taken? | | | |
| **PL-2 Measurement Traceability Policy** | | | | |
| | Does the laboratory have documented policies and procedures regarding measurement traceability and reference this traceability on test/calibration reports? | | | |
| | Does the laboratory have documented procedures detailing the verification, transport and storage of reference standards? | | | |

| Section | Assessment | Yes | No | Comments |
|---|---|---|---|---|
| | Has the laboratory employed the services of an external calibration provider(s) that are accredited to ISO/IEC 17025:2005 for the calibration(s) performed? | | | |
| | *If not, can the laboratory demonstrate reverse traceability, an uninterrupted chain, back to NIST or another NMI? | | | |
| | Does the laboratory have on file and available the current certificates and scopes of accreditation for the external calibration laboratories employed? | | | |
| **PL-3 Policy on Measurement Uncertainty for Calibration and Testing Laboratories** | | | | |
| | **For applicant laboratories:**<br>Has the laboratory applied its documented procedure to provide measurement uncertainties for every measured quantity, instrument or gage listed in its scope of accreditation?<br>(Well recognized test methods or calibration procedures that specify limits to the values of major sources of uncertainties will meet this requirement) | | | |
| | **For accredited laboratories:**<br>Are stated uncertainties periodically reviewed and updated to evaluate changes to be made to any influence listed in an uncertainty budget? | | | |
| | Does the laboratory include a metrological statement or reference estimated uncertainties on calibration/test reports? | | | |
| **Surveillance of Previous Nonconformities and Corrective Action** | | | | |
| | The assessor shall verify that previous nonconformities have been resolved and that corrective actions have been effectively implemented. | | | |

## Appendix A: Equipment

| Considerations | Action | Frequency | Yes | No | Comments |
|---|---|---|---|---|---|
| Autoclaves | Calibrate temperature sensing system | At installation (or initial use) | | | |
| | Verify accuracy of temperature sensing system | Annually | | | |
| | Verify maximum temperature achieved | Each day | | | |
| | Verify performance with biological sterility indicator | Weekly | | | |
| | Uniformity of temperature[a] | At installation (or initial use) and annually thereafter | | | |
| | Stability of temperature | At installation and annually as needed[b] | | | |
| Automated colony counters | Verify accuracy against manual count | Annually | | | |
| Balances | Verify mass measurement | Each day of use | | | |
| | Calibrate[c] | Annually<br>When moved to different location or after repair | | | |
| Chromatographic systems (GC, IC, LC) | Verify detector response for the analytical methods[d] | At least once with each batch | | | |
| Dispensing equipment and vial fillers used in microbiology | Verify mass/volume measurement at each volume dispensed | At installation and each day of use | | | |
| Freeze-dryers, vacuum ovens | Verify ability to achieve and sustain vacuum | At installation and annually thereafter | | | |
| | Verify vacuum gauges against traceable calibrated gauge | At installation and annually thereafter | | | |
| Hydrometer, reference | Calibrate | Every 2 years | | | |
| Hydrometer, working | One point comparison to reference hydrometer | Annually | | | |
| Microscopes used for measuring | Calibrate stage micrometer | At installation or initial use | | | |
| pH meters ion selective, and related conductivity equipment[e] | Calibrate against reference buffer[e] or reference solution at level of use or bracketing range of use | Each day of use | | | |

| | | | | | |
|---|---|---|---|---|---|
| Temperature-controlled chambers used for storage (e.g., refrigerators and freezers) | Verify temperature | Frequency is dependent upon mechanism of monitoring[f] | | | |
| | Uniformity of temperature by mapping the chamber | At installation (or initial use) and after nonroutine maintenance[g] | | | |
| Temperature-controlled chambers used for testing (e.g., ovens, furnaces, incubators, water baths, and autoclaves) | Verify temperature | Minimum twice daily on each day of use with at least 4 hours between verifications | | | |
| | Uniformity of temperature[a] by mapping the chamber | At installation (or initial use) and after nonroutine maintenance[g] | | | |
| Temperature sensing devices/systems, reference (e.g., thermometers, thermocouples, data loggers, data tracers, thermistors, digital displays, continuous monitors, etc.) | Calibrate temperature to the appropriate traceable standard | Every 2 years | | | |
| Temperature sensing devices/systems, working (e.g., thermometers, thermocouples, data loggers, data tracers, thermistors, digital displays, continuous monitors, etc.) | Verify temperature against reference device | Annually | | | |
| Timers and internal timing devices[h] | Time | Verify working device annually against reference or against NIST time clock[i] | | | |
| UV-Vis spectrophotometer | Verify blank reading | Daily when in use | | | |
| | Verify wavelength | At installation and annually | | | |
| Volumetric delivery devices: mechanical pipets, mechanical burets, and liquid dispensers | Verify accuracy using mass of water at a known temperature or by spectrophotometric method | Upon receipt (manufacturer's Certificate of Accuracy may be accepted) Minimum every 6 months | | | |

