

# Best Practices for Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories



NOVEMBER 2016

**Publication date:** October 2016

**First revision:** November 2016

APHL gratefully acknowledges the APHL Data Acceptance Work Group for their participation and assistance in this project.

APHL also thanks the Association of Food and Drug Officials (AFDO) and the Association of American Feed Control Officials (AAFCO) for their technical and editorial contributions towards this publication. We appreciate the collaborative relationship built among our three associations through our Cooperative Agreement with FDA.



This project was 100% funded with federal funds from a federal program of \$1,500,000. This publication was supported by Cooperative Agreement # 1U18FD004710 from the Food and Drug Administration (FDA). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of FDA.

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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 customers 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) 17025:2005 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), 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 food and feed testing, especially when that data could become relevant to regulatory partners. External accreditation by independent auditors to ISO/IEC 17025 standards 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 food and feed laboratories, particularly those testing products imported into the United States. Although governmental laboratories are not referenced in FSMA, accreditation may help laboratories meet the requirements of a variety of customers at the local, state and national levels.

Some governmental laboratories operate in an environment in which ISO accreditation may not be fiscally justifiable. Food and feed testing may be performed only in rare instances, 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 document 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 it 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 Food/Feed Testing Laboratories Best Practices Manual (Draft)* (PFP Manual; under revision).

This document also holds value for food and feed testing laboratories that have achieved ISO/IEC 17025 accreditation. 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 food or feed safety emergencies, newly developed methods may fall into this category (e.g., melamine, oil spill contaminants, etc.) and yet it may be very important to share results from these analyses. This document is intended to assist laboratories in identifying those specific policies, procedures and records that should be in place in order to share such food and feed 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 *this comparison*.
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 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 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 definitions on page 20 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. Comments and suggested revisions are encouraged and may be sent to [foodsafety@aphl.org](mailto: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

Laboratory workflow begins when the sample is received and ends when results are reported and sample dispensation occurs. However, the pre-analytical process begins much earlier. The sampling conducted and the testing required are often dependent on specific program requirements delineated in contracts or other work orders. The collection of appropriate representative samples under optimal conditions and ongoing discussions with the entity requesting the testing to determine their requirements and needs is critical.

#### **Requirements for Chain of Custody**

Laboratories should have a chain of custody (security, accountability, and integrity) process that meets the needs of the customers and includes sample receipt and follows the sample through the laboratory. Discussions between the laboratory and the customer regarding chain of custody should occur prior to sampling. An example chain of custody form can be found in Appendix B.

### **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 food or feed 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 food or feed 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 \(GOODSamples\)](#), the [PFP Manual](#) (Sampling, Chapter 4), and [FDA Investigations Operations Manual](#), most recent version (Chapter 4, Sampling).

### **Analytical Phase**

The QMS elements covering the analytical phase of testing include multiple components including a Quality Assurance Plan, staff training, demonstration of capability and competency, the selection of analytical methods, and test method validation and verification to ensure fit for purpose. 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 the documentation of raw data results via 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. Handling of samples (this may be in the method SOP), including receipt and log-in of samples; a system for unique identification; sample preparation procedure including any subsampling and particle size reduction; and sample preservation and storage
2. Selection of the analytical test method(s)
3. Handling and traceability of analytical reference material and standards
4. Equipment calibration, verification and maintenance
5. Document management and control to ensure use and availability of only the most current procedures, worksheets, etc.
6. Record management and control to ensure accurate, complete and secure records and data (including records retention considerations)
7. 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
8. Non-conforming testing or calibration(s) and 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, limit of quantitation, selectivity, stability in matrix, stability, robustness, sensitivity, reproducibility, uncertainty, and linearity, where applicable (See ISO/IEC 17025:2005 Section 5.4.5 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 if quality critical, supplies, equipment and instrument identification if quality critical items, weights, dilutions, concentrations, calculations, test results, and any deviations or modifications from the 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) or within a reasonable timeframe.

## **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 included comments. 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. 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 policies and procedures on record creation and retention. The laboratory should ensure that customers (programs and data users) are aware of these policies and procedures.

### **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. These records include sample chain of custody, technical data and associated records, equipment records, 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 if available, external) audits provides 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 food or feed 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 17025:2005 (or current version) standards to analyze food and environmental samples. The laboratory's accreditation body must be a full member of the ILAC and a signatory to the ILAC MRA. If the State laboratory is not ISO/IEC 17025:2005 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 17025:2005. Standard 10 of the MFRPS describes the 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 feed testing services, the January 2014 version of the AFRPS requires that the laboratory should follow the Association of American Feed Control Officials (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, 2015 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 list of laboratory contacts that can provide analytical assistance in the event of a food-related emergency that exceeds the capability of the primary laboratory.

