ISO/IEC 17025: 2005 WORKING DOCUMENT WITH AOAC, AAFCO, AND APLAC T007 GUIDANCE

NOTES:

1. This working document is intended as a checklist for the assessor when conducting Testing and Calibration Laboratory Accreditation Assessments according to **ISO/IEC 17025: 2005**, **AOAC Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals – An Aid to the Interpretation of ISO/IEC 17025:2005 (2015)" (ALACC Guidelines), and (AAFCO)-- Quality Assurance/Quality Control Guidelines For Feed Laboratories supplement to ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories including AAFCO Accreditation Requirements 2014**. This standard incorporates all elements of ISO 9001 relevant to testing and calibration laboratories.

2. Please note 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. **Note: At least 1 comment per section is required**

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. **Green Highlighted** items indicate **TC007** requirements, **Red Highlighted** items indicate AAFCO requirements, and **Blue Highlighted** items indicate AOAC requirements. All other items are ISO/IEC 17025 requirements

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

8. If, at any time, the assessment team requires assistance in the interpretation of the standard requirements, the PJLA office should be contacted immediately.

Assessment Number: _____ Date:_____

Client: _____

Address: _____

_____

Contract/Management Rep: _____

Lead Assessor: _____

Assessment Team Member(s):_____

PJLA

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
MANAGEMENT REQUIREMENTS				
4.1 Organization				
4.1.1	Is the laboratory or the organization of which it is part an entity that can be held legally responsible?			
4.1.2	Does the laboratory uphold its responsibility to carry out its testing and calibration activities in such a way as to meet the requirements of this standard? Does the laboratory carry out its testing and calibration activities in such a way as to meet the requirements of the customer, the regulatory authorities or organizations providing recognition?			
4.1.3	Does the management system cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities?			
4.1.4	If the laboratory is part of an organization performing activities other than testing and/or calibration, are the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities defined in order to identify potential conflicts of interest?			
4.1.5	Does the laboratory (a-j): a) have managerial and technical personnel with the authority and resources needed to: - perform their duties? - identify departures from the management system or from the procedures for performing tests and/or calibrations? - initiate actions to prevent or minimize such departures?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	- implement, maintain and improve the management system irrespective of other responsibilities?			
4.1.5	b) have arrangements to ensure that its management & personnel are free from any undue internal and external commercial, financial and other pressures that may adversely affect the quality of their work?			
AOAC International Guidelines	Have conflict of interest agreements been established along with appropriate training programs for entry personnel?			
AOAC International Guidelines	Do all affected staff members annually attest that they understand the conflict of interest agreement and adhere to the requirements?			
4.1.5	c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results?			
4.1.5	d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity?			
4.1.5	e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services?			
AOAC International	Is there an organizational description that could include			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
Guidelines	organizational chart or charts indicating all reporting relationships and responsibilities readily available to staff members?			
AOAC International Guidelines	Does the organizational chart include the most responsible position for the unit and all positions in that hierarchy?			
4.1.5	f) specify the responsibility, authority, and interrelation of all personnel who manage, perform or verify work affecting the quality of tests and/or calibrations?			
4.1.5	g) provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, the purpose of each test and/or calibration and the assessment of the results?			
4.1.5	h) have technical management with overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of laboratory operations?			
4.1.5	i) appoint a member of staff as quality manager (however named)? - does this quality manager have defined responsibility and authority for ensuring that the management system is implemented and followed at all times? - does this quality manager have direct access to the highest level of management at which decisions are made on laboratory policy or resources?			
4.1.5	j) appoint deputies for key			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	managerial personnel?			
4.1.5	k) ensure that personnel are aware of the relevance and importance of their activities and how they contribute to overall management system goals?			
4.1.6	Does top management ensure that communication processes are established and that communication regarding the effectiveness of the management system takes place?			
4.2	**Management system**			
4.2.1	Appropriate to the scope of its activities, has the laboratory: - established - implemented - maintained a management system?			
4.2.1	Are the policies, systems, programs, procedures and instructions of this system documented to the extent necessary to assure the quality of the test and/or calibration results?			
4.2.1	Is the system documentation communicated to, understood by, available to, and implemented by the appropriate personnel?			
AOAC International Guidelines"	If the laboratory's management system is incorporated into a quality manual for a multifunctional laboratory, are there specific sections pertaining to special needs for various analytes and/or techniques that are easily identifiable? (There may be specific subsections for various analytes included in the document)			
AOAC International	Is the quality system communicated, understood, available, and			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
Guidelines	implemented to ensure that testing is in conformance to customer requirements and to the requirements of ISO/IEC 17025:2005 (documented evidence)?			
4.2.2	Are the lab's management system policies and objectives defined in a quality manual (however named)?			
4.2.2	Are the objectives established and reviewed during management review?			
4.2.2	Are the overall objectives documented in a quality policy statement?			
4.2.2	Has the quality policy statement been issued under the authority of top management?			
4.2.2	Does the quality policy statement include at least the following (a-e): a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers?			
4.2.2	b) the management's statement of the laboratory's standard of service?			
4.2.2	c) the purpose of the management system related to quality?			
4.2.2	d) a requirement that all personnel concerned with testing and calibration activities within the lab familiarize themselves with the quality documentation and implement the policies and procedures in their work?			
4.2.2	e) the laboratory management's commitment to compliance with this standard and to continually improve the effectiveness of the management system?			
4.2.2	NOTE: The quality policy statement should be concise and may include the			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements.			
4.2.3	Has top management provided evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness?			
4.2.4	Has top management communicated to the organization the importance of meeting customer, statutory and regulatory requirements?			
4.2.5	Does the quality manual include or make reference to supporting and technical procedures and does it outline the structure of the documentation used in the management system?			
4.2.6	Does the quality manual define the roles and responsibilities of the technical and quality managers, including the roles which ensure compliance with this standard?			
4.2.7	Has Top Management ensured that the integrity of the management system is maintained when changes are planned and implemented?			
4.3 Document Control				
4.3.1	Has the laboratory established procedures to control all documents that form part of its management system (internally generated or from external sources) such as regulations, standards, other normative documents, test and/or calibration methods, as well			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	as drawings, software, specifications, instructions and manuals? Does the laboratory maintain procedures to control the above documents?			
4.3.2.1	Are all documents issued to laboratory personnel as part of the management system reviewed and approved for used by authorized personnel prior to issue?			
4.3.2.1	Is there a master list (or equivalent procedure) identifying the current revision status and distribution of documents in the management system? Is this master list readily available to preclude the used of invalid and/or obsolete documents?			
4.3.2.2	Does the adopted procedure ensure that (a-d): a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed?			
4.3.2.2	b) documents are periodically reviewed and where necessary, revised to ensure continuing suitability and compliance with applicable requirements?			
APLAC TC007	Does the laboratory monitor *Codex Alimentarius* (Codex) and national regulatory authorities to ensure the documents and method continue to be acceptable and in compliance with applicable requirements especially for tests done for regulatory purposes?			
4.3.2.2	c) invalid or obsolete documents are			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	promptly removed from all points of issue or use, or otherwise assured against unintended use?			
4.3.2.2	d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked?			
4.3.2.3	Are management system documents generated by the laboratory uniquely identified? Does this identification include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies)?			
4.3.3.1	Are changes to documents reviewed and approved by the same function that performed the original review unless specifically designated otherwise? Do designated personnel have access to pertinent background upon which to base their review and approval?			
4.3.3.2	Where practicable, is the altered or new text identified in the document or the appropriate attachments?			
4.3.3.3	If the laboratory's document control system allows for the amendment of documents by hand pending the re-issue of the documents, are the procedures and authorities defined? Are amendments clearly: - marked? - initialed? - dated?			
4.3.3.3	Is a revised document formally re-issued as soon as practicable?			
4.3.3.4	Are procedures established to describe how changes in documents maintained			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	in computerized systems are made and controlled?			
4.4	**Review of Requests, Tenders and Contracts**			
4.4.1	Has the laboratory established procedures for the review of requests, tenders and contracts? Are these procedures maintained?			
4.4.1	Do the policies and procedures for these reviews leading to a contract for testing and/or calibration ensure that (a-c): a) the requirements, including the methods to be used, are adequately defined, documented and understood?			
4.4.1	b) the laboratory has the capability and resources to meet the requirements?			
4.4.1	c) the appropriate test and/or calibration method is selected and capable of meeting the customers' requirements?			
4.4.1	Are any differences between the request or tender and the contract resolved before any work commences? Is each contract acceptable to both the laboratory and the customer?			
APLAC TC007	Does the laboratory take into account the regulatory requirements when selecting the appropriate test method and subcontractors when necessary?			
APLAC TC007	Does testing in support of export certification take into account the regulatory and contractual requirements of the importing economy or organization?			
4.4.2	Are records of reviews, including any significant changes, maintained?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	Are records maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of contract execution? NOTE: For review of routine and other simple tasks, the date and identification (e.g. initials) of person responsible for carrying out the work are adequate. For repetitive routine tasks, the review need only be made at the initial inquiry stage or on granting of the contract for ongoing routine work, provided that the customer's requirements remain unchanged. For new or complex tasks, a more comprehensive record should be maintained.			
4.4.3	Does the review also cover any work that is subcontracted by the laboratory?			
4.4.4	Is the customer informed of any deviation from the contract?			
4.4.5	If a contract needs to be amended after work has commenced, is the same contract review process repeated? Are any amendments communicated to all affected personnel?			
4.5	**Subcontracting of Tests and Calibrations**			
4.5.1	When a laboratory subcontracts work, whether because of unforeseen reasons (workload, need for further expertise or temporary incapacity) or on a continuing basis (permanent subcontracting, agency or franchising arrangements), is this work placed with a competent subcontractor? A competent subcontractor is one who complies with this standard for the work in question.			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.5.2	Does the laboratory advise the customer of the arrangement in writing? When appropriate, does the laboratory gain the approval of the customer, preferably in writing?			
4.5.3	Does the laboratory show responsibility to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used?			
4.5.4	Does the laboratory maintain a register of all subcontractors that it uses for tests and/or calibrations? Does the laboratory maintain a record of evidence of compliance with this standard for the work in question?			
4.6	**Purchasing Services and Supplies**			
4.6 AAFCO Quality Assurance / Quality Control Guidelines For Feed Laboratories supplement to ISO/IEC 17025:2005	State/government purchasing systems often approve or restrict vendors based on price, accounts receivable, or state-wide contract agreements. The laboratory must maintain its own list of quality critical approved suppliers based on its evaluation of the quality of goods or services received. At times this may be used to support state/government purchasing systems regarding why one vendor should be used over another.			
4.6.1	Does the laboratory have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.6.1	Do procedures exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations?			
4.6.2	Does the laboratory ensure that purchased supplies, reagents and consumable materials affecting the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned?			
4.6.2	Are the services and supplies used compliant with specified requirements? Are records maintained of action taken to check compliance?			
AOAC International Guidelines	In some industries, such as pharmaceutical, the authoritative body, for example, the USP Reference Standards or the EP Certified Reference Standards, mandates the use of specific reference materials. Reference Materials/Standards obtained from such authoritative sources are presumed to be suitable for their defined uses.			
AOAC International Guidelines	Does the laboratory ensure that the quality of the reagents used is appropriate for the tests concerned?			
4.6.3	Do purchasing documents for items affecting the quality of laboratory output contain data describing the services and supplies ordered? Are these purchasing documents reviewed and approved for technical content prior to release?			
4.6.4	Does the laboratory evaluate suppliers			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	of critical consumables, supplies and services that affect the quality of testing and calibration?			
4.6.4	Are records maintained of these evaluations? Do they list those approved?			
AOAC International Guidelines	Once a supplier has been evaluated and approved, is there a program to ensuring the continued suitability of the supplier?			
4.7 Service to the Customer				
4.7.1	Does the laboratory afford customers or their representatives cooperation to clarify the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers? NOTES: Such cooperation may include a) providing reasonable access for the witnessing of tests and/or calibrations and b) preparation, packaging and dispatch of test and/or calibration items needed by the customer for verification purposes. Communication with the customer, especially in large assignments, should be maintained throughout the work. The lab should inform the customer of any delays or major deviations.			
4.7.2	Does the laboratory seek both positive and negative feedback and is the feedback used to improve the management system, testing and calibration activities and customer service?			
4.8 Complaints				

