

Best Practices for Submission of Actionable Human and Animal Food Testing Data Generated in State and Local Laboratories



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I. Introduction and Purpose

Laboratory accreditation has been identified as a critical element for ensuring the integrity and accuracy of food testing results. Third party accreditation gives end users confidence in the laboratory data, as the laboratory has been audited to a high standard and is deemed to be proficient when operating under the scope of accreditation. The International Organization for Standardization, also known as ISO, maintains a set of standards that are highly recognized and respected internationally. The ISO/International Electrotechnical Commission (IEC) 17025:2017 standard establishes a minimum threshold of acceptance for activities and systems in the laboratory and stresses the importance of establishing a quality management system (QMS), also called a quality assurance plan, which aims to improve the laboratory's ability to consistently produce valid results.

State and local regulatory laboratories are strongly encouraged to consider becoming accredited to the ISO/IEC 17025 standard for human and animal food testing, especially when that data could become relevant to regulatory partners. External accreditation by independent auditors to the ISO/IEC 17025 standard demonstrates a significant commitment to developing and maintaining a QMS. While rule-making is still in process, the Food Safety Modernization Act (FSMA) includes provisions that may soon require accreditation of private human and animal food laboratories, particularly those testing products imported into the United States. Although governmental laboratories are not referenced in FSMA, accreditation may help these laboratories meet the requirements of a variety of customers at the local, state and national levels.

Governmental human and animal food testing laboratories often face unique situations that result in data produced outside of their accreditation scope. Some governmental laboratories operate in an environment in which ISO accreditation may not be fiscally justifiable. Human and animal food testing may be performed only in rare instances, such as during foodborne outbreak investigations where the volume of routine testing may be very low, or the requests received may be for esoteric testing that would fall outside of scope. This white paper is primarily designed to advise such non-accredited governmental laboratories which may have a QMS in place that demonstrates their ability to provide reliable data, but some methods are not covered by that QMS or the QMS is not based on ISO/IEC 17025. Its aim is to describe the phases of testing included in an ISO-based QMS, which can instill confidence in laboratory data submitted to regulatory agencies. This document does not take the place of regulatory requirements. It is intended to be a tool to assist laboratories and end users in data review and acceptability. Additional requirements may be needed to meet specific needs of regulatory partners; please refer to the Regulatory Elements chapter of the Partnership for Food Protection Human and Animal Food Testing Laboratories Best Practices Manual (PFP Manual).

This white paper also holds value for human and animal food testing laboratories that have achieved ISO/IEC 17025 accreditation. The checklist located in Appendix A of this document can be used as a self-assessment tool. State and local regulatory laboratories may be accredited for nearly all or only a fraction of their methodologies. In some accredited laboratories, entire programs within their organizations may be outside their scope of accreditation and may not be subjected to all the requirements of their QMS. These may include infrequently used methods, alternative methods or qualitative methods that are used for confirmation of primary screening test results. In the case of human or animal food safety emergencies, new and/or rapidly developed methods may fall into this category (e.g., testing for melamine, oil spill contaminants) and yet it may be very important to share results from these analyses. This document is intended to assist laboratories in identifying those specific procedures and records that should be in place in order to share such human and animal food data.

II. White Paper Development

In December 2013, the Laboratory Task Group of the PFP released the *PFP Manual*. The *PFP Manual* recognizes that other laboratory quality programs exist, such as the Clinical Laboratory Improvement Act (CLIA) regulation for testing human specimens. Options in the *PFP Manual* for CLIA-certified laboratories

involved in regulatory food testing include:

1. Seek full ISO/IEC 17025 accreditation for the food testing section of the laboratory.
2. CLIA laboratories occasionally performing food testing could apply their current requirements (CLIA) to their food safety section and fill in the gaps found in the comparison within the PFP Manual).
3. Consider deferring food testing to another agency within the state public health system or to another state or local laboratory accredited to ISO/IEC 17025.

In 2014, the Association of Public Health Laboratories (APHL) convened a Data Acceptance Work Group to further define and clarify the gaps that would need to be filled primarily by state and local public health laboratories choosing Option 2 above. The Data Acceptance Work Group comprises members of APHL, the Association of Food and Drug Officials (AFDO), the Association of American Feed Control Officials (AAFCO), the US Food and Drug Administration (FDA), and the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS). While many factors are involved in data acceptance, this workgroup came together to focus on the steps state and local laboratories can take to encourage the acceptance and use of laboratory data by federal and other state and local regulatory programs, irrespective of laboratory accreditation status.

As part of this focus, the work group reviewed and pulled data acceptance criteria from the PFP Manual in addition to obtaining laboratory perspectives on data packages submitted to various partners. Through the use of the PFP Manual, the laboratory perspectives, and discussions with federal partners, the work group developed best practices in a white paper to enhance the likelihood of data acceptability.

The checklist (Appendix A) included in this document offers a tool for laboratories to easily review their system against the recommended key elements. In addition, a glossary of terms has been provided to ensure uniform understanding of the terminology used in the following paragraphs.

This white paper is available on the APHL website and through the partnering organizations that helped create the document. The third revision brings the white paper into conformance with the ISO/IEC 17025:2017 standard. Comments and suggested revisions are encouraged and may be sent to foodsafety@aphl.org.

III. Quality Management Systems

The QMS includes all activities that contribute, directly or indirectly, to the quality of test results. A QMS covers three major phases of testing: pre-analytical, analytical, and post-analytical.

Pre-Analytical Phase

The pre-analytical process begins when program management, inspection, sampling, quality control and laboratory staff, work together to define the question to be answered, the decision unit,¹ and the required precision. Despite any division of labor among departments or agencies, data collected as a result of sampling a decision unit is within a single measurement system. Data quality and evidentiary integrity are a reflection of the entire process. While laboratory workflow begins when the laboratory sample is received and ends when results are reported and sample dispensation occurs, defensible data may not be generated from an incorrectly collected primary sample, which can result in false negative or biased results. In addition, the combination of statistical error from each process, collecting primary sample to selecting a test portion to generating an analytical result, must be communicated clearly and taken into consideration by persons making regulatory decisions.