## 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 conform 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 laboratory’s customers should evaluate the utility of the data provided to them. This may include customers within the same agency (i.e., a state department of agriculture), customers contracting

with the laboratory (i.e., the USDA Pesticide Data Program, the MFRPS program, AFRPS program, the Food Emergency Response Network), another state agency, and other regulatory agencies who require the data due to interstate commerce (i.e., FDA). 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.

The essence of data acceptance is best described in the ISO/IEC 17025 management requirements and customer service clauses, which say that the laboratory should be willing to cooperate with customers in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed. It is the responsibility of the laboratory to carry out its testing and calibration activities 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 policies and 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.

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 food and feed testing community strengthens food safety protections and improves public health nationally.

## **VI. Conclusion**

FSMA includes provisions that may soon require accreditation of private food and feed 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 these best practices 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. Likewise, 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 stream-lined 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. 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 case, but by working together laboratories and their partners can achieve a level of quality and efficiency that supports the protection of food and feed 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](mailto: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 quality management system 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. Are the following procedures in place:
  - a. Corrective actions
  - b. Preventive actions
  - c. Complaint process
  - d. Control of non-conforming work
6. Does the laboratory perform a management review at least annually covering the following:
  - a. Suitability of policies and procedures
  - b. Review of internal and external audits
  - c. Corrective and preventative actions
  - d. Volume and type of work
  - e. Feedback from customers including complaints
  - f. Resources which include personnel and equipment
  - g. Other relevant factors that impact quality of testing

### Document Control

7. 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 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. Suitable markings of retained obsolete documents or segregation?
- g. Documents are uniquely identified and accurately cross-referenced? (i.e., have a naming convention)?
- h. Are the external documents, regulations, standards and manuals controlled?

### **Laboratory/Customer agreements**

- 8. 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, etc.)?
  - a. Does the system consider actionable levels and applicable laws?
  - b. Does the system include management approval prior to testing?

### **Subcontracting of test services**

- 9. If the laboratory subcontracts work, did it do so to laboratories that are either accredited to the ISO/IEC 17025 standard for that work or per the requirements of the customer?
  - a. Is a record maintained for all such subcontractors, along with evidence of their stated accreditation or compliance?

### **Purchasing**

- 10. Does the laboratory have a procedure or policy for the selection and purchasing of critical supplies, reagents, consumable materials, and services?
- 11. Does the laboratory verify that supplies comply with the standard specifications or requirements defined in the methods being used?
- 12. Is the laboratory ensuring that services and supplies meet pre-established specifications and will not adversely affect the quality of results?
- 13. Does the laboratory have an approved vendor list with regularly scheduled reviews?
- 14. Are the reviews documented?
- 15. Is the approved vendor list based on the laboratory's own evaluation of the quality of goods or services received (not just the state/government purchasing system approved vendors)?
- 16. Is the laboratory able to provide traceability for the critical supplies, reagents, and consumable materials?

### **Control of Non-conforming Work, Corrective Action, and Preventive Action**

- 17. Does the laboratory have policies and procedures detailing the acceptable handling of

nonconforming work or any departure from the policies and 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. Identify the personnel who have the authority to resume the work if the work was stopped?
- d. Require corrective actions to be taken immediately, together with any decision about the acceptability of the nonconforming work, including notifying the customer?
- e. Include the monitoring of results to ensure that the corrective actions taken have been effective?
- f. Identify needed improvements and potential sources of nonconformance, and does the laboratory take preventive action to reduce the likelihood of the reoccurrence of such nonconformance?

## **Records**

18. 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, corrective and preventive 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)?
19. 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?
20. Are all records secure and held in confidence? Does the laboratory have policies to prevent unauthorized access to computers or data stored in computers or lab information systems?
21. Does the laboratory have procedures to protect and back-up records held on computers or laboratory information systems?
22. 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**

23. 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?
24. 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)?
25. Do records contain sufficient information to recreate the testing including, but not limited to, dates, personnel, equipment, materials, method used, etc.?

### **Technical Personnel**

26. Are training/education/experience records available for all technical personnel generating test data?
27. Does the laboratory establish and maintain a training program?
28. Does the laboratory establish and maintain an ongoing competency/continuing demonstration of assessments for technical personnel?