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	Does the laboratory have a policy and procedure for the resolution of complaints received from customers or other parties? Are records maintained of all complaints and of the investigations and corrective actions taken?			
AOAC International Guidelines"	For dietary supplements and pharmaceuticals, does a qualified person review complaints for possible failures and investigate where needed?			
4.9	**Control of Nonconforming Testing and/or Calibration Work**			
4.9.1	Does the laboratory have a policy and procedures that are implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer?			
4.9.1	Do the policy and procedures ensure that (a-e): a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified?			
4.9.1	b) an evaluation of the significance of the nonconforming work is made?			
4.9.1	c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work?			
4.9.1	d) where necessary, the customer is notified and work is recalled?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.9.1	e) the responsibility for authorizing the resumption of work is defined?			
AOAC International Guidelines"	*Note:* Specifications may be an important aspect of the laboratory's samples, therefore procedures for responding to out-of-specification (OOS) results should be considered. The degree to which 00S results are investigated can vary, so the laboratory is encouraged to design procedures that suit the industries they serve. Guidelines are available from organizations such as FDA and TGA.			
4.9.2	Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, are the corrective action procedures promptly followed?			
4.10 Improvement				
	Has the laboratory improved the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review?			
4.11 Corrective Action				
4.11.1	Has the laboratory established a policy and procedure for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified? Has the laboratory designated appropriate authorities for			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	implementing corrective action in the above situations?			
4.11.2	Does the procedure for corrective action start with an investigation to determine the root cause(s) of the problem?			
4.11.3	Where corrective action is needed, does the laboratory identify potential corrective actions? Does the laboratory select and implement the action(s) most likely to eliminate the problem and to prevent recurrence?			
4.11.3	Are corrective actions to a degree appropriate to the magnitude and risk of the problem?			
4.11.3	Does the laboratory document and implement any required changes resulting from corrective action investigations?			
4.11.4	Does the laboratory monitor the results to ensure that the corrective actions taken have been effective?			
4.11.5	Where the identification of nonconformities or departures casts doubt on the laboratory's compliance with its own policies and procedures, or on its compliance with this standard, does the laboratory ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible? NOTE: An additional audit should be necessary only when a serious issue or risk to the business is identified.			
APLAC TC007	Does the laboratory seek regulatory guidance if necessary and ensure that			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	the needs of the customers are met? Rapid notification of nonconforming results to customers and, if necessary, to regulators may be necessary to prevent or reduce public health incidents.			
APLAC TC007	Does the laboratory notify the customer of nonconforming results and, if necessary, to regulators to prevent or reduce public health incidents?			
4.12 Preventive Action				
4.12.1	Are needed improvements and potential sources of nonconformities, either technical or concerning the management system, identified?			
4.12.2	If preventive action is required, are action plans: - developed - implemented - and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement?			
4.12.2	Do procedures for preventive actions include the initiation of such actions and application of controls to ensure that they are effective?			
4.13 Control of Records				
4.13.1.1	Has the laboratory established procedures for: - identification - collection - indexing - access - filing - storage - maintenance - disposal of all quality and technical records?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.13.1.1	Does the laboratory maintain these procedures?			
4.13.1.1	Do the quality records include reports from internal audits and management reviews as well as records of corrective and preventive actions?			
AOAC International Guidelines	Is maintenance and security of all records consistent with the customer's requirements?			
4.13.1.2	Are all records legible? Are all records retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss? Are the retention times established?			
AOAC International Guidelines	Are the record retention policies consistent with the customer's requirements and the requirements of the laboratory?			
4.13.1.3	Are all records held secure and in confidence?			
4.13.1.4	Does the laboratory have procedures to protect and back up records stored electronically and to prevent unauthorized access to or amendment of these records?			
4.13.2.1	Does the laboratory retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period? NOTE: In certain fields it may be impossible or impractical to retain records of all original observations.			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.13.2.1	Do the records for each test or calibration contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original?			
4.13.2.1	Do the records include the identity of personnel responsible for the - sampling? - performance of each test and/or calibration? - and checking of results?			
AOAC International Guidelines	Are quality-critical reagents prepared in the laboratory labeled and the preparation **recorded** to identify substance, strength, solvent (where not water), any special precautions or hazards, restrictions of use, and date of preparation and/or expiration?			
AOAC International Guidelines	Is the person responsible for the preparation of the reagent shall be traceable through the information on both the label and in the records?			
AOAC International Guidelines"	Does the requirement for an audit trail in laboratory records apply to:			
	a) sample receipt (check-in)?			
	b) sample preparation?			
	c) sample handling and storage?			
	d) sample analysis?			
	e) equipment qualification and maintenance?			
	f) equipment performance - (e.g. using CRMs, proficiency checks and daily checks)?			
	g) calibration records with traceability to CRMs?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	h) traceability to each analyst performing steps in the testing process?			
	i) analyst training with traceability to RMs and proficiency checks?			
	j) results?			
	k) reviews?			
	l) reports (mailed reports, faxes)?			
	m) review - electronic transmissions (e.g. LIMS acquisitions)?			
	n) proficiency test results			
AOAC International Guidelines	If a method allows multiple testing options does the laboratory record document which option was followed?			
AOAC International Guidelines	Is the option selected recorded in a way to include the information in a laboratory work instruction or on a space on a form or LIMS entry?			
AOAC International Guidelines	Note: The independent system to collect the data can vary from manually recording the times to using electronic recording of the time such as HPLC electronic files, printouts or chart recordings. Also, for systems that are automatically controlled, it may be adequate to periodically verify the automatic control. However, if the verification fails, all runs since the most recent successful verification are suspect. An example of such an automatic control is an autclave.			
4.13.2.2	Are observations, data and calculations recorded at the time they are made? Are they identifiable to the specific task?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
4.13.2.3	When mistakes occur in records, is each mistake crossed out, not erased, made illegible or deleted, and the correct value entered alongside? Are all such alterations to records signed or initialed by the person making the correction? In the case of electronic records, are equivalent measures taken to avoid loss or change of original data?			
AOAC International Guidelines	Do all alterations to records shall also include the date(s) of the change?			
4.14 Internal Audits				
4.14.1	Does the laboratory periodically, in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this standard? NOTE: The cycle for internal auditing should normally be completed in one year.			
4.14.1	Does the internal audit program address all elements of the management system, including the testing and/or calibration activities?			
4.14.1	Is it the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management? Are such audits performed by trained personnel who are, wherever resources permit, independent of the activity to be audited?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
AOAC International Guidelines	Do Internal audit programs include both horizontal and vertical investigation? Horizontal audits examine a particular management system requirement, activity or process in detail, e.g. across multiple samples, persons, equipment, etc. Vertical audits trace a single sample through all aspects of handling, e.g. from sample receipt to data reporting.			
4.14.2	When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, does the laboratory take timely corrective action? Does the laboratory notify customers in writing if investigations show that the laboratory results may have been affected?			
4.14.3	Are the following recorded: - area of activity audited? - audit findings? - corrective actions that arise?			
4.14.4	Do follow-up audit activities verify and record the implementation and effectiveness of the corrective action taken?			
4.15 Management Reviews				
4.15.1	In accordance with a predetermined schedule and procedure, does the laboratory's top management periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements?			
4.15.1	Does the review take account of: - the suitability of policies and			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	procedures? - reports from managerial and supervisory personnel? - the outcome of recent internal audits? - corrective and preventive actions? - assessments by external bodies? - the results of inter-laboratory comparisons or proficiency tests? - changes in the volume and type of work? - customer feedback? - complaints? - recommendations for improvement? - other relevant factors, such as quality control activities, resources and staff training? NOTE: A typical period for MR is once every 12 months.			
AOAC International Guidelines	Do the records for management review identify the top management responsible for and conducting the management review process?			
4.15.2	Are findings from management reviews and ensuing actions recorded? Does management ensure that those actions are carried out within an appropriate and agreed timescale?			