The sampling conducted and the testing required are often dependent on specific program requirements as delineated in contracts or other work orders. Ongoing discussions with the entity requesting the testing

¹The material from which the primary sample(s) is collected and to which the inference(s) is made

to determine their requirements and needs is critical to assure the collection of appropriate, representative samples.

Requirements for Evidentiary Integrity

Laboratories should have a process that ensures evidentiary integrity and meets the needs of the customer. Evidentiary integrity, in legal terms, is the identification and authentication of the evidence. This includes documentation that samples have been properly collected, transported, received, handled, processed and stored in a manner to ensure that test result(s) can be traced to the decision unit and accurately represent the analyte of interest in the material from which a sample was collected. Records of chain of custody, representative sampling procedures, and processes ensuring analyte integrity should be maintained. Discussions between the laboratory and the customer regarding evidentiary procedures should occur prior to sampling.

Requirements for Representative Sampling

Representative and fit-for-purpose sample collection is essential to achieve consistent laboratory analytical results between multiple federal, state and local human and animal food safety agencies. Laboratories and sampling organizations should coordinate sampling plans and procedures to assure the appropriateness and quality of samples. Sample quality criteria (SQC), as defined in the glossary and described in *GOODSamples*, provide the framework for managing sampling and analytical operations consistent with the human or animal food program needs and include the purpose for the analyses (objective), the product studied (decision unit) and desired confidence (the probability that the analytical value is greater or less than the average of the decision unit) in the data. Wherever possible, harmonized sampling protocols, designed to meet SQC should be used.

For detailed information on samples and sampling, see [Guidance on Obtaining Defensible Samples \(GOODSamples\)](#), [Guidance on Obtaining Defensible Test Portions \(GOOD Test Portions\)](#), the 2018 [PFP Manual](#) (Sampling, Chapter 4), and the [FDA Investigations Operations Manual](#), most recent version (Chapter 4, Sampling).

Analytical Phase

The QMS elements covering the analytical phase of testing include a quality assurance plan, staff training, demonstration of capability and competency, the selection of analytical methods, as well as test method validation and verification to ensure fitness for purpose. Among many possible additional components are proficiency testing or inter-laboratory comparisons that demonstrate the laboratory's ability to achieve comparable results with external sources; quality controls (e.g., blanks, replicates, spikes, reference materials) that provide monitoring of performance on analytical methods at the time of analysis and documentation of raw data results and analytical worksheets. While not all-inclusive, the following are some of the most critical QMS elements of the analytical phase of testing:

Quality Assurance Plan

Laboratories must have a set of Standard Operating Procedures (SOPs) defining the analytical work process, at a minimum including:

1. Evidentiary integrity processes including receipt and log-in of samples; a system for unique identification; records tracing staff possession, receipt, testing, storage, and disposal of samples.
2. Validated laboratory sampling procedures to ensure selection of a representative test portion, including all non-selection (e.g., comminution, preservation) and selection processes (e.g. mass reduction, splitting).
3. Validated and performance verified analytical test method(s).
4. Use and traceability of analytical reference material and standards.
5. Equipment calibration, verification and maintenance.

6. Document management and control to ensure use and availability of only the most current procedures, worksheets, etc. and archiving of retired documents.
7. Record management and control to ensure accurate, complete and secure records and data (including records retention considerations).
8. The type, frequency, and evaluation criteria of quality control samples, such as certified reference materials, positive controls (spikes), negative controls (blanks), field duplicates, and laboratory replicates.
9. Detection of non-conforming testing or calibration(s) and implementation of corrective action(s).

Staff Training and Demonstration of Capability and Competency

Before handling customer samples, laboratory staff performing testing must possess the education, training and demonstrated capability and competency to perform laboratory testing.

Analytical Method(s), Validation and Verification

The method(s) used must be appropriate for the test item(s) matrix and analyte(s) of interest.

Official and reference methods must be verified by the testing laboratory using representative matrices and analyte concentrations. Official, reference and standard methods are methods

which have been validated through a multi-laboratory collaborative study, approved, published and disseminated by regulatory agencies such as the FDA and/or international, national, and regional standards organizations such as AOAC International, American Oil Chemists Society, American Association of Cereal Chemists, AAFCO or ISO.

Non-standard (i.e., not from an authoritative and validated source; including scientific journals) and laboratory-developed methods must be validated and approved by the testing laboratory prior to analysis of the test item(s). Validation must include accuracy, precision, limit of detection (where applicable), limit of quantitation and/or reporting limit, linearity, selectivity, stability in matrix, robustness, sensitivity, reproducibility and uncertainty where applicable (See ISO/IEC 17025:2017 Section 7.2.2 for more information).

Proficiency Testing/ Proficiency Evaluation (PT/PE)

Laboratories must participate in PT and PE programs, check sample programs or inter-laboratory comparisons that are accredited or approved by the customer or regulatory body (such as FDA), whenever available. When PT/PE are not available, more responsibility is put on the laboratory to conduct comprehensive validation or confirm findings by an alternate method.

Quality Control

Laboratories must establish quality control procedures and be able to provide records of the quality control events (e.g., blanks, replicates, spikes, reference materials) used to establish acceptability of performance during the testing, including test results, acceptance criteria, and evaluation (pass/fail).

Analytical Worksheet(s)

Laboratories must be able to provide records of the analysis performed including analyst(s), date(s) of testing, analytical method citation(s), reference material and traceability that affect laboratory activities, supplies, equipment and instrument identification that affect laboratory activities, weights, dilutions, concentrations, calculations, test results, and any deviations or modifications from the documented method.

Raw Data

Laboratories must be able to provide raw data generated during the analysis, including the instrumental conditions (parameters), chromatograms, spectra, instrument or equipment printouts, and hand-recorded observations generated during testing of the sample(s).

Post-Analytical Phase

The pre-analytical and analytical phases of testing generate results that are reported according to predetermined customer requirements. Reporting of these results comprises the post-analytical phase of testing. The final reports given to the data users should provide clear identification of the type of report (e.g., preliminary/interim, final, amended), the results, and any critical comments, explanations and/or conclusions. It is important to ensure that procedures are in place to prevent the generation of unauthorized reports or documents.