| | | | | | |
|---|---|---|---|---|---|
| Volumetric delivery devices: positive displacement syringes used for volumetric delivery | Verify accuracy | Upon receipt (manufacturer's Certificate of Accuracy may be accepted) | | | |
| Volumetric non-class A glassware: pipets, burets, and volumetric flasks | Accuracy using mass of water at a known temperature or by spectrophotometric method | Upon receipt | | | |
| Water activity meter | Verify water activity of known solutions | Daily when in use[e] | | | |
| Water, used in all analyses to meet method requirements | Method specific water quality attributes | Minimally every month | | | |
| Water, used for microbiological analyses | Acceptable levels of chlorine and aerobic plate count | Monthly | | | |
| Water used for pharmaceutical analyses | The eight types of water are as follows:<br>1. Nonpotable<br>2. Potable (drinkable) water<br>3. USP purified water<br>4. USP water for injection<br>5. USP sterile water for injection<br>6. LUSP sterile water for inhalation<br>7. USP bacteriostatic water for injection<br>8. USP sterile water for irrigation | Meet FDA Inspection Technical Guide Requirements: https://www.fda.gov/ICECI/Inspections/ InspectionGuides/InspectionTechnicalGuides/ ucm072925.htm | | | |
| Weights, reference | Calibrate mass | Every 5 years[c] | | | |
| Weights, working | Verify mass against reference weights | Annually | | | |
| [a] Uniformity may not be needed for low-capacity equipment. For example, a small muffle furnace | | | | | |
| [b] Autoclaves equipped with a calibrated temperature sensing device that provides a record of temperature are considered to meet this requirement. | | | | | |
| [c] All weights and balances shall be calibrated traceable to recognized national or international calibration units (i.e., National Institute for Standards and Technology, Bureau International des | | | | | |

| | | | |
|---|---|---|---|
| [d] For quantitative methods, an analytical standard at the mid-range or lower of the calibration curve can verify detector response. For qualitative assessments, the appropriate response material must be used. | | | |
| [e] When pH or water activity results are reported to the customer or may be a significant component of overall uncertainty of the measurand, the reference material (e.g., buffer or water activity analytical standard) must satisfy the requirements for metrological traceability (clause 6.5.1). Accreditation bodies may require buffers obtained from an ISO 17034-accredited manufacturer. | | | |
| [f] The intent is the laboratory must be able to verify that samples were stored at the proper temperature for the duration of storage. Continuous monitoring with a calibrated and validated system meets this requirement. A min/max data logging thermometer would require verification at a frequency dependent upon the amount of data it can store. | | | |
| [g] When determining mapping schedules, attention should be paid to extremes in laboratory ambient conditions (such as those brought on by seasonal changes) that can influence the performance of equipment. Initial and nonroutine maintenance monitoring can be done with no load. | | | |
| [h] Timers and internal timing devices only need to be verified when time is a critical factor in the test method. Time may not be a critical factor when time is not the reported result or a precise time is not required for the test method. | | | |
| [i] Accrediting bodies may require initial calibration by an ISO 17025-accredited calibration laboratory. | | | |