TECHNICAL REQUIREMENTS				
5.1 General				
5.1.1	Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include: - human factors - accommodation and environmental conditions - test and calibration methods and method			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	validation - equipment - measurement traceability - sampling - handling of test and calibration items			
5.1.2	The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and calibrations. Does the laboratory take account of these factors in developing: - test and calibration methods and procedures? - training and qualification of personnel? - selection and calibration of the equipment it uses?			
5.2	**Personnel (Not required for surveillance unless critical changes have occurred)**			
AOAC International Guidelines	Do training records include verification of the effectiveness of the training action and an evaluation?			
APLAC TC007	When undertaking contract review and selecting methods, do personnel understand the nature of the foods they are testing, and the purposes for the testing?			
5.2.1	Does the laboratory management ensure the competence of all who: - operate specific equipment? - perform tests and/or calibrations? - evaluate results? - sign test reports and calibration certificates?			
5.2.1	NOTE: The personnel responsible for the opinions and interpretation in test reports should, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing, also have relevant knowledge of the technology used for			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service; knowledge of the general requirements expressed in the legislation and standards; understanding of the significance of deviations found with regard to the normal use of the items concerned.			
5.2.1	When using staff undergoing training, is appropriate supervision provided?			
5.2.1	Are those personnel performing specific tasks qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required?			
AOAC International Guidelines	Does the laboratory have procedures for defining the initial and ongoing competency of all personnel?.			
AOAC International Guidelines	Is there evidence that personnel have demonstrated their competency prior to working on customer samples?			
AOAC International Guidelines	Whenever a trainee is performing tasks on customer samples, is the trainee under the supervision of a trained analyst and does the trained analyst takes responsibility for these tasks?			
AOAC International Guidelines	Does the laboratory ensure that the trainee performing the tasks does not impact the analysis?			
AOAC International Guidelines	Is data demonstrating the initial and ongoing competency of all personnel retained along with the training records?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
AOAC International Guidelines	Is a review of the completeness of training records, ongoing analytical performance (i.e., control charts, etc.) and training requirements shall be performed periodically?			
AOAC International Guidelines	At that time, is the need for re-verification assessed and, if needed, is a re-verification performed and recorded?			
AOAC International Guidelines	Are personnel working in teams or work groups qualified as a team or work group, and are records of competency for the team placed in the individual personnel's training records?			
AOAC International Guidelines	Does each person engaged in the process have training and experience that is appropriate to their assigned functions?			
AOAC International Guidelines	Are sufficient supervisory resources available to ensure appropriate supervision and oversight of all personnel?			
AOAC International Guidelines	Is the number of personnel reporting to supervisors and managers established based on the complexity and diversity of the testing work within the organization?			
5.2.2	Does the laboratory management formulate the goals with respect to the education, training and skills of the laboratory personnel?			
5.2.2	Does the laboratory have a policy and procedures for identifying training needs and providing training of personnel?			
5.2.2.	Is the training program relevant to the laboratory's present and anticipated tasks?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.2.2	Is the effectiveness of the training actions taken evaluated?			
AOAC International Guidelines	Does the laboratory management retain records that demonstrate that each individual has the required knowledge, skills and abilities to adequately perform their assigned tasks?			
AOAC International Guidelines	Is there evidence of annual training of all personnel operating under this document in their roles and responsibilities in the quality system and in its proper maintenance?			
5.2.3	Does the laboratory use personnel who are employed by, or under contract to, the laboratory? Where contracted and additional technical and key support personnel are used, does the laboratory ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's management system?			
5.2.4	Does the laboratory maintain current job descriptions for the following types of personnel involved in tests and/or calibrations: - managerial? - technical? - key support? NOTE: Job descriptions, as a minimum, should define: - responsibilities for performing tests/calibrations - responsibilities for planning and evaluation of results of tests/calibrations - responsibilities for reporting interpretations			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	- responsibilities for method modifications and development and validation of new methods - expertise/experience required - qualifications/training programs - managerial duties			
5.2.5	Does the management authorize specific personnel to: - perform particular types of sampling, test and/or calibration? - to issue test reports and calibration certificates? - to give opinions and interpretations? - to operate particular types of equipment?			
5.2.5	Does the laboratory maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel? Is this information readily available? Does it include the date on which authorization and/or competence was confirmed?			
5.3	**Accommodation and Environmental Conditions**			
5.3.1	Are laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, such as to facilitate correct performance of the tests and/or calibrations?			
5.3.1	Does the laboratory ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement?			
5.3.1	Is particular care taken when sampling and tests and/or calibrations are undertaken at sites other than a			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	permanent laboratory facility?			
5.3.1	Are the technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations documented?			
APLAC TC007	Were the Codex guidelines for the design of a food testing laboratory and other regulations and Standards consulted?			
5.3.2	Does the laboratory: - monitor? - control? - and record? environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of results?			
5.3.2	Is due attention paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound/vibration levels, as appropriate to the technical activities concerned?			
5.3.2	Are tests and calibrations stopped when the environmental conditions jeopardize the results of tests and/or calibrations?			
AOAC International Guidelines	Are environmental monitoring requirements planned and results recorded?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
AOAC International Guidelines	Is the monitoring consistent with the industry standard for the field of testing on the scope of accreditation?			
AOAC International Guidelines	Does the environmental monitoring meet the requirements of the test methods listed on the scope of the accreditation?			
AOAC International Guidelines	Does the monitoring include the requirements necessary to operate instrumentation properly? Examples of microbiological monitoring are laboratory swabbing, hand swabbing, air plates, water testing, and polymerase chain reaction (PCR) amplicon swabbing. Examples of chemistry monitoring are instrument room temperatures and water testing.			
AOAC International Guidelines	Does the grade of any reagent or reference material used (including water) that affects the quality of tests stated in the method together with guidance on any particular precautions that should be observed in its preparation or use documented?			
AOAC International Guidelines	Are samples, reagents, measurement standards and reference materials used, stored so as to ensure their integrity?			
AOAC International Guidelines	Has the laboratory the grade of the laboratory water to ensure the water is fit for that use?			
5.3.3	Is there effective separation between neighboring areas in which there are incompatible activities? Are measures taken to prevent cross-contamination?			
AOAC	When selecting designated areas for			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
International Guidelines	special work, has the previous use of the area been taken into account?			
AOAC International Guidelines	Before use, has the area been confirmed it is ready for use?			
AOAC International Guidelines	Once in use, is access to such areas restricted, as needed, and the type of work undertaken there carefully controlled?			
5.3.4	Are access to and use of areas affecting the quality of the tests and/or calibrations controlled? Has the laboratory determined the extent of control based on its particular circumstances?			
AOAC International Guidelines	If it is necessary to restrict access to particular areas of the laboratory because of the natures of the work carried out there, and where such restrictions are in force, have the staff been **appropriately trained on the**:			
	• intended use of the particular area?			
	• the restrictions imposed on working within such areas?			
	• the reasons for imposing such restrictions?			
	• procedures to follow when such restrictions are breached?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
APLAC TC007	When entry into laboratory areas is restricted, as appropriate, have the staff been made aware of the intended use of the areas and the restrictions imposed when working within such areas?			
5.3.5	Are measures taken to ensure good housekeeping in the laboratory? Are special procedures prepared where necessary?			
AOAC International Guidelines AOAC International Guidelines	For pharmaceutical laboratories, are cleaning and sanitization schedules established by the laboratory for laboratory areas (benches, floors, etc.) and for laboratory equipment (incubators, water baths, centrifuges, refrigerators, freezers, etc.)? Are sanitization records of key areas and equipment available?			
AOAC International Guidelines	For microbiological testing, in cases where sterile supplies are necessary, are the supplies purchased as sterile or sterilized in the laboratory (e.g., gloves, pipettes, pipette tips, petri dishes, tongs, etc.)? If the laboratory sterilizes the item, are records maintain and has the item been maintained in a sterile condition / environment.			
5.4 Test and Calibration Methods and Method Validation				