Reports

When reporting results, it is critical to ensure that the laboratory is providing what the end user needs and that report elements are clearly defined. Some end users will be satisfied with a summary report that provides only the final result; however, some end users will want to see supporting data such as analytical worksheets, raw data, quality control, sample submission form, and other documentation as part of the final report package. Before testing begins, the laboratory and its customers should agree on what elements will be included in the report. The laboratory may suggest the minimum elements that are typically included in reporting. Prior communication with the end users is needed to ensure that the appropriate information is provided.

Record Creation and Retention

The laboratory should have clearly established procedures on record creation and retention. The laboratory should ensure that customers (programs and data users) are aware of these procedures. Regulatory programs may have their own requirements for record retention. The laboratory should retain records for no less than the minimum time required by any regulatory program. Absent any regulatory requirements, it is recommended that records are retained for a minimum of two years.

Data Packages

Evidence is maintained that could potentially be used for regulatory action internally or by an external regulatory body, such as FDA or USDA FSIS. The laboratory should maintain records documenting evidentiary integrity; testing and other technical data; equipment performance and maintenance; training and competency and other supporting information that may be specified by the customer.

The information described above provides laboratories with a foundation to build their QMS. Having these elements in place and confirming they are maintained via internal and external audits provide the laboratory and end users with confidence in the data quality. While having a

QMS in place will not ensure automatic acceptance of the data produced, it will demonstrate the laboratory's commitment to producing quality data and provide the end users with confidence that staff have been trained and analytical methods have been followed.

IV. Requirements for State Cooperative and Regulatory Programs

The data received from the laboratory must be accurate, timely, and reliable. Prior to entering an agreement, the laboratory must work closely with the human or animal food regulatory program to ensure it provides the service needed and to encourage data acceptance for regulatory action. This includes the use of test methods which meet the needs of the customer and are appropriate for the tests undertaken. The following are laboratory-specific program requirements for Manufactured Food, Animal Feed, Grade "A" Milk, Retail Food and Shellfish Programs.

State Manufactured Food Regulatory Programs

Laboratory services performed for State Manufactured Food Regulatory Programs enrolled in the FDA Manufactured Food Program Regulatory Standards (MFRPS) must meet the program elements in Standard No. 10, Laboratory Support. For food testing services, the 2016 Standards require that State regulatory programs use laboratories that have a current accreditation to the ISO/IEC 17025 standard to analyze food

and environmental samples. The laboratory's accreditation body must be a full member of the International Laboratory Accreditation Cooperation (ILAC) and a signatory to the ILAC Mutual Recognition Arrangement. If the laboratory being used is not ISO/IEC 17025 accredited for the analysis of food and environmental samples, the laboratory should have a quality system in place which incorporates described management and technical requirements of ISO/IEC 17025. Standard 10 of the MFRPS describes the minimum criteria needed for non-ISO accredited laboratories (10.3.3.1 - 10.3.3.6).

State Animal Feed Regulatory Programs

Laboratory services performed for State Animal Feed Regulatory Programs enrolled in the Animal Feed Regulatory Program Standards (AFRPS) must meet the program elements in Standard 10, Laboratory Services. For animal food testing services, the February 2017 version of the AFRPS requires that the laboratory should follow the AAFCO Quality Assurance/Quality Control Guidelines and comply with the managerial and technical requirements of ISO/IEC 17025, or be accredited by an ILAC-recognized accreditation body for the appropriate analytical testing methodology.

FDA Grade "A" Milk Program

Official regulatory sample analysis is required to be conducted by Interstate Milk Shippers (IMS)-listed laboratories utilizing National Conference on Interstate Milk Shipments (NCIMS)-approved methods. All States and Puerto Rico have access to State and industry laboratories that are IMS Listed. The Evaluation of Milk Laboratories (EML) provides the standards, procedures and requirements of State and industry milk laboratories to be IMS Listed and to perform official regulatory milk sample testing and reporting under the Grade "A" Milk Safety Program. IMS Listed laboratories are evaluated and accredited by FDA-certified Laboratory Evaluation Officers every three years and, if in compliance with the EML, they are IMS Listed. IMS Listed State central milk laboratories are evaluated and accredited by FDA Laboratory Proficiency Evaluation Team every three years, and, if they are in compliance with the EML, they are IMS Listed. All IMS Listed laboratories require the successful completion of annual proficiency sample testing (examination of split milk samples). The IMS List documents accredited State and industry laboratories, including the test methods they are approved to perform.

Retail Food Programs

The Voluntary National Retail Food Regulatory Program Standard 5, (Foodborne Illness and Food Defense Preparedness and Response, 2017 Version), requires the regulatory program to have an established agreement with a laboratory or laboratories that can provide analytical support for the analysis of environmental, food, and clinical samples. Programs are also required to maintain a contact list for laboratories that may provide additional assistance in food-related emergencies that exceed the capacity or capability of the primary laboratory(s).

FDA National Shellfish Sanitation Program

Each state or tribe participating in the FDA National Shellfish Sanitation Program (NSSP) must have access to a laboratory for the analysis shellfish and/or marine waters that is used for growing area classification requirements, shellfish testing for pathogens, and/or marine biotoxin testing.

All records and documentation of laboratory services for routine and non-routine analyses such as biological hazard determinations must be maintained. A state or tribe may also contract with outside laboratories as needed. All laboratory analyses shall be performed by a laboratory found to conform or provisionally conforms to the FDA Shellfish Laboratory Evaluation Officer or FDA-certified State Shellfish Laboratory Evaluation Officer in accordance with the requirements established under the NSSP. The laboratory must develop and implement a written quality assurance plan.

V. Evaluation of Data by Laboratory Customers

The end users of laboratory-generated results should evaluate the utility of the data provided to them. This may include customers within the same agency (e.g., a state department of agriculture), customers contracting with the laboratory (e.g., the USDA Pesticide Data Program, the MFRPS program, AFRPS program, the Food Emergency Response Network), another state agency, an agency in another state, and other regulatory agencies who require the data due to interstate commerce (e.g., FDA, USDA). These end users may have specific requirements which should be provided to the laboratory. The customer may require assurance of laboratory support of analytical results if their data is used in a contested enforcement case. Prior to testing, the laboratory and its customer should discuss the laboratory's ability and willingness to support the data, including testifying in a legal action. End users who are not direct customers may use data generated by a laboratory. Recommendations such as those found in this document and the PFP Manual can facilitate the ability to use a laboratory's data with confidence.