| Appendix B: Microbiology<br><br>Considertations | Yes | No | Comments |
|---|---|---|---|
| **1. Organisms** | | | |
| Are the organisms required for testing checked for purity (no contamination with other organisms), enumeration, and demonstration of biochemical or other biological characteristics, as appropriate for their application? | | | |
| Are the organisms traceable and documented from date of possession? | | | |
| **2. Media** | | | |
| 2.1 Is every batch of media examined to ensure it is suitable for use? Do the records include preparation instructions (when internally prepared), traceability to dehydrated media (if internally prepared), pH, appearance, sterilization batch (see below), fill volumes (if appropriate), batch size, and quantity? | | | |
| 2.2 Does each batch of media undergo QC verification of the following parameters: productivity (+ culture), selectivity (if appropriate), and sterility? | | | |
| Are records traceable to the person approving or rejecting the media? | | | |
| **3. Reagents/Kits/Identification Systems** | | | |
| Does the laboratory approve every lot of material? Do records include the date approved and traceability to the person approving or rejecting the material, at a minimum? | | | |
| **Note:** For identification systems that speciate organisms (e.g., API 20E, VITEK, Biolog), it is sufficient to confirm acceptability of the kit by using a single control organism appropriate for that system. It is not necessary to confirm multiple organisms are identified correctly, unless the laboratory has a need for that information. | | | |
| **4. Sterilization for Media and Reagents** | | | |
| Do autoclave records show date, run number, autoclave identifier, nature of material/load, time at desired temperature, and traceability to persons performing the activities? | | | |
| For other sterilization means, do records show date, nature of material, and confirmation of sterilization procedure (including heating condition, filtration, and chemical denaturation) and traceability to persons performing the activities? | | | |

| Appendix C: Chemistry Assessment | | | |
|---|---|---|---|
| **Considerations** | **Yes** | **No** | **Comments** |
| When applicable to the method, are acceptance criteria defined in the method for calibration curves, calibration checks, standard preparations, quality control samples, blanks, spikes, matrix spikes, and duplicates? | | | |
| Does the laboratory have a policy or procedure for how and when manual processing and/or integrating of chromatographic data is appropriate? | | | |

| Appendix D: Pharmaceutical Analysis Assessment | | | |
|---|---|---|---|
| **Considerations** | **Yes** | **No** | **Comments** |
| Do the laboratory controls include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity? | | | |
| Additional Notes | | | |
| The pharmaceutical industry operates under the cGMP laws, guidance, and regulations. These incorporate many of the requirements in International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025. | | | |
| Both pharmaceutical cGMP and ISO/IEC 17025 are based on good science and sound metrological practices The U S regulations in the 21CFR 211 Subpart 1, Laboratory Controls, 211 160 b) state | | | |
| ISO/IEC 17025 and cGMP align in most requirements; hence, a laboratory meeting cGMP requirements will meet many ISO/IEC 17025 requirements. In this Analytical Laboratory Accreditation Criteria Committee guide, additional information is added for the pharmaceutical industry to indicate these similarities or differences or point to a cGMP system that meets an ISO/IEC requirement. It is not practical to identify all the cGMP documents and systems that address the ISO/IEC 17025 requirements, so only the most relevant are identified. | | | |
| The following are such requirements: | | | |
| (a) Decision rules —Decision rules are not required in the cGMP They are discussed in USP stimuli article “Fitness for Use: Decision Rules and Target Measurement Uncertainty”; USP Pharmacopeia Forum 42(2), Stimuli Article, usp.org | | | |
| (b) Proficiency testing (PT) —PT is not required in cGMP but is required for ISO/IEC 17025. | | | |
| (c) Quality control checks (independent checks).—The cGMP guides provide information on confirmatory checks, such as System Suitability checks ISO/IEC 17025 provides additional information on what these checks are and how to use them. | | | |
| (d) Equipment qualification —(1) In cGMP, equipment qualification follows a rigorous qualification program including Installation Qualification/Operational Qualification/Performance Qualification. | | | |
| (2) In cGMP, autoclave validation and water purification are rigorously described | | | |
| (e) Measurement uncertainty and target measurement uncertainty —(1) The evaluation and use of measurement uncertainty are required in ISO/IEC 17025. | | | |
| (2) The USP published a Pharmacopeia Forum stimuli article on Measurement “Uncertainty for the Pharmaceutical Industry”; USP Pharmacopeia Forum 44(1), usp.org. | | | |
| (3) Target measurement uncertainty for the pharmaceutical industry is discussed in “Fitness for Use: Decision Rules and Target Measurement Uncertainty”; USP Pharmacopeia Forum 42(2), Stimuli Article, usp.org. | | | |
| (f) Metrological traceability.—Metrological traceability is not directly required by cGMP; however, traceability to standards such as USP reference materials is often required | | | |
| (g) Out of specification (OOS) results —OOS would be dealt with under Nonconforming work in ISO/IEC 17025 The cause analysis and risk assessment for OOS results is rigorous and defined in detail in the cGMP. | | | |