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.4.1	Does the laboratory use appropriate methods and procedures for all tests and/or calibrations within its scope? These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.			
5.4.1	Does the laboratory have instructions on the operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration where the absence of such instructions could jeopardize the results of tests and/or calibration?			
5.4.1	Are all instructions, standards, manuals and reference data relevant to the laboratory's work kept up to date and made available to personnel?			
5.4.1	Does deviation from test and calibration methods occur ONLY if the deviation has been: - documented? - technically justified? - authorized? - accepted by the customer?			
AAFCO Quality Assurance / Quality Control Guidelines For Feed Laboratories supplement to ISO/IEC 17025:2005	Are analytical methods evaluated based on attributes such as accuracy, precision, specificity, sensitivity, detectability and practicality? Compromise between attributes is inherent in the selection of methods. However, is any method selected for use appropriate to the requirements of the regulatory function and within the capabilities of the laboratory staff (fit for purpose)?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	Depending on the documentation available on a method, has method verification or validation been completed before it is adopted for routine use?			
AOAC International Guidelines	Are reagents, reagent solutions, and sample solutions not being used past their expiry date without verification that they are still suitable for use?			
	Is the water used in the laboratory fit for intended use and are there documents that state specifications for water, such as USP, EP and the Standard Methods for the Examination of Water and Waste Water (SMEWW)?			
AOAC International Guidelines	Has the laboratory defined the use of the water and to ensure the water is fit for that use (AOAC)?			
5.4.2	Does the laboratory use test and/or calibration methods, including methods for sampling, which meet the needs of the customer? Are these methods appropriate for the tests and/or calibrations they undertake?			
5.4.2	Are methods published in international, regional or national standards preferably used? Does the laboratory ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so? Is the standard supplemented with additional details to ensure consistent application?			
5.4.2	When the customer does not specify the method, does the laboratory select			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	appropriate methods that have been published either in international, national standards, by technical organizations, in relevant scientific texts or journals, or as specified by the manufacturers of the equipment? If the above does not apply, are the laboratory-developed methods or methods adopted by the laboratory appropriate for the intended use and validated?			
5.4.2	Is the customer informed as to the method chosen?			
5.4.2	Is the laboratory able to confirm that it can properly operate standard methods before introducing the tests or calibrations? If the standard method changes, is the confirmation repeated?			
AAFCO Quality Assurance / Quality Control Guidelines For Feed Laboratories supplement to ISO/IEC 17025:2005	These include, but are not limited to, methods that have been collaboratively studied, approved and published by AOAC, AOCS, or ISO, as well as compendium methods published by USDA, FDA, EPA, AVVVVA, US-CFR and USP with a scope applicable to the intended use. When a laboratory chooses a standard or official method for use, something is already known about the method's performance in other laboratories, but it is necessary to establish and document the method's performance in-house. Laboratories should verify their own ability to achieve satisfactory performance of the method before any customer samples are analyzed. The type of method and its intended regulatory use will influence the details of the			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	in-house verification. At a minimum, representative matrices and concentration ranges shall be included in the in-house verification.			
5.4.2	Does the laboratory inform the customer when the method proposed by the customer is considered inappropriate or out of date?			
APLAC TC007	Where regulatory authorities prescribe methods to be used for testing under their regulations, does the laboratory ensure that the requisite method is used?			
APLAC TC007	Is the Codex Alimentarius Harmonization of Food Standards, used as acceptable reference for sources of test methods when they are not specified by regulation or by the customer?			
AOAC International Guidelines	Are matrix and analyte matched Certified Reference Materials, when available, used to determine any systematic method bias?			
AOAC International Guidelines	Where this is not possible, has method bias been determined by using other techniques, preferably based on different principals of analysis?			
AOAC International Guidelines	Are all laboratory-developed or non-standard methods fully documented including validation data, limitations of applicability, procedures for quality control, and calibration?			
AOAC International Guidelines	Has a determination of measurement uncertainty been performed as part of the validation process?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
AOAC International Guidelines	Has the laboratory confirmed that it can properly perform standard methods ***before*** these are used in routine testing? Note: e.g. it is not appropriate for the laboratory to run concurrent controls and/or reference materials in order to qualify their competence to perform the method at same time they are running the sample, rather the laboratory must be able to properly prove the method is fit for purpose beforehand.			
AOAC International Guidelines	Where no method is specified, has the laboratory chosen an appropriate method?			
AOAC International Guidelines	Has the laboratory recorded [the name of] the laboratory representative who authorized adoption of the method and the date this authorization was granted?			
AOAC International Guidelines	Adjustments to maintain system suitability specifications that do not alter the fundamental nature of the method may be made without validation. Are modifications of methods that alter the fundamental nature of the method validated to demonstrate that equivalent results are obtained and that the method is suitable for its intended use?			
5.4.3	Is the introduction of test and calibration methods developed by the laboratory for its own use a planned activity? Is the introduction assigned to qualified personnel equipped with adequate resources?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.4.3 5.4.3	Are plans updated as development proceeds? Is effective communication amongst all personnel involved ensured?			
5.4.4	When it is necessary to use methods not covered by standard methods, are these subject to agreement with the customer? Do they include a clear specification of the customer's requirements and the purpose of the test and/or calibration? Had the method developed been validated appropriately before use?			
5.4.4	NOTE: For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following:			
5.4.4	a) appropriate identification b) scope c) description of item being tested/cal. d) parameters or quantities/ranges to be determined e) apparatus and equipment, including technical performance requirements f) reference standards/materials req. g) environmental conditions required and stabilization period needed h) description of procedure, including: - affixing of identification marks, handling, transporting, storing and prep. of items - checks to be made before work starts - checks that equipment is working properly, and where required,			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	calibration and adjustment of equipment before use - method of recording observations and results - any safety measures observed i) criteria and/or req. for approval/rejection j) data to be recorded and method of analysis and presentation k) uncertainty or procedure for estimating uncertainty			
APLAC TC007	Does the laboratory use standard methods to ensure comparability of results?			
APLAC TC007	When laboratory-developed methods used, are matrix interferences considered?			
APLAC TC007	Are laboratory-developed test methods validated either by using a matched matrix reference material or, if it is not available, a sample spiked with the analytes of interest? (recommended)			
5.4.5.1	Does the laboratory follow the definition of validation as the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled?			
5.4.5.2	Does the laboratory validate the following to confirm that the methods are fit for the intended use? - non-standard methods - lab-designed/developed methods - standard methods used outside their intended scope - amplifications/modifications of standard methods			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.4.5.2	NOTE: The techniques used for determination of performance of a method should be one of, or a combination of, the following: - calibration using reference standards or materials - comparison of results achieved with other methods - inter-laboratory comparisons - systematic assessment of the factors influencing the result - assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience			
5.4.5.2	Is the validation as extensive as is necessary to meet the needs of the given application or field of application? NOTE: When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should occur.			
5.4.5.2	Does the laboratory record: - the results obtained? - the procedure used for the validation? - a statement as to whether the method is fit for the intended use?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
AOAC International Guidelines	*Note:* There are many documents that provide guidance for method verifications and validations such as, "AOAC Reference Guidelines for Validation of Qualitative Binary Chemical Methods," "AOAC Reference Guidelines for Validation of Microbiology Methods for Food and Environmental Surfaces," RTPAC "Guidelines for Single-Laboratory Validation of Methods of Analysis," and "Definitions and Calculations of HorRat Values from Intralaboratory Data."			
AOAC International Guidelines AOAC International Guidelines	*Note:* The AOAC Food Triangle, along with the applicable National Institute of Standards and Technology Standard Reference Materials (NIST SRMs) is a useful tool for food when determining how many different food matrices should be part of the validation or how to select representative matrices when expanding the scope of an existing method. There are limitations in the assumptions inherent in the triangle (e.g., a method for shellfish toxins in oysters does not necessarily work well for scallops and the Food Triangle would not show this).			
5.4.5.3	Are the range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object) as assessed for the intended use, relevant to the customers' needs?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.4.5.3	NOTE: Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method and a statement on the validity. As method-development proceeds, regular review should be carried out to verify that the customer's needs are still being met. Any change in requirements requiring modifications to the development plan should be approved and authorized.			
AOAC International Guidelines	*Note:* Accuracy can be established by analyzing a suitable Reference Material. It is preferable to work with well characterized, homogenized, and stable materials such as NIST SRMs or proficiency test samples; however, an estimation of accuracy can be obtained by spiking test portions. The value of spiking is limited, as it can only be used to determine the accuracy of those stages of the method following the spiking. Accuracy can also be established by comparison with results obtained by a definitive method or other alternative procedures and via interlaboratory comparison studies.			
APLAC TC007	Does the laboratory use for estimation of measurement uncertainty, make reference to ISO 21748:2010, *Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation*?			
APLAC TC007	Often for food testing, overall intermediate precision or inter-laboratory precision will include most, if not all, major sources of uncertainty. Does the laboratory investigate other factors when estimating measurement			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	uncertainty?			
5.4.6.1	Does the calibration laboratory, or a testing laboratory performing its own calibrations, have a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations? Is the procedure applied?			
5.4.6.2	Does the testing laboratory have procedures for estimating uncertainty of measurement? Are these procedures applied?			
5.4.6.2	In certain cases, the nature of the test method may preclude rigorous, metrologically and statistically valid calculation of uncertainty of measurement. In these cases, does the laboratory at least attempt to identify all the components of uncertainty and make a reasonable estimation?			
5.4.6.2	Does the laboratory ensure that the form of reporting of the result does not give a wrong impression of the uncertainty?			
5.4.6.2	Is reasonable estimation based on knowledge of the performance of the method and on the measurement scope?			
5.4.6.2	Does the reasonable estimation make use of, for example, previous experience and validation data?			
5.4.6.2	NOTE: In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the lab is considered to have satisfied this clause by following the test method and reporting instructions.			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
APLAC TC007	Every measurement has an uncertainty associated with it, resulting from ***some*** of the following sources: a) sampling and sub-sampling; lack of sample homogeneity; b) extraction; digestion; sample preparation; c) inherent instability of reference standards and reference materials; d) calibration of equipment and instruments; e) variation of environmental and supply conditions; f) operator variation; g) bias, if not corrected.			
5.4.6.3	When estimating the uncertainty of measurement, are all elements in the uncertainty budget appropriate methods of analysis included in the calculation? NOTE: The predicted long-term behavior of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty.			
AOAC International Guidelines	Uncertainty of measurement can be estimated using quality control data, such as the analysis of reference materials. The standard deviation of data points is multiplied by the uncertainty coverage factor, k, obtained from the Student t-tables. At least 20 data points should be used, though it can be calculated using fewer points, as long as the appropriate coverage factor is used. If using this approach, has the laboratory demonstrated that all uncertainty components of importance in this given situation been taken into account? Sampling may not be a component in the uncertainty estimated from the analysis of reference materials used in			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	validation or verification. Method validation data, if available and appropriate, may be used to estimate uncertainty of measurement. If the test method is a collaboratively studied method, the reproducibility standard deviation may be used to estimate the uncertainty.			
AOAC International Guidelines	Does the laboratory understand what are the sources of the major factors of uncertainty and provide appropriate control of all such factors? See the *Eurachem/ CITAC Guide on Quantifying Uncertainty in Analytical Measurement*.			
5.4.7.1	Are calculations and data transfers subject to appropriate checks in a systematic manner?			
5.4.7.2	When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, does the laboratory ensure that (a-c): a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use? NOTE: Commercial off-the-shelf software is sufficiently validated. However, lab software configuration or modifications should be validated as in 5.4.7.2a.			
5.4.7.2	b) for protecting the data, procedures are: - established? - implemented?			
5.4.7.2	Do such procedures include, but are not limited to: - integrity and confidentiality of data entry or collection?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	- data storage? - data transmission? - data processing?			
5.4.7.2	c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data?			
5.5 Equipment				
5.5.1	Is the laboratory furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data)?			
5.5.1	In those cases where the laboratory needs to use equipment outside its permanent control, does it ensure that the requirements of this standard are met?			
5.5.2	Is equipment and its software used for testing, calibration and sampling capable of achieving the accuracy required? Does it comply with specifications relevant to the tests and/or calibrations concerned?			
5.5.2	Have calibration programs been established for key quantities or values of the instruments where these properties have a significant effect on the results?			
5.5.2	Before being placed into service, is			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	equipment (including that used for sampling) calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications? Is it checked and/or calibrated before use?			