It is the responsibility of the laboratory to carry out its testing and calibration activities with integrity and impartiality but in such a way as to satisfy the needs of the customer and the regulatory authorities. The customer has an obligation to understand that the laboratory has procedures in place for accepting requests for testing. Any differences between the request and contract should be resolved before work commences. The documented adherence to and understanding of the laboratory-customer dynamic is why regulatory agencies prefer to accept data packages from accredited laboratories.

As emphasized in the pre-analytical phase, it is also important that the laboratory understands the processes used by the inspectors and samplers, as well as the objectives for sampling and testing, to determine if any additional factors need to be considered. Without this communication, the potential exists for technical errors and misunderstandings between the partners. In a regulatory setting, this miscommunication will invariably result in costly delays in data package submission and acceptance and negatively impact public health. Establishing the foundational needs of all stakeholders of the regulatory human and animal food testing community strengthens food safety protections and improves public health nationally.

VI. Conclusion

FSMA includes provisions that may soon require accreditation of private human and animal food laboratories, particularly those testing products imported into the United States. Although governmental laboratories are not referenced in FSMA, accreditation helps laboratories meet the requirements of a variety of customers at the local, state and national levels. Following the best practices in this white paper can instill more confidence that laboratory data submitted by a non-accredited laboratory operating under a robust QMS will be acceptable to the end user for its intended purpose. Also, it should not be inferred that data will be accepted by a customer solely based on the accreditation status of the laboratory. Customer-derived criteria beyond those standard elements for which accreditation is granted will bear equal weight to the acceptability of data. Discussions on defining such additional criteria continue; however, the importance cannot be overstated. The outcome of this on-going effort will instill consistency in expectations between laboratory and customer and facilitate a streamlined data acceptance pipeline.

While this document does not take the place of any regulatory requirements or any customer-specific requirements, the work group believes it provides a foundation that state and local regulatory laboratories and their partners can use regarding data acceptability. One of the most critical factors in achieving data acceptability is frequent communication among partners. Communication at multiple levels is key for regulators and other customers to understand the laboratory's requirements for remaining compliant with their QMS. For best customer service and to create flexibility and ability to respond to emerging food safety issues, the laboratory should discuss with their accrediting bodies if flexible-scope—applied to a technology rather than a method—could be utilized. The understanding of ISO/IEC 17025 accreditation standards by both the laboratories and the customers enhances this communication and provides a clearer path to data acceptance. Laboratories should focus on achieving ISO/IEC 17025 accreditation when the time and cost

can be justified by customer needs. Many factors must be taken into consideration for each laboratory, but by working together laboratories and their partners can achieve a level of quality and efficiency that supports the protection of human and animal food products through the sharing of data and information.

The authors encourage comments on this white paper, which can be submitted via email to foodsafety@aphl.org.

Appendix A: Checklist

This checklist will assist the laboratory in becoming compliant with ISO/IEC 17025 standard but does not imply accreditation. Some items may not be applicable for all laboratory sections. This checklist can be used as a tool to review a laboratory QMS (or quality assurance plan) against the key elements recommended in the white paper. Please refer to the MFRPS 2016 version, Standard 10, Section 10.3.3 for some additional considerations regarding criteria needed for non-ISO accredited laboratories.

Management Guidelines

1. Does the laboratory have both a document and records management and control procedure?
2. Does the laboratory quality system cover all sites used to generate data including any secondary and/or temporary or mobile facilities?
3. Does the laboratory have managerial and technical personnel with both the authority and resources to identify departures from the quality system?
4. Does the laboratory have managerial and technical personnel to initiate actions to prevent or minimize any such departures?
5. Does the laboratory have a procedure for and conduct internal audits?
6. Are the following procedures in place:
 - a. Corrective actions
 - b. Complaint process
 - c. Control of non-conforming work
 - d. Training and competence requirements
7. Does the laboratory perform a management review at least annually covering the following:
 - a. Changes in internal and external issues relevant to the laboratory
 - b. Fulfillment of objectives
 - c. Suitability of procedures
 - d. Review of internal and external audits
 - e. Status of action items from previous management reviews
 - f. Corrective actions
 - g. Volume and type of work
 - h. Feedback from customers and personnel including complaints
 - i. Effectiveness of implemented improvements
 - j. Adequate resources which include personnel and equipment
 - k. Results of risk identification
 - l. Outcomes of assurance of validity of results
 - m. Other relevant factors that impact quality of testing

8. Does the laboratory ensure the following outcomes are recorded from the management review?
 - a. Decision and actions related to effectiveness of QMS
 - b. Improvement activities related to fulfillment of QMS
 - c. Provision for required resources
 - d. Needed changes or improvements

Document Control

9. Does the laboratory control all documents that form part of its quality system (e.g. methods, software, and instructions), including procedures for ensuring:
 - a. Approval of all documents for adequacy before use?
 - b. Periodic review of all documents?
 - c. Any changes to documents are recorded?
 - d. Any changes to documents are approved?
 - e. Only the current revision is being used?
 - f. Archiving of retired documents?
 - g. Suitable markings of retained obsolete documents or segregation?
 - h. Documents are uniquely identified and accurately cross-referenced?
 - i. Control of external documents, regulations, standards and manuals?

Laboratory/Customer Agreements

10. Does the laboratory have a system (agreement, documentation or procedure) in place for services with the customer (e.g. contract, memorandum of understanding [MOU], sampling plan)?
 - a. Does the system consider actionable levels and applicable laws?
 - b. Does the system consider any decision rules and, if so, how these are communicated to the customer?
 - c. Does the system include management approval prior to testing?