| |
|---|
| (h) Risk analysis and International Committee of Harmonization (ICH) Q10, 11, 12 —ISO/IEC 17025 emphasizes the risk analysis approach to processes and procedures It does not prescribe procedures and emphasizes outcomes The use of risk analysis to control outcomes is in line with the ICH Q9 Quality Risk Management guide http://www ich org/products/ guidelines/quality/article/quality-guidelines html |

| Appendix E Dietary Supplement Laboratories Assessment<br><br>Considerations | Yes | No | Comments/Policy/ Procedure/Record |
|---|---|---|---|
| **1. Validation of Methods** | | | |
| Dietary supplement analytical laboratories are facing unique challenges dealing with ever-changing new formulations, ingredients, and matrixes. Dietary supplement laboratories should ensure that their methods are adequate and “fit for purpose ” During the method validation, it is preferable to work with well-characterized, homogenized, and stable materials such as Certified Reference Materials (CRMs) and/or Standard Reference Materials (SRMs); however, the availability of CRMs and SRMs specific to dietary supplements is limited. CRMs and SRMs can be obtained from a variety of sources, including, but not limited to, National Institute of Standards and Technology (NIST), United States Pharmacopeia, British Pharmacopoeia, European Pharmacopoeia, American Herbal Pharmacopoeia, and PhytoLab | | | |
| **2. Ensuring the Validity of the Results: Proficiency Testing** | | | |
| As appropriate PT programs are currently not available for the dietary supplement laboratories, the laboratory shall document in its plan its planned participation in interlaboratory comparisons. One of the recommended interlaboratory comparison/quality assurance program is the NIST established Health Assessment Measurements Quality Assurance Program Participants measure concentrations of nutritional and toxic elements, fat- and water-soluble vitamins, fatty acids, active and/or marker compounds, and contaminants in samples distributed by NIST Participant data are compiled at NIST and analyzed for accuracy, precision, and concordance within the community. | | | |
| When no interlaboratory comparison is available, does the laboratory develop and justify an alternative plan for monitoring data? | | | |

| 3. Out of Specification (OOS) Investigation | | | |
|---|---|---|---|
| A) When investigating the operator, have the following concerns been addressed: | | | |
| A1) Operator followed correct test method? | | | |
| A2) Operator followed test method as written? | | | |
| A3) Has operator trained on the procedure? | | | |
| B) When investigating the equipment, have the following concerns been addressed: | | | |
| B1) Correct equipment used? | | | |
| B2) Equipment examined and found to be functioning? | | | |
| B3) Equipment calibration is current? | | | |
| C) When investigating the materialst, have the following concerns been addressed: | | | |
| C1) Were the samples handled, stored, and prepared properly? | | | |
| C2) Correct standard(s) used? | | | |
| C3) Are standards within expiration date? | | | |
| C4) Were standard(s) and/or sample(s) prepared correctly? | | | |
| C5) Correct chemicals/reagents used according to test method? | | | |
| C6) Are chemicals/reagents used within expiration date? | | | |
| C7) Were chemicals/reagents (including buffers and solutions) prepared correctly? | | | |
| D) When investigating the data, have the following concerns been addressed: | | | |
| D1) Raw data properly and completely documented on appropriate controlled form? | | | |

| | | | |
|---|---|---|---|
| D2) Calculations performed properly? | | | |
| D3) Assay controls within acceptance criteria or specification? | | | |
| D4) System suitability parameters within acceptance criteria? | | | |
| During the laboratory investigation conclusion, do the following respor | | | |
| a) For an Assignable Cause, does the response include initial results invalidation, repeat of test, retained initial data, but initial data not used? | | | |
| b) For No Assignable Cause, does the response include a statement of inconclusive finding and retest the sample? | | | |

| 4. Equipment Qualification | | | | |
|---|---|---|---|---|
| Detector response (UV, diode-array detection, fluorescence, electron ionization, RI, evaporative light scattering detection, MS) | | | | |
| Does verification of detector response/linearity occur with at least three concentrations of analytical standard or certified reference standard if available? Do concentrations include the low, high, and the mid-range of the calibration curve? | Does it occur at the following frequency: At least once with each batch | | | |
| Chromatographic systems (GC, ion chromatography, LC) | | | | |
| Has the lab verified pump flow accuracy and precision, column temperature accuracy and stability, wavelength accuracy, signal-noise and drift, injection precision, injection carry-over, gradient composition accuracy, gradient composition noise and drift, sample temperature accuracy? | Does it occur at the following frequency: Annually, or after maintenance and repair | | | |