AOAC International Guidelines	Does the laboratory have in place a program for the calibration and verification of equipment per requirements in Appendix A?			
AOAC International Guidelines	Does the laboratory have a written program for the regular maintenance (including cleaning, and if necessary, sanitizing) of its equipment per recommendation by manufacturer or per laboratory SOPs, and a written procedure for recording all calibrations, verifications and maintenance performed?			
5.5.3	Is the equipment operated by authorized personnel?			
5.5.3	Are current instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer) readily available for use by the appropriate laboratory personnel?			
5.5.4	Is each item of equipment and its software used for testing and calibration and significant to the result, when practicable, uniquely identified?			
5.5.5	Are records of each item of equipment and its software significant to the tests and/or calibrations performed maintained?			
5.5.5	Do the records include at least the following (a-h): a) the identity of the item of			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	equipment and its software?			
5.5.5	b) the manufacturer's name, type identification, and serial number or other unique identification?			
5.5.5	c) checks that equipment complies with the specification?			
5.5.5	d) the current location, where appropriate?			
5.5.5	e) the manufacturer's instructions, if available, or reference to their location?			
5.5.5	f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria and the due date of next calibration?			
5.5.5	g) the maintenance plan, where appropriate, and maintenance carried out to date?			
5.5.5	h) any damage, malfunction, modification or repair to the equipment?			
5.5.6	Does the laboratory have procedures covering the following to ensure proper functioning and in order to prevent contamination or deterioration: - safe handling? - transport? - storage? - use and planned maintenance of measuring equipment?			
5.5.7	Is equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits taken out of service?			
5.5.7	Is it isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.5.7	Does the laboratory examine the effect of the defect or departure from specified limits on previous tests and/or calibrations? Does the lab institute the "Control of Nonconforming Work" procedure?			
5.5.8	Whenever practicable, is all equipment under the control of the laboratory and requiring calibration labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when re-calibration is due?			
5.5.9	When, for whatever reason, equipment goes outside the direct control of the laboratory, does the laboratory ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service?			
5.5.10	When intermediate checks are needed to maintain confidence in the calibration status of the equipment, are these checks carried out according to a defined procedure?			
5.5.11	Where calibrations give rise to a set of correction factors, does the laboratory have procedures to ensure that copies (e.g. in computer software) are correctly updated?			
5.5.12	Is test and calibration equipment, including both hardware and software, safeguarded from adjustments that would invalidate the test and/or calibration results?			
5.6 Measurement Traceability				
Note: Must include evidence of traceability for all aspects of 5.6				
AOAC International Guidelines	If the calibration of instruments used in testing contributes significantly to the overall uncertainty of the measurement result the requirements			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	of traceability to the International System of units should be met. Is the laboratory taking this into account when calculating Measurement Uncertainty? If the equipment or instrument does not contribute significantly to the overall uncertainty, demonstrated by calculation of a full uncertainty budget, the traceability to the SI may not be required.			
AOAC International Guidelines	Depending on regulations, the frequency of verifications or calibrations may need to be increased; in these cases, has the laboratories always follow the most stringent requirements to remain in compliance with their specific programs?			
5.6.1	Is all equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling calibrated before being put into service? Does the laboratory have an established program and procedure for the calibration of its equipment?			
5.6.2.1.1	For calibration laboratories, is the program for calibration of equipment designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI)?			
5.6.2.1.1	Does a calibration laboratory establish traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI measurement units?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.6.2.1.1	Is the link to SI units achieved by reference to national measurement standards?			
5.6.2.1.1	Are the national measurement standards primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or; Are they secondary standards (standards calibrated by another national metrology institute)?			
5.6.2.1.1	When using external calibration services, is traceability of measurement assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability?			
5.6.2.1.1	Do the calibration certificates issued by these laboratories contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification?			
5.6.2.1.2	There are certain calibrations that currently cannot be strictly made in SI units. In these cases, does calibration provide confidence in measurements by establishing traceability to appropriate measurement standards such as: - the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material? - the use of specified methods and/or consensus standards that are clearly described and agreed by all parties			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	concerned?			
5.6.2.1.2	Does the laboratory participate in a suitable program of proficiency testing? **(Assessor must provide copies of PT reports in package.)**			
APLAC TC007	Most food testing methods are empirical (the result depends on the defined method) and therefore traceability is to the consensus result for that method and matrix. Are even minor deviations from the detail of a standard method validated for all practices to which the method is to be applied and for all matrices, to confirm that the results are the same as those obtained from defined standard methods?			
5.6.2.2.1	For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result.			
5.6.2.2.1	When the above situation arises, does the laboratory ensure that the equipment used can provide the uncertainty of measurement			
5.6.2.2.2	Where traceability of measurements to SI units is not possible and/or not relevant, does the calibration laboratory follow the same requirements for traceability to, for example, certified reference materials, and agreed methods and/or consensus standards?			
5.6.3.1	Does the laboratory have a program and procedure for the calibration of its reference standards?			
5.6.3.1	Are reference standards calibrated by a body that can provide traceability as			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	described in 5.6.2.1?			
5.6.3.1	Are such reference standards of measurement held by the laboratory used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated?			
5.6.3.1	Are reference standards calibrated before and after any adjustment?			
AOAC International Guidelines	Is the documentation accompanying the reference standard stored in the laboratory's record management system?			
AOAC International Guidelines	Are reference standard used past their expiry date without verification that they are still suitable for use?			
5.6.3.2	Are reference materials, where possible, traceable to SI units of measurement, or to certified reference materials?			
5.6.3.2	Are internal reference materials checked as far as is technically and economically practicable?			
AOAC International Guidelines	Are all Reference Materials labeled using an identification scheme that allows the laboratory to trace the lot of chemical Reference Material used in any analysis?			
AOAC International Guidelines	In addition, is each chemical reference material labeled with the date received and expiration date?			
AOAC International Guidelines	Upon receipt of the chemical Reference Material, are records kept to include chemical name or description, manufacturer's lot number, assigned laboratory number, date received, manufacturer's expiration date if available, or laboratory determined			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	expiration date , and traceability to the person assuming responsibility for the chemical Reference Material?			
AOAC International Guidelines	Are Reference Materials used past their expiry date without verification that they are still suitable for use?			
	If possible, Are Reference Materials obtained from Reference Material producers accredited to ISO Guide 34, "General requirements for the competence of reference material producers "?			
APLAC TC007	Pure substance reference materials should be used whenever possible to demonstrate traceability of instrument calibration. Does the laboratory document and characterize reference materials which, in some disciplines are currently synthesized or available from limited sources such as pharmaceutical companies and research and development laboratories?			
5.6.3.3	Are checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials carried out according to defined procedures and schedules?			
5.6.3.4	Does the laboratory have procedures for safe handling, transport, storage and use of reference standards and materials in order to prevent contamination or deterioration and in order to protect their integrity?			
5.7 Sampling				
AOAC International Guidelines	In cases where the laboratory is required to conduct field sampling of products, are they complying with established procedures for those programs (for example, the Meat			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	Importers Council of America sampling plan for fat testing) and these requirements?			
AOAC International Guidelines	Does the laboratory have a documented procedures for sub-sampling and/or homogenization to ensure that a representative test portion is used for analysis?			
5.7.1	Does the laboratory have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration?			
AOAC International Guidelines	Note: See *CITAC/EURACHEM Guide to Quality in Analytical Chemistry: An Aid to Accreditation (2002)* for sampling records, legal purposes/seals, multi-phase and labile samples, aseptic handling, cross-contamination, other heterogeneity, etc.			
AAFCO Quality Assurance / Quality Control Guidelines For Feed Laboratories supplement to ISO/IEC 17025:2005	The laboratory shall ensure that sample integrity and representativeness is maintained for all processes under their control. Feed laboratories are, in many instances, not responsible for field sampling. As such, sampling considerations begin for the laboratory upon receipt of the laboratory sample.			
	When the laboratory is also the sampling entity, the laboratory shall have in place sampling plan(s) and sampling procedures that define the types of samples collected, sampling equipment and the process(es). Sample collection procedures used by the laboratory shall be based on appropriate scientific/statistical principles. Properly trained field staff should collect, document, preserve and ship samples using established			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	guidelines.			
	The laboratory shall have documented procedures for sub-sampling and preparation to ensure that representative test portions are used for analyses. The laboratory shall have written procedures dealing with the preparation of analytical samples covering the range of sample types and analytical tests. The Laboratory sampling procedure(s) shall document the process to be used for reception, identification, processing (e.g. grinding, mixing), sub-sampling (if applicable), storage and disposal of feed samples received at the laboratory.			
5.7.1	Is the sampling plan available at the location where sampling is undertaken? Is the sampling procedure available at the location where sampling is undertaken?			
5.7.1	Are sampling plans, whenever reasonable, based on appropriate statistical methods?			
5.7.1	Does the sampling process address the factors to be controlled to ensure the validity of the test and calibration results?			
APLAC TC007	Does the laboratory provide to those submitting samples information regarding sample collection and handling in the field, and do they provide special sample containers to customers?			
APLAC TC007	Are published standards for sampling plans available from regulatory authorities and Codex? Perishable product or with the possibility of cross contamination.			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
APLAC TC007	Does the laboratory provide information on preserving sample integrity and preventing contamination, especially when dealing with a perishable product or the possibility of cross contamination?			
APLAC TC007	Does the laboratory where the report is used to "certify" results for a food shipment, is valid statistical sampling required and is a component for sampling variation included in the measurement uncertainty estimate?			
5.7.2	Where the customer requires deviations, additions or exclusions from the documented sampling procedure, are these recorded in detail with the appropriate sampling data? Are these included in all documents containing test and/or calibration results? Are these communicated to the appropriate personnel?			
5.7.3	Does the laboratory have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration done?			
5.7.3	Do these records include: - the sampling procedure used? - the identification of the sampler? - environmental conditions (if relevant)? - diagrams or other equivalent means to identify the sampling locations as necessary? - if appropriate, the statistics the sampling procedures are based upon?			
5.8	**Handling of Test and Calibration Items**			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.8.1	Does the laboratory have procedures for the following regarding test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and customer: - transportation? - receipt? - handling? - protection? - storage? - retention and/or disposal?			
AOAC International Guidelines	Are storage areas kept clean and organized so there is minimized risk of contamination or cross-contamination?			
AOAC International Guidelines	Are the samples stored in such a way that the packaging, and/or any related seals are not damaged?			
AOAC International Guidelines	Are adverse extremes of environmental conditions avoided?			
AOAC International Guidelines	If necessary is environmental monitoring being used to monitor conditions?			
AOAC International Guidelines	Is an appropriate level of security being exercised to restrict unauthorized access to the samples?			
APLAC TC007	It is critical that food testing laboratories preserve sample integrity and avoid contamination and deterioration of the samples. Does the Laboratory have procedures for the storage of perishable foods to prevent deterioration?			
APLAC TC007	Does the Laboratory have a process to prioritize the analysis for unstable parameters that need to be done upon			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	receipt?			
APLAC TC007	Does the laboratory have record of the Chain of custody regulatory samples?			
5.8.2	Does the laboratory have a system for identifying test and/or calibration items?			
5.8.2	Is the identification retained throughout the life of the item in the laboratory?			
5.8.2	Is the system designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents? Does the system, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory?			
AOAC International Guidelines	Is labeling firmly attached to all of the sample portions packaging and where appropriate, resistant to fading, autoclaving, sample or reagent spillage, and reasonable extremes of temperature and humidity?			
AOAC International Guidelines	If bar-coded labels are used, do they conform to the requirements listed above?			
5.8.3	Upon receipt of the test or calibration item, are abnormalities or departures from normal or specified conditions, as described in the test or calibration method, recorded?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.8.3	When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, does the laboratory consult the customer for further instructions before proceeding? Is the discussion recorded?			
5.8.4	Does the laboratory have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation?			
5.8.4	Are handling instructions provided with the item followed?			
5.8.4	When items have to be stored or conditioned under specified environmental conditions, are these conditions maintained, monitored and recorded?			
5.8.4	Where at test or calibration item or a portion of an item is to be held secure, does the laboratory have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned?			
AOAC International Guidelines	Are all staff associated with administration of the sample handling system properly trained on these procedures?			
AOAC International Guidelines "April 2015"	Are minimum sample retention periods and storage conditions documented in the management system and communicated to customers so that all parties are aware of how long the sample will be available for retesting or retrieval?			
5.9 Assuring the Quality of Test and Calibration Results				