Subcontracting of Test Services

11. If the laboratory subcontracts work, is the subcontracted laboratory either accredited to the ISO/IEC 17025 standard for that work or is the work according to the requirements of the customer?
 - a. Is a record maintained for all such subcontractors, along with evidence of their stated accreditation or compliance?
 - b. Is the customer aware of and approves of the subcontracted work?

Externally Provided Products and Services

12. Does the laboratory have a procedure for the selection and purchasing of supplies, reagents, consumable materials, and services (including subcontracting of test services) that affect laboratory activities?

13. Does the laboratory verify that supplies comply with the standard specifications or requirements defined in the methods being used?
14. Does the laboratory ensure that services and supplies meet pre-established specifications and will not adversely affect the quality of results?
15. Does the laboratory have defined criteria for evaluation and re-evaluation of external providers?
 - a. Are the evaluations documented?
16. Is the external provider reviews based on the laboratory's own evaluation of the quality of goods or services received (not just the state/government purchasing system approved and evaluated vendors)?
17. Does the laboratory communicate its requirements to external providers?

Control of Non-conforming Work and Corrective Action

18. Does the laboratory have procedures detailing the acceptable handling of nonconforming work or any departure from the procedures in either its quality system or technical operations that:
 - a. Identify the responsibilities and authorities for the management of nonconforming work?
 - b. Identify the actions to be taken when nonconforming work is identified (including the halting work and holding test reports, as necessary)?
 - c. Ensure that actions taken are based on laboratory established risk levels and that risks and opportunities are updated if necessary?
 - d. Identify the personnel who have the authority to resume the work if the work was stopped?
 - e. Require corrective actions to be taken immediately, together with any decision about the acceptability of the nonconforming work, including notifying the customer?
 - f. Include the monitoring of results to ensure that the corrective actions taken have been effective?
 - g. Identify needed improvements?
 - h. Identify potential sources of nonconformance, and does the laboratory take action to reduce the likelihood of the reoccurrence of such nonconformance?

Risks and Opportunities

19. Does the laboratory consider the risks and opportunities associated with laboratory activities that:
 - a. Assure the QMS achieves its goals?
 - b. Enhance opportunities to meet the purpose and objectives of the laboratory?
 - c. Prevent or reduce undesired impacts or potential failures?
20. Does the laboratory have actions to address the risks and opportunities?
21. Are these actions integrated into the QMS and evaluated for effectiveness?

Records

22. For the purposes of establishing traceability, does the laboratory have procedures in place for the following steps, as they pertain to technical and quality records, including original observations,

derived data, test reports, calibration records, staff records, internal audit reports, management reviews, and corrective actions, as well as any other information:

- a. Collection of these records?
 - b. Identification of these records?
 - c. Storage of these records?
 - d. Access to these records?
 - e. Inventory of these records?
 - f. Electronic data records verified for accuracy (e.g. eLEXNET data reporting)?
23. Are all records legible, held secure and in confidence for a defined period (e.g. regulatory, customer requests or in-house records retention policies) and in such a way that they are readily retrievable, and are they retained in a suitable environment to prevent alteration, damage, deterioration and/or loss?
24. Are all records secure and held in confidence? Does the laboratory have procedures to prevent unauthorized access to computers or data stored in computers or laboratory information systems?
25. Does the laboratory have procedures to protect and back-up records held on computers or laboratory information systems?
26. Does the laboratory have procedures to ensure that any mistakes occurring in records are not deleted, or otherwise made illegible, but instead are crossed out and the correction entered alongside, with the person making the correction signing or initialing and dating the change in ink (or likewise, using electronic measures if records are in a laboratory information system or other electronic record)?

Technical Requirements

27. Does the laboratory have procedures to ensure that observations, data, and calculations used to generate this data are recorded at the time they are made and are identifiable to a specific task and person?
28. Do the observations, data and calculations contain sufficient information to help facilitate identification of factors that may affect the uncertainty (e.g. show calculations clearly, show equations for standard curves, percent recovery, and units of measurement are clear)?
29. Do records contain sufficient information to recreate the testing including, but not limited to, dates, personnel, equipment, materials, method used, etc.?
30. Is the laboratory able to provide traceability for the supplies, reagents, and consumable materials that affect laboratory activities?
31. Are amendments to records traceable to previous or original versions?

Technical Personnel

32. Are training/education/experience/competency records available for all technical personnel generating test data?
33. Does the laboratory authorize personnel to develop/verify/validate methods, analyze results with opinions and interpretations, and report/review/authorize results?

34. Does the laboratory have a procedure that establishes and maintains a training program that:
- Determines the competence requirements?
 - Identifies the selection, training and supervision of personnel?
 - Identifies how personnel are authorized?
 - Identifies how competence is monitored?
35. Does the laboratory establish and maintain an ongoing competency/continuing demonstration of assessments for technical personnel?

Facilities and Environmental Conditions

36. Does the laboratory have procedures to ensure that environmental conditions do not affect the quality of test results (e.g., maintaining separation between areas with incompatible activities, ensuring good housekeeping, monitoring environmental conditions [where critical to test] such as temperature, lighting and humidity)?
37. Does the laboratory monitor, control and record environmental conditions where they influence the validity of laboratory activities?
38. Are the measures to control facilities periodically reviewed?

Selection and Validation of Laboratory Sampling Methods

39. Does the laboratory have procedures to document that the laboratory sampling methods (for both nonselection and selection procedures) used are fit for purpose and that any deviation from these methods occurs only if the deviation is technically justified, authorized, validated/verified, and documented?
40. Does the laboratory have procedures to validate/verify the performance of laboratory sampling methods (including all nonselection and selection procedures) used to generate this data as written?
- Have reference methods performance been verified for use in the laboratory?
 - Have laboratory developed methods been validated?

Selection, Verification and Validation of Test Methods

41. Does the laboratory have procedures to ensure that the test methods used are fit for purpose and that any deviation from these methods occurs only when technically justified, authorized, validated or verified, and recorded?
42. Does the laboratory have procedures to ensure that test methods used are validated or verified before use?
- Are reference methods verified for use in the laboratory?
 - Are laboratory methods validated or verified for use in the laboratory?
43. Does the laboratory maintain the following records when a method is validated or verified:
- Validation or verification procedure used?
 - Anticipated method performance requirements (e.g. accuracy, measurement uncertainty, selectivity, repeatability, detection limit)?
 - Actual method performance characteristics?