### **Accommodation and Environmental Conditions (Facility)**

29. 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)?

### **Selection and Validation of Sample Preparation Methods**

30. Does the laboratory have policies and procedures to document that the sample preparation methods (including all mass reduction 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?
31. Does the laboratory have policies and procedures to validate/verify the performance of sample preparation methods (including all mass reduction procedures) used to generate this data as written?
  - a. Have reference methods performance been verified for use in the laboratory ?
  - b. Have laboratory developed methods been validated?

### **Selection and Validation of Test Methods**

32. 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/verified, and recorded?

33. Does the laboratory have procedures to ensure that test methods used are validated/verified before use?
  - a. Are reference methods verified for use in the laboratory ?
  - b. Are laboratory methods validated/verified for use in the laboratory?

### **Control of Data**

34. 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)?
35. Does the laboratory have procedures to ensure that any computer software developed by the user and used to generate this data is validated?

### **Equipment**

36. 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?
37. Does the laboratory have procedures in place to ensure the proper use of equipment is used to generate data?
38. 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?
39. Does the laboratory have procedures for the calibration of equipment, including calibrations and verifications performed prior to being placed in service?
40. 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?



## Sample Handling

Note: If your laboratory is not responsible for sampling, please communicate these best practices with your sampling organization and/or provide them with a copy of the sampling procedure.

For those laboratories responsible for sample collection:

41. 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 samplers?
  - 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)?
42. Does the laboratory have procedures in place for:
  - a. Developing sampling plans with the sampling entity, including establishment of sample quality criteria 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 of samples?
  - h. Sampling protocols assuring the confidence needed to make relevant regulatory inference and decisions?
43. Does the laboratory and/or regulatory program have adequate sampling data and records (product lot identification, description, sampling methodology and traceability to manufacturers/owners/suppliers/growers, etc.?)

## Quality Control of Test Results

44. 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, but not limited to, the following:
  - a. Regular use of certified reference materials, cultures and/or internal quality controls?
  - b. Participation in inter-laboratory comparison or proficiency-testing programs, where

available, or in an intra-laboratory proficiency-testing program with the methods used to generate this data?

- c. Implement and assess quality control (e.g., controls, blanks, replicates, spikes, reference materials) with each batch run for the batch used to generate this data?
45. 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 reported accurately and in accordance with any specified instructions in the test methods?
46. Does the laboratory have quality control procedures in place to monitor the error (uncertainty) associated with each sample preparation (mass reduction) and test procedure?

### **Reporting of Test Results**

47. Does the laboratory have procedures established to prevent the production of unauthorized reports or other documents?
48. Are preliminary/interim reports so marked?
49. 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 of the laboratory where the testing was carried out
  - f. Accurate and complete identification of sample (description of sample, product, lot/s, labeling, container, condition of custody seal, reserve sample, photograph, etc.)
  - g. Status of sample (surveillance, violation, detention, etc.)
  - h. Verification of shipment lot, composition, and availability for sampling (if needed)
  - i. Identification of sample source/owner/traceback (retailer, warehouse, shipper, grower, importer, exporter, import entry number, etc.)
  - j. Identification and detailed description of sampling procedure (date, sampler, equipment, containers, total lot size, number increments and location, increment and total sample weight, photographs, any deviations from sampling plan, etc.)
  - 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 like thermometers and balance (for traceback)
  - p. Any dates associated with the testing (i.e. sample receipt, testing date, etc.)
  - q. The name(s), title(s), and signatures (or other equivalent approval stamp) of person(s) approving the release of test data for reporting
50. Does the laboratory report error (uncertainty) associated with all the sample preparation and test procedures (combine repeatability or uncertainty)?
- a. Or, if 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?

## Appendix B Example of Collection Report

<b>ANALYST WORKSHEET</b>	<b>1. PRODUCT</b>		<b>2. SAMPLE NUMBER</b>
<b>3. SEALS</b> <input type="checkbox"/> INTACT <input type="checkbox"/> BROKEN <input type="checkbox"/> NONE	<b>4. DATE REC'D</b>	<b>5. RECEIVED FROM</b>	<b>6. DISTRICT OR LABORATORY</b>
<b>7. DESCRIPTION OF SAMPLE</b>			
<b>8. NET CONTENTS</b>	<input type="checkbox"/> NOT DETERMINED <input type="checkbox"/> NOT APPLICABLE UNITS EXAMINED _____	DECLARE/UNIT _____ AMOUNT FOUND _____ % OF DECLARED _____	<b>9. LABELING</b> _____ ORIGINAL(S) SUBMITTED _____ COPIES SUBMITTED <input type="checkbox"/> NONE
<b>10. SUMMARY OF ANALYSIS</b>			
Container:			
Labeling:			
Code:			
Product:			
Analysis:			
Method:			
Results:			
<b>11. RESERVE SAMPLE</b>			
<b>12.a. ANALYST SIGNATURE (Broke Seal <input type="checkbox"/>)</b>		<b>13.</b>	<b>a. BY</b>
<b>b.</b>		<b>WORKSHEET CHECK</b>	<b>b. DATE</b>
<b>c.</b>		<b>14. DATE REPORTED</b>	
<b>ATTACHMENTS</b>		PAGE _____ OF _____ PAGES	