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.9.1	Does the laboratory have quality control procedures for monitoring the validity of tests and calibrations undertaken?			
5.9.1	Is the resulting data recorded in such a way that trends are detectable, and where practicable, statistical techniques applied to the reviewing of the results? Is this monitoring planned and reviewed?			
5.9.1	Does this monitoring include, (but is not limited to) (a-e): a) regular use of certified reference materials and/or internal quality control using secondary reference materials?			
5.9.1	b) participation in inter-laboratory comparison or proficiency-testing programs? *Assessor must show evidence that this is taking place.*			
5.9.1	c) replicate tests or calibrations using the same or different methods?			
5.9.1	d) retesting or recalibration of retained items?			
5.9.1	e) correlation of results for different characteristics of an item?			
Quality Control Samples				
AOAC International Guidelines	Are quality control procedures in place for both quantitative and qualitative methods?			
	Do these procedures include the use of quality control samples (QCS), with each batch of samples in order to demonstrate that the test worked properly?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	Has the laboratory defined and justified what constitutes a batch of samples?			
	Does the laboratory use quality control samples (QCS) that can includes CRMs/RMs, replicate analyses, positive/negative control samples, laboratory control samples, blanks, and matrix spikes?			
AOAC International Guidelines	When testing for pathogens or select agents, does the Laboratory use a quality control sample that contains a surrogate analyte?			
	Has the laboratory determined for itself the maximum number of samples that can be analyzed in one batch, or run contiguously between QCSs?			
	Has the laboratories defined the term it used define "batches" or "lots."? Any term is acceptable; but, the laboratory must define the term unambiguously.			
	Analysis of a Certified Reference Material is the best measure of method accuracy; however; for some analytical sectors there may not be a Certified Reference Material. If this is the case, the laboratory must determine an appropriate RM or secondary RM that can provide a measure of accuracy. Has the laboratory performed accuracy and precision for the methods it uses?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	[A CRM may be available, but may be so scarce or expensive that it limits the ability of the laboratory to use the CRM routinely. In this case it might only be used to qualify secondary RMs.]			
AOAC International Guidelines	Has the laboratory defined the use of the CRM/RM's and the frequency with which it is used? In the absence of any CRM/RM, has the laboratory done its best to obtain a material with some limited consensus of accuracy (e.g. by subjecting material to multiple orthogonal methods in-house, sharing material with another laboratory(ies) to determine an average result, etc.)?			
	In cases where duplicate or replicate analyses do not yield useful data (e.g. where there are a high percentage of negative samples), does the laboratory have suitable procedures for estimating the precision?			
	Has the laboratory defined and justified its technique for assessing method precision?			
	Are appropriate statistical process control (SPC) techniques, such as SPC charts used to detect trends?			
	Are these charts reviewed on a regular basis to that ensure the laboratory is reporting reliable results?			
AAFCO Quality Assurance / Quality	Note: The laboratory is encouraged to participate in the AAFCO Check Sample Program because of its broad inclusion of analytes in feed matrices.			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
Control Guidelines For Feed Laboratories supplement to ISO/IEC 17025:2005				
APLAC TC007	Does the accredited laboratory participate in a minimum number of proficiency testing (PT) activities required by PJLA?.			
APLAC TC007	Do laboratory proficiency testing records include the following? - full details of the analyses or examinations undertaken, the results and conclusions drawn; - an indication that performance in the program has been reviewed; - details of the investigations and corrective action undertaken, where necessary.			
Proficiency Test Samples				
AOAC International Guidelines	Does the laboratory have a documented proficiency testing plan for all test methods on the scope of accreditation?			
	Is the proficiency testing performed following the normal working practices operated in the laboratory? They are not intended to represent individuals in the laboratory, unless this represents the normal mode of operation where only one person is involved in the analysis.			
	Are these proficiency samples rotated among qualified analysts?			
	When selecting an external scheme, did the laboratory consider using a scheme that is based on the requirements of ISO/IEC 17043:2010,			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	and, when available, one that is accredited to this standard?			
	For those tests/methods/techniques which are not covered by external schemes or if existing schemes are not suitable/feasible, the laboratory does the demonstrate competency for its entire scope, justifying its actions?			
Laboratory On-going Competency:				
AOAC International Guidelines	Does the laboratory participate in at least one PT event annually for each test, type of test/method, and/or technique on the scope of accreditation?			
Pre-accreditation				
AOAC International Guidelines "April 2015	Has the laboratory successfully analyzed proficiency testing samples for each test, type of test/method, and/or technique for which the laboratory wants to become accredited. When a relevant external PT program is not available, alternative means of evaluation may be used as described below.			
Competency by Alternative Means of Evaluation:				
AOAC International Guidelines	For those tests/methods and/or techniques which are not covered by relevant and available external PT schemes, has the laboratory demonstrated competency by an alternative means of evaluation, justifying its actions? **See PL-1 Proficiency Testing Requirements**			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.9.2	Is quality control data analyzed and, where it is found outside pre-defined criteria, planned action taken to correct the problem and to prevent incorrect results from being reported?			
Quality Control Sample Acceptability				
AOAC International Guidelines	Does the laboratory have procedures that define the acceptability of quality control samples?			
	Are laboratory's SPC data reviewed on a regular basis that ensures it is reporting reliable data?			
	Has the laboratory defined what constitutes a trend in the SPC data and investigate trends where necessary?			
	Is Corrective action initiated when controls do not meet the established acceptability criteria?			
AOAC International Guidelines	Is the laboratory's criteria balanced: avoiding unproductive corrective actions for statistically random events, yet not so broad as to ignore correctable, non-random errors?			
	Does the laboratory's criteria take into consideration the fact that for some multi-analyte 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?			
Proficiency Test Sample Acceptability				
AOAC International Guidelines	Does the laboratory evaluate PT results when they are received?			
	Does the laboratory use the PT provider's criteria to evaluate the results?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	If the PT provider does not issue acceptability criteria or the laboratory is performing proficiency testing by the alternative means, does the laboratory have procedures that define the acceptability of the results?			
5.10	**Reporting the Results**			
AOAC International Guidelines ”	Does the laboratory have procedures established to prevent the production of unauthorized reports or other documents?			
	Do these steps include the restriction of access to word processing packages and company letterhead to authorized people?			
	Are electronic records, electronic signatures, and handwritten signatures executed to electronic records equivalent to proper records and handwritten signatures executed to electronic records equivalent to proper records and handwritten signatures executed to paper?			
	Do electronic records and signatures meet the requirements of USA Title 21, Code of Federal Regulations Part 11?			
	Are the results of each test, calibration, or series of tests or calibrations carried out by the laboratory reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.10.1	Are the results reported, usually in a test report or calibration certificate? Does the report include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used? (This information is normally that required by 5.10.2 and 5.10.3 or 5.10.4.)			
5.10.1	In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, are the results reported in a simplified way?			
5.10.1	Is any information listed in 5.10.2 to 5.10.4, which is not reported to the customer, readily available in the laboratory that carried out the test and/or calibrations?			
5.10.1	Does each test or calibration certificate include at least the following information (a-k), unless the laboratory has valid reasons for not doing so:			
5.10.2	a title (e.g. “Test Report” or “Calibration Certificate”)?			
5.10.2	a) b) the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory?			
5.10.2	c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the report or certificate?			
5.10.2	d) the customer’s name and address?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.10.2	e) identification of the method used?			
5.10.2	f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated?			
5.10.2	g) the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration?			
5.10.2	h) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results?			
5.10.2	i) the test or calibration results with, where appropriate, the units of measurement?			
5.10.2	j) the name(s), function(s), and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate?			
5.10.2	k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated?			
5.10.2	NOTE: Hard copies of test reports and calibration certificates should also include the page number and total number of pages. Labs should include a statement specifying report/certificate shall not be reproduced except in full, without written approval by the laboratory.			
5.10.2	In addition to the requirements listed in 5.10.2, do test reports, where necessary, include the following (a-e):			
5.10.3.1	a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	conditions?			
5.10.3.1	b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications?			
5.10.3.1	c) where applicable, a statement on the estimated uncertainty of measurement? (information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit.)			
5.10.3.1	d) where appropriate and needed, opinions and interpretations?			
5.10.3.1	e) additional information that may be required by specific methods, customers, or groups of customers?			
5.10.3.1	In addition to the requirements listed in 5.10.2 and 5.10.3.1, do test reports containing the results of sampling include the following (a-f), where necessary, for the interpretation of test results:			
5.10.3.2	a) the date of sampling?			
5.10.3.2	b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate)?			
5.10.3.2	c) the location of sampling, including any diagrams, sketches or photographs?			
5.10.3.2	d) a reference to the sampling plan and procedures used?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
5.10.3.2	e) details of any environmental conditions during sampling that may affect the interpretation of the test results?			
5.10.3.2	f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concerned?			
5.10.3.2	In addition to the requirements listed in 5.10.2, do calibration certificates include the following (a-c), where necessary, for the interpretation of calibration results:			
5.10.4.1	a) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results?			
5.10.4.1	b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof?			
5.10.4.1	c) evidence that the measurements are traceable?			
5.10.4.1	Does the calibration certificate relate only to quantities and the results of functional tests?			
5.10.4.2	If a statement of compliance with a specification is made, does this identify which clauses of the specification are met or not met?			
5.10.4.2	When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, does the laboratory record those results and maintain them for possible future reference?			
5.10.4.2	When statements of compliance are made, is the uncertainty of			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	measurement taken into account?			
5.10.4.2	When an instrument for calibration has been adjusted or repaired, are the calibration results before and after adjustment or repair, if available, reported?			
5.10.4.3	Do the calibration certificates (or calibration labels) contain any recommendation on the calibration interval, except where this has been agreed with the customer? This requirement may be superseded by legal regulations.			
5.10.4.4	When opinions and interpretations are included, does the laboratory document the basis upon which the opinions and interpretations have been made? Are opinions and interpretations clearly marked as such in a test report?			
5.10.5	When the test report contains results of tests performed by subcontractors, are these results clearly identified? Does the subcontractor report the results in writing or electronically?			
5.10.6	When a calibration has been subcontracted, does the laboratory performing the work issue the calibration certificate to the contracting laboratory?			
5.10.6	In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, are the requirements of this standard met?			
5.10.7	Is the format designed to accommodate each type of test or			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	calibration carried out and to minimize the possibility of misunderstanding or misuse?			
5.10.8	Are material amendments to a test report/calibration certificate after issue made only in the form of a further document, data transfer, including a statement equivalent to "Supplement to Test Report (or Calibration Certificate)"?			
5.10.9	Do such amendments meet all the requirements of this standard?			
5.10.9	When it is necessary to issue a complete new test report or calibration certificate, is this uniquely identified? Does this contain a reference to the original that it replaces?			
5.10.9	Does the laboratory seek regulatory guidance if necessary and ensure that the needs of the customers are met?			
APLAC TC007	Does the laboratory provide rapid notification of nonconforming results to customers and, if necessary, to regulators may be necessary to prevent or reduce public health incidents?			
APLAC TC007	Does the laboratory provide rapid notification of nonconforming results to customers and, if necessary, to regulators may be necessary to prevent or reduce public health incidents?			
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 not limited to (Website page, letterhead, test or calibration report including subcontracted results if utilized and calibration labels)				
If any of the requirements of SOP-3 are not followed a nonconformance must be written				
PJLA SOP - 03 Use of the Symbol For applicant laboratories:				