- d. Results obtained?
- e. Statement of validity of method indicating fitness for intended use?

Control of Data

- 44. Does the laboratory have procedures to ensure that all calculations and data transfers are subject to appropriate checks in a systematic manner?
 - a. Are spreadsheet formulas verified and locked to prevent accidental changes?
 - b. Are data transfers verified to ensure no loss of data or transcription or translation of results?
 - c. Are final results protected from changes?
 - d. Are changes captured (e.g. automated audit trails in software or other means)?
- 45. Does the laboratory have procedures to ensure that any computer software used to generate data, including any software developed by the user, is validated?

Equipment

- 46. Does the laboratory have procedures to ensure that equipment and software used to generate data is uniquely identified, capable of achieving the accuracy required, and complies with the specifications relevant to the tests prior to being placed into service?
- 47. Does the laboratory have procedures in place to ensure the proper use of equipment to generate data including, handling, transport, storage, use and planned maintenance of the equipment?
- 48. Are records for equipment and software used to generate data maintained and do they include at least the following:
 - a. The identity and unique identification of the equipment and/or software?
 - b. Checks that the equipment complies with the required specifications?
 - c. Dates, results, and copies of reports and certificates of all maintenance, calibrations, and adjustments, including any damage, malfunctions, modifications, or repair to the equipment?
- 49. Does the laboratory have procedures for the calibration of equipment, including calibrations and verifications performed prior to being placed in service?
- 50. Does the laboratory have procedures for the use of reference standards and materials, and do they include at least the following:
 - a. Instructions and records for the use and traceability of reference standards and reference materials in order to prevent contamination or deterioration and to protect their integrity (e.g. this does not need to be a single document)?
 - b. Instructions for the safe handling, transport, storage of reference standards and reference materials?

Laboratory Sampling

Note: If your laboratory is not responsible for collecting the primary sample from the decision unit, please communicate these best practices with customer/sampling organization and/or collaborate with sampling personnel on best practices.

- 51. For those laboratories responsible for sample collection:

- a. Does the laboratory have protocols for sampling, based on the appropriate statistical methods?
- b. Are training/education/experience/competency records available for sampling personnel?
- c. Are traceability records maintained for this sampling that include clear identification of the sample, identification of the sampler, the environmental conditions, the start date of sampling, the protocol used for sampling, and the identification of the sampling location (when necessary)?

52. Does the laboratory have procedures in place for:

- a. Developing sampling plans with the sampling entity, including establishment of SQC and development of a jointly agreed upon sampling protocol?
- b. Documenting chain-of-custody for samples?
- c. Demonstrating that the samples and their associated records can be uniquely identified and retained while maintained in the laboratory?
- d. Recording, upon receipt of the samples, any abnormalities or departures from normal or specified conditions?
- e. Providing secure storage, handling and preparation to avoid deterioration, loss or damage to the samples?
- f. Ensuring samples are tracked and logged into the laboratory's system?
- g. Sampling records adequately describing the process to assure the integrity and quality (representivity) of samples?
- h. Laboratory sampling protocols that are validated as fit for purpose to assure the confidence needed to make relevant regulatory inference and decisions?

53. Does the laboratory and/or regulatory program have adequate sampling data and records (e.g., product lot identification, description, sampling methodology and traceability to manufacturers/owners/suppliers/growers)?

Quality Control of Test Results

54. Does the laboratory have quality control procedures with acceptance criteria for monitoring (e.g., control charting) the accuracy of the test methods undertaken to generate this data to include where appropriate, but not limited to, the following:

- a. Regular use of certified reference materials, live or inactivated cultures, molecular controls and internal quality controls?
- b. Ensuring that alternative instrumentation used has been calibrated?
- c. Ensuring that functional checks of measuring and testing equipment have occurred?
- d. Implementation and assessment of quality control (e.g., controls, blanks, replicates, spikes, reference materials) with each batch run for the batch used to generate this data?
- e. Performance of intra-laboratory comparisons and testing of blind samples?

55. Does the laboratory have procedures to ensure that the results of tests or series of tests carried out by the laboratory to generate this data are reviewed, reported accurately and in accordance with any specified instructions in the test methods?

56. Does the laboratory have quality control procedures in place to monitor the error (uncertainty) associated with each sample preparation (mass reduction) and test procedure?
57. Does the laboratory participate in proficiency testing programs and/or inter-laboratory comparison with the methods used to generate this data?

Reporting of Test Results

58. Does the laboratory have procedures established to prevent the production of unauthorized reports or other documents?
59. Can amended records (technical) be tracked to previous or original versions?
60. Are preliminary/interim reports so marked?
61. Does the laboratory sample records contain at least the following, or the information is accessible for action as needed (i.e. stored by an inspection entity) to ensure traceability:
 - a. Identification of the personnel and employer who collected and shipped samples
 - b. Identification of the personnel preparing samples
 - c. Identification of the personnel performing tests
 - d. Unique sample identification given to the sample
 - e. The name and address of the laboratory where the testing was carried out
 - f. Accurate and complete identification of sample (e.g., description of sample, product, lot(s), labeling, container, condition of custody seal, reserve sample, photograph)
 - g. Status of sample (e.g., surveillance, violation, detention)
 - h. Verification of shipment lot, composition, and availability for sampling (if needed)
 - i. Identification of sample source/owner for traceback (e.g., retailer, warehouse, shipper, grower, importer, exporter, import entry number)
 - j. Identification and detailed description of sampling procedure (e.g., date, sampler, equipment, containers, total lot size, number increments and location, increment and total sample weight, photographs, any deviations from sampling plan)
 - k. Clear description of sample receipt, condition and receiver
 - l. Complete and unbroken records of chain of custody documented from sample collection to discard
 - m. Accurate and complete identification and description of subsamples
 - n. Identification/name/source of the method used for the testing, along with any deviation from or additions to the test method
 - o. Identification of equipment for traceback (e.g. thermometers, balance)
 - p. Any dates associated with the testing (e.g., date of sample receipt, testing date)
 - q. The name(s), title(s), and signature(s) (or other equivalent approval stamp) of person(s) approving the release of test data for reporting

- r. The date the report was issued and clear identification that all parts of the report belong together and clear identification of end
 - s. When applying a statement of conformity of a specification or standard, document the decision rule applied and take into account the level of risk
62. Does the laboratory report error (uncertainty) associated with all the sample preparation and test procedures (combine repeatability or uncertainty)?
- a. If error is not reported, is the laboratory able to produce this information?
 - b. Can the laboratory contribute sufficient information so that the customer/ organization can calculate global estimation error?
63. Does the laboratory let the customer know what methods are under the scope of accreditation?