GENERAL SAMPLE INFORMATION & CHAIN OF CUSTODY

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## Appendix C

### 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 17025:2005. 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.
Action Level	Level of concern or target level for an analyte that must be reliably identified or quantified in a sample.
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 collection of the primary sample through 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 <sup>1</sup>	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 (CRM)	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	The order of places where, and the persons with whom, physical evidence was located from the time it was collected to its submission at trial. Laboratory samples are physical evidence. Chain of custody includes policy and procedure for handling and transfer of laboratory samples, as well as the full documentation of compliance with this policy and procedure for each laboratory sample. Documentation of chain of custody, including all test portions and test solutions, provides evidence that sample accountability, integrity, and security have been maintained.
Competency	Possession of required skill, knowledge and qualifications to perform a task.
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 policy or 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.
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	The over-all system of an organization or company for accessing, reviewing, revising, approving, disposition, and obsolescence of all documents, data, and software that are part of the laboratory’s management system (internally generated or from external sources); includes regulations, standards (such as ISO/IEC 17025), other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.
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.
Estimation of Uncertainty <sup>1</sup>	A non-negative parameter characterizing the dispersion of the quantity values being attributed to a measure and (the quantity to be measured), based on the information used.
Evidentiary integrity	Demonstration that the analytical result(s) can be traced to the decision unit and have not been compromised. In legal terms, it is 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 (GEE)	Total errors in the entire measurement process, from primary sampling through final measurement.
Instruments	Measuring equipment
ISO/IEC17025	Published standard by the International Organization for Standardization (ISO) which outlines the general requirements for the competence of testing and calibration laboratories to establish management systems to help ensure the acquisition of consistent and reliable laboratory data.
Limit of Detection (LOD)	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 (LOQ)	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 Management System and to use this review as an opportunity for improvement of that system; "Is what we 'say' OK?"
Mass Reduction	The process of selecting a smaller mass from a larger mass (not to be confused with comminution/particle size reduction).
Measurement Traceability <sup>1</sup>	The property of a result of a measurement whereby the result can be related to a reference (standard or material) through a recorded unbroken chain of calibrations or comparisons; essentially, the establishment of the accuracy of the results.
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.
Non-Conformance	A departure from established policies and procedures.
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 policies, procedures, instructions, etc. or the nonfulfillment of a specified requirement.
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.
Preventive Action	Actions taken to prevent a non-conformity or departure from established policies and procedures; a proactive process to identify opportunities for improvement rather than a simple reaction to identified problems or complaints.
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	an independent and unbiased assessment of the performance of all aspects of a laboratory, both human and equipment/instruments; analysis of samples of known value(s) obtained from approved providers to evaluate/monitor continuing acceptable performance.
Quality Assurance Plan	A formal document describing the Quality Assurance system.
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	a structured, non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.
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 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 <sup>1</sup>	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 portion of a material selected from larger quantity of material. The word “sample” should only be used with a modifier as follows:</p> <p>Primary sample: The collection of one or more increments taken from a decision unit according to a sampling protocol.</p> <p>Laboratory sample: The portion of material received by the laboratory.</p> <p>Analytical sample: Results from any manipulation of a laboratory sample.</p> <p>Test portion: The quantity of material taken for measurement.</p> <p>Replicate sample(s): Additional samples collected under comparable conditions at any point in the sampling process.</p> <p>Split sample(s): Portions obtained when a primary, laboratory or analytical sample is subdivided.</p> <p>Composite sample: A term often misused and avoided in this document. A mixture of primary samples or laboratory samples, combined prior to analysis 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.
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 <sup>1</sup>	Non-negative parameter characterizing the dispersion of the values being attributed to the measured value.
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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## **Association of Public Health Laboratories**

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.



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