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
Does the applicant laboratory use the PJLA Logo? Note Applicant laboratories are not permitted to use the PJLA logo until official accreditation is granted by executive				
SOP-3	Is the accredited laboratory utilizing the correct symbol (i.e. testing and/or calibration)?			
SOP-3	Is the symbol reproduced in a size that is clearly distinguishable?			
SOP-3	Is the symbol reproduced in the PJLA specified/approved colors or in a single-color (black or a single color belonging to the house-style of the accredited lab)? Is the symbol identifiable?			
SOP-3	Is the accredited laboratory properly stating their accreditation status? "Accredited to ISO/IEC 17025:2005" or utilizing the ILAC criteria listed in the SOP-3 Procedure. (ILAC guidance not mandatory)			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
SOP-3	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."			
SOP-3	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? c) any documentation of sites that			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	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"?			
SOP-3	**Subcontracted Tests or Calibrations**			
	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?			
	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?			
SOP-3	**Calibration Labels on Equipment**			
	Does the laboratory utilize the PJLA accreditation symbol on their calibration labels?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	If yes, does the labels contain: a) the name of the accredited calibration laboratory or its accreditation number? b) equipment identification? c) date of current calibration? d) cross-reference to the calibration certificates issued in respect of the calibration?			
	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?			
****To be reviewed at all assessments (Accreditation, Surveillance and Reaccreditation****				
PL-1 Proficiency Testing Requirements for Applicant and Accredited Laboratories				
PL-1	For applicant laboratories: 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?			
PL-1	For accredited laboratories: 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?			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
	Has the proficiency plan or schedule been approved by PJLA?			
PL-2 Measurement Traceability Policy				
PL-2	Does the laboratory have documented policies and procedures regarding measurement traceability and reference this traceability on test/calibration reports			
PL-2	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?			
PL-2	If not, can the laboratory demonstrate reverse traceability, an uninterrupted chain, back to NIST or another NMI?			
PL-2	Does the laboratory have on file and available the current certificates and scopes of accreditation for the external calibration laboratories employed?			
PL-2	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				
PL-3	For applicant laboratories: Has the laboratory applied its documented procedure to provide measurement uncertainties for every measured quantity, instrument or gage listed in its scope of accreditation? (Well recognized test methods or calibration procedures that specify limits to the values of major sources of uncertainties will meet this requirement)			