Appendix B: Glossary of Terms

Accreditation	Formal recognition of a laboratory by an independent science-based organization that the laboratory is competent to perform specific tests.
Accreditation Body	An independent entity that operates in conformity with the standard ISO/IEC 17011 and that is technically competent to accredit testing laboratories using the standard ISO/IEC 17025. The 2016 MFRPS Standards require the laboratory's accreditation body to be a full member of the ILAC and a signatory to the ILAC MRA.
Accredited Laboratories	Formal recognition that a testing or calibration laboratory is competent to carry out specific tests or calibrations.
Accuracy	The closeness of agreement between a test result and an accepted reference value. When applied to test results, accuracy includes a combination of random and systematic error. When applied to test method, accuracy refers to a combination of trueness and precision.
Analyte	The chemical substance measured and/or identified in a test sample by the method of analysis.
Analyte Integrity	The characteristic or concentration of the analyte of interest is maintained from selection of the primary sample through selection of the test portion (maintain sample correctness).
Analytical Worksheet	An internal document in printed form for recording information about the sample, the test procedure and the results of testing. It may be complemented by the raw data obtained in the analysis.
Audit or Internal Audit ¹	A process that checks that the quality procedures are in place and fully implemented; "Are we doing what we say?"
Blank	A substance that does not contain the analytes of interest and is subjected to the usual measurement process. Blanks can be further classified as method blanks, matrix blanks, reagent blanks, instrument blanks, and field blanks.
Calibration	Determination of the relationship between the observed analyte signal generated by the measuring/detection system and the quantity of analyte present in the sample measured. Typically, this is accomplished through the use of calibration standards containing known amounts of analyte.
Calibration Records	The records generated from the set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.
Certified	Result of a procedure by which a third party gives written assurance (certificate of conformity) that a product, process or service conforms to specified requirements.
Certified Reference Material	Reference material accompanied by documentation (certificate) issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceability, using valid procedures.

Chain of Custody	Procedures for formal chronological documentation that records the sequence of collection, custody, control, transfer, receipt, analysis, and disposition of physical (e.g., laboratory sample) or electronic evidence.
Competency	Possession of required skill, knowledge and qualifications to perform a task.
Complaint	Expression of dissatisfaction by any person or organization to a laboratory relating to the activities or results of that laboratory, where a response is expected
Contract	The final agreement or covenant between the customer and the laboratory – does not have to be a legal or written contract.
Control Chart	A graphical plot of LCS or other QC results over time which include upper and lower warning and control limits; control chart limits are defined above in “Intermediate Precision.”
Confidence	Full trust; belief in the powers, trustworthiness, or reliability of a person or thing.
Correction	Action to eliminate a detected nonconformity; the immediate action taken to correct a problem, usually to allow data to be reported to a customer; examples include making an adjustment, fixing a mistake, taking immediate remedial action, repeating analyses or recalibrating equipment.
Corrective Action	The long-term action taken to investigate and eliminate the cause(s) of an existing nonconformity through root cause analysis, departure from a procedure, or other undesirable situation in order to prevent recurrence.
Departure	See “Nonconformity”
Decision Unit	A material from which a sample is collected and to which an inference is made.
Decision Rule	Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.
Defensible	Sufficient in scientific quality and evidentiary integrity to justify the action/ outcome (e.g. data, decision).
Deviation – Test Method	A temporary change to a test method; requires a document to be prepared, approval by the document owner; technical justification to demonstrate the ability to get the correct result and approval from the customer (this could also be a contract deviation.
Document Control	A system to track, manage and store documents, data and software that support the laboratory’s quality management system.
Documents	Anything that tells a person in the laboratory what to do or how to do it.
Environmental Conditions	Laboratory conditions, such as temperature, humidity, biological sterility and electrical supply that would negatively affect the ability to get correct results.
Evidentiary integrity	The identification and authentication of the evidence.
Feedback	Communication from customers about how delivered test results and other services compare with customer expectations.
Fit for Purpose	Degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose.
Global Estimation Error	Total errors in the entire measurement process, from primary sampling through final measurement.

Impartiality	Presence of objectivity
Instruments	Measuring equipment
Inter-laboratory comparison	Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions
Intra-laboratory comparison	Organization, performance and evaluation of measurements or tests on the same or similar items within the same laboratory in accordance with predetermined conditions
ISO/IEC 17025	Published standard by the International Organization for Standardization (ISO) which outlines the general requirements for the competence of testing and calibration laboratories to establish
quality management systems to help ensure the acquisition of consistent and reliable laboratory data.	Standard methods are those published by international, regional or national standards-writing bodies; by reputable technical organizations; in legal references; and federal methods, such as FDA published methods. The laboratory's procedures should be traceable to a recognized, validated method, if one is available.
Laboratory	Body that performs one or more of the following activities: a. Testing b. Calibration c. Sampling, associated with subsequent testing or calibration
Limit of Detection	The minimum amount or concentration of analyte that can be reliably distinguished from zero. The term is usually restricted to the response of the detection system and is often referred to as the Detection Limit.
Limit of Quantitation	The minimum amount or concentration of analyte in the test sample that can be quantified with acceptable precision. Limit of quantitation (or quantification) is variously defined but must be a value greater than the MDL and should apply to the complete analytical method.
Linearity	The ability of a method, within a certain range, to provide an instrumental response or test results proportional to the quantity of analyte to be determined in the test sample.
Management Review	A periodic management meeting to review the status and effectiveness of the laboratory's quality management system and to use this review as an opportunity for improvement of that system; "Is what we 'say' OK?"
Mass Reduction Process	Selection of a smaller mass or volume from a larger mass or volume.
Method, Laboratory Developed (In House)	Design, optimization and preliminary assessment of the performance characteristics of a method within the laboratory. This includes methods from scientific journals and unpublished laboratory-developed methods.
Method, Standard, Official, or Reference	Standard methods are those published by international, regional or national standards-writing bodies; by reputable technical organizations; in legal references; and federal methods, such as FDA published methods. The laboratory's procedures should be traceable to a recognized, validated method, if one is available.
Nonconforming Work	When one or more characteristics of a project fail to meet specified requirements including testing data, calibration data, and quality control/proficiency test failures.