ISO Req.	Characteristic	Yes	No	Comments regarding deficiencies/effectiveness (if applicable)
PL-3	For accredited laboratories: Are stated uncertainties periodically reviewed and updated to evaluate changes to be made to any influence listed in an uncertainty budget?			
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.				

Additional Notes:

Additional Notes:

PJLA

Additional Notes:

These additional requirements imposed by the AOAC guidelines are considered to be minimum requirements. Table 1 provides requirements for the calibration.
In the event that a calibration or verification parameter fails, all data collected since the last successful calibration/verification are suspect. The laboratory shall institute the "Control of nonconforming work" procedure *(see* ISO 17025 Sec. 4.9).

Equipment/System	AOAC Parameter	Frequency	Compliance		Objective Evidence	Comments
			Yes	No		
Autoclaves	Accuracy of temperature sensing system, uniformity and stability of temperature	Calibrate at installation (or initial use) Verify annually				
	Temperature and Pressure	Verify each load				
	Performance	Verify weekly with *Bacillus Stearothermophilus* biological sterility indicator				
	Uniformity and stability of temperature *	Conduct an initial mapping of the chamber and annually thereafter				
	Service	As recommended by manufacturer or per laboratory procedure				
Automated Colony Counters	Accuracy	Verify annually with manual count				

Equipment/System	AOAC Parameter	Frequency	Compliance		Objective Evidence	Comments
			Yes	No		
Balances	Mass Measurement	Verify daily when in use with internal calibration or with a working weight				
	Calibrated reference weights	Calibrate annually[8]				
Chromatographic systems (GC, IC, LC)	Detector response	Verify at a frequency established by the test method or laboratory using multi-level standards that establish a correlation between analytical standard concentrations and instrument response[0]				
D1 Systems	Conductivity	Weekly				
Dispensing equipment and vial fillers used in microbiology	Mass measurement/volume	Verify at installation and daily when in use at each volume dispensed				
Freeze-dryers, vacuum ovens	Ability to achieve and sustain vacuum; gauges calibrated or verified	Verified annually				
Fume hoods	Service	Annually				

Equipment/System	AOAC Parameter	Frequency	Compliance		Objective Evidence	Comments
			Yes	No		
Hydrometer, reference	Specific gravity	Calibrated every 2 years				
Hydrometer, working	One point comparison to reference hydrometer	Verify annually				
Microscope	Length	Calibrate stage micrometer				
pH meters, ion selective, and related conductivity equipment	Reading with standard reference buffers[0]	Verify (bracketing range of use)				
Safety cabinets and laminar airflow	Magnehelic gauge	Verify at installation an each day of use.				
Cabinets (if used for culture of sterility work)	Open media control (sterility check)	During each use				
	Service	As recommended by manufacturer				
Temperature controlled chambers (refrigerators, freezers, ovens, furnaces, water baths)	Temperature	Monitor continuously with a validated system or check daily when in use				
	Uniformity and stability of temperature *	Conduct an initial mapping of the chamber; verify annually and/or if the instrument has had maintenance repairs that would affect the inner chamber				

Equipment/System	AOAC Parameter	Frequency	Compliance		Objective Evidence	Comments
			Yes	No		
Temperature controlled chambers used for incubation (incubators, water baths)	Temperature	Check daily a.m. and p.m. when in use				
	Uniformity and stability of temperature *	Conduct an initial mapping of the chamber; verify annually and/or if the instrument has had maintenance repair that would affect the inner chamber^				
Temperature sensing devices/systems (e.g., thermometers, thermocouples, data loggers, data tracers, thermistors, digital displays, continuous monitors, etc.)	Temperature	Reference device: calibrate annually				
		Working device: verify annually against reference device[F]				
Timers and internal timing devices'[3]	Time	Calibrate reference device annually if used				
		Verify annually working device against reference or against NIST time clock[F]				

Equipment/System	AOAC Parameter	Frequency	Compliance		Objective Evidence	Comments
			Yes	No		
UV/Vis spectrophotometer	Blank reading	Verify daily when in use				
Volumetric delivery devices; mechanical pipets, micropipettors, mechanical burets and bottle-top dispensers	Accuracy and precision using mass of water or by spectrophotometric method	Verify every 6 months or at an increased frequency if required by regulation or test method				
Volumetric delivery devices: positive displacement syringes use for volumetric delivery	Accuracy	Verify upon receipts; (manufacture's Certificate of Accuracy may be accepted)				
Volumetric glassware, non-class A-pipets, burets, and volumetric flasks	Accuracy and precision using mass of water or by spectrophotometric method	Verify upon receipt (manufacture's Certificate of Accuracy may be accepted)				
Water activity meter	Water activity of known solutions	Verify daily when in use[0]				
Weights, reference	Mass	Calibrate every 5 years[8]				
Weights, working	Mass	Verify against reference weights annually				

Notes	
A	Uniformity and stability may not be needed for the following equipment: small chambered autoclaves, incubators, ovens, and refrigerators; circulating water baths; muffle furnaces; and freezers based on use or design. In these cases, the laboratory should have reasonable justification and document the justification for not determining uniformity and stability.
B	All weights and balances shall be calibrated traceable *to* recognized national or international calibration units [i.e.. National Institute of Standards and Technology (NIST), Bureau International des Poids et Mesures (BIPM), Organisation Internationale de Metrologie Legale (OIML), or equivalent traceable weights]. Accrediting bodies may require calibration by an ISO 17025 accredited calibration laboratory.
C	Frequently, an instrument such as a gas chromatograph does not lend itself to calibration using a national or international standard. In these cases, adequate performance of the whole method involving the instrument is ensured by using a Certified Reference Material (CRM) or Reference Material (RM).
D	When pH and water activity are used to generate results reported *to* the customer, the traceability requirement is critical; hence, the reference material (e.g., buffer or water activity analytical standard) needs to be one that has the estimate of uncertainly available in the Calibration Certificate. In addition, the calibration must be done in a defined manner to take into account the measurement uncertainty. Accreditation bodies may require buffers obtained from a Guide 34 accredited manufacturer.
E	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.
F	Accrediting bodies may require initial calibration by an ISO 17025 accredited calibration laboratory.
G	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 specific time requirement is not required for the test method.

AOAC Appendix B Microbiological		Compliance		Objective Evidence	Comments
		Yes	Deficient		
Organisms and Certified Reference Materials	Are the organisms required for the tests stored appropriately?				
	Are the organisms traceable and documented from date of possession?				
	Where Reference Materials are certified, are copies of the certificate are available for inspection?				
Dehydrated Media Requirements and Records	Is there a lot acceptance procedure where each lot will be evaluated for suitability before use?				
	Are Records of commercially purchased dehydrated media shall be kept to include media name or description, manufacturer's lot number, assigned laboratory identification, date received, date opened, date prepared for quality control (QC), manufacturer's expiration date, and initials of responsible person providing this information. All dehydrated media shall be labeled with laboratory identifier, date received, and date opened?				

AOAC Appendix B Microbiological		Compliance		Objective Evidence	Comments
		Yes	Deficient		
Dehydrated Media Requirements and Records	Are there rrecords for every batch of media prepared internally or purchased externally, indicating that it has been examined to ensure it is suitable for use?				
Prepared Culture Media QC/Batch	Do the media records include preparation, traceability to media, pH (as specified in the instructions / recipe), appearance, sterilization batch (with related records), fill volumes (if appropriate), batch size, and quantity?				
Reagents/Kits/Identification Systems	As with media, is every lot of materials approved following a specified procedure? Do these records satisfy the requirements for technical records, and do they include the date approved and traceability to the person approving or rejecting the material? Do serological tests include a positive control and a saline negative control?				

AOAC Appendix B Microbiological		Compliance		Objective Evidence	Comments
		Yes	Deficient		
Autoclave Sterilization	Do autoclave records for media, reagents, and laboratory infectious waste are technical records and show date, run number, autoclave number (where applicable), nature of material/load, time into autoclave, time at desired temperature, time out of autoclave, and traceability to persons performing the activities?				
	Are sterilization equipment and sterilization processing cycles validated and documented?				
Other Sterilization Techniques	For other sterilization means, are records shall 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		Compliance		Objective Evidence	Comments
		Yes	Deficient		
Method Criteria	Has the laboratory defined the acceptance criteria for each test method for the following items (when included in the test method): calibration curves, calibration checks, second source standards, quality control samples, blanks, spikes, matrix spikes, and duplicates?				
	Does the laboratory have a procedure or policy that provides guidance and/or criteria for the reprocessing and/or reintegrating of analytical data?				
Standards for Laboratory Grade Water	Is the water used in the laboratory fit for use? Has the laboratory defined the use of the water and ensure the water is fit for that use?				
	Is Quality of reagent water suitable for use in microbiological methods should have been treated to be free from traces of dissolved metal, and bactericidal, and inhibitory compounds? Is this water used to prepare culture media, reagents, and dilution blanks?				
	Is purified water as defined by USP and EPA would be suitable for microbiology use?				

Appendix D: Pharmaceutical Analysis and Legal Standards		Compliance		Objective Evidence	Comments
		Yes	Deficient		
	A pharmaceutical product shall conform to its Legal Standard Requirements throughout its expiry period.				
	The Legal Standard Requirements include an allowable statement of uncertainty. Uncertainty or variance components resulting from sampling,				
Appendix E: Legal Samples					
	Does the laboratory collect legal samples, these are samples that are used in a court of justice or samples taken under the authority of a government agency for legal testing?				
	Does the laboratory used all legal procedures prescribed by the agency or the body requiring the samples followed?				
	Does the laboratory have a chain of custody procedure that is applied for all samples and fully documented?				
	Are retain samples, if available or sufficient, for additional testing or to fulfill the right to access a second opinion or expertise must be kept according to the body requiring the sample?				