Nonconformity	Departure, deficiency, nonconformance; the failure to properly follow procedures, instructions, etc. or the nonfulfillment of a specified requirement.
Nonselection process	Manipulation of a sample (e.g., comminution, removal of extraneous material, removal of water), usually performed before a selection (e.g., mass reduction) process.
Obsolete Document	A document that is no longer in use, but describes the process from time “A” to time “B.”
Precision	The closeness of agreement between independent test results obtained under specified conditions. The precision is described by statistical methods such as a standard deviation or confidence limit of test results.
Procedure	The “step-by-step” instructions or the “how” or “the steps in a process and how these steps are to be performed for the process to fulfill specified requirements.”
Proficiency Testing	Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.
Quality Assurance Plan	A formal document describing the quality assurance system; QMS
Quality Control	Those activities that are performed during the analysis to fulfill the requirements for quality; normally quality control is applied to the full method, as opposed to just the final determinative step; e.g. using a “Laboratory Control Sample” or LCS.
Quality Management System (QMS)	A structured, non-technical system describing the procedures, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services; quality assurance plan.
Raw Data	Information collected from the original source that has not been subjected to processing or any other manipulation, also referred to as primary data.
Records	The “proof” that documents in the laboratory’s quality management system have been followed. The assessor/auditor believes that if there is no record, the task has not been done.
Reference	External or internal document that was used to develop the test method or is closely associated with the test method.
Reference Material ¹	A material, sufficiently homogenous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process or in examination of nominal properties.
Reference Standard	A standard, generally having the highest metrological quality available at a given location in a given organization, from which measurements are made or derived. Note: Generally, this refers to recognized national or international traceable standards provided by a standards producing body such as the National Institute of Standards and Technology (NIST).
Regulatory Action	When a governmental agency acts to enforce compliance with a law or administrative rule or regulation adopted by a governmental agency pursuant to authority conferred by law.
Reproducibility	Precision obtained under observation conditions where independent test results are obtained with the same method on identical test items in different test facilities with different operators using different equipment.
Requirement	Need or expectation that is stated, generally implied or obligatory. An imperative or a must.

Robustness	A measure of the capacity of an analytical procedure to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage.
Sample	<p>A mass or volume of a material selected from larger mass or volume of material using the principles of Theory of Sampling. The word “sample” should only be used with a modifier as follows:</p> <p>Primary sample: The material selected from a decision unit.</p> <p>Laboratory sample: The material received by the laboratory.</p> <p>Analytical sample: The material from which a test portion is selected.</p> <p>Test portion: The mass or volume of material selected from an analytical sample for a single test.</p> <p>Replicate sample(s): Multiple samples collected under comparable conditions.</p> <p>Split sample(s): Equal portions obtained by dividing a primary, laboratory or analytical sample in its entirety.</p> <p>Composite sample: Multiple laboratory samples, multiple analytical samples, or multiple test portions, combined solely for the purpose of analytical efficiency.</p>
Sample Quality Criteria (SQC)	A series of statements that clarify program technical and quality requirements to support defensible decisions. These statements include the question to be answered, definition of the decision unit, and the desired confidence in the inference.
Sampling Plan	Defines the purpose and frequency of sampling, the types of food/feed commodities, and the firms/locations that may be samples.
Sampling Protocol	A detailed procedure for obtaining a representative sample from a specific decision unit that meets the sample quality criteria. The protocol includes appropriate mass, number of increments, sample correctness, quality control, and procedures for maintaining evidentiary integrity.
Scope of Accreditation	The fundamental document attesting to an organization’s competence to perform test and/or calibration services; detailed statement from the accrediting body of the activities for which a laboratory is accredited.
Selection process	The act of selecting a smaller mass or volume from a larger mass or volume. There are two types of selection processes: mass reduction and splitting.
Selectivity	The extent to which a method can determine particular analyte(s) in a mixture(s) or matrix(ces) without interferences from other components of similar behavior. Selectivity is generally preferred in analytical chemistry over the term Specificity.
Sensitivity	The change in instrument response which corresponds to a change in the measured quantity (e.g., analyte concentration). Sensitivity is commonly defined as the gradient of the response curve or slope of the calibration curve at a level near the LOQ.
Should	Strong recommendation or “guideline”. A note in ISO/IEC 17025
Software	A general term used to describe a collection of computer programs, procedures and documentation that perform some data-related task on a computer system.

Stability	Variation of a test, test item, reference material, etc. with time under the influence of a variety of environmental factors, such as temperature, humidity and light.
Standard Operating Procedure	A written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.
Technical Data and Records	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.
Test Method	All of the critical activities to be performed to obtain analytical results; same as “procedure.”
Uncertainty ¹	Non-negative parameter characterizing the dispersion of the values being attributed to the measured value; error.
Validation	The process of demonstrating or confirming that a method is suitable for its intended purpose. Validation includes demonstrating performance characteristics such as accuracy, precision, specificity, limit of detection, limit of quantitation, linearity, range, ruggedness and robustness.
Verification	The process of demonstrating that a laboratory is capable of replicating a validated method with an acceptable level of performance.
Violation	When it is established through competent and substantial evidence that an action, including the manufacture or distribution of a product, or a failure to act does not meet the requirements of a law or administrative rule or regulation adopted by a governmental agency pursuant to authority conferred by law.

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