Sections in This Document

1. Introduction

MAN-000044 ORA Lab Manual Vol. II - Reporting Laboratory Results (ORA-LAB.5.10), defines how the Office of Regulatory Science (ORS) meets accreditation requirements for reporting regulatory laboratory data. This document provides additional instructions for FDA policies and practices in the preparation of analytical packages, including block-by-block guidance for completing an Analyst Worksheet and other associated documentation. This document also describes laboratory protocols for recording observations and analytical findings in various formats.

2. Analyst Worksheets

The analyst worksheet package, including supporting documents, is prepared to provide a complete, accurate, and legible account of sample handling and analysis to support regulatory action. It is the record that will be used and referenced in a court of law, should regulatory action be taken.

2.1. Regulatory Worksheets

FORM FDA 431 and FORM FDA 431a templates comprise the standard requirements and structure for all regulatory reporting.

A variety of harmonized worksheets, worksheet templates, and web applications have been developed to support laboratory sample data recording and handling. Sections 4 and 5 provide specific instructions for completing regulatory worksheets and continuation forms.

A. Regulatory worksheets must follow the general template and format of the FDA FORM 431 and 431a when continuing information is needed; and be consistent with this manual.

B. These forms are used to record raw analytical data, calculations, quality controls, calibrations, standardizations, materials, and instruments or equipment used to complete the analysis, or reference to attachments, logbooks, or appropriate worksheets containing this information.

   1. FDA FORM 431 serves as the template containing all required elements in reporting data. FORM 431a is a continuation of this data or observations used with the FORM 431.

   2. The ALIS web application generates an ALIS Summary Report (ASR) and ALIS Continuation Report (ACR) that comprise the Regulatory Worksheet for ALIS. For programs using ALIS, the automatically generated reports must be used. The ASR and ACR

contains the same elements and functionality as the traditional FORM 431 and FDA Form 431a. Early versions of the ASR and ACR may be referred to as the ALIS e431 and ALIS e431a, respectively.

4. For programs that have undergone Harmonization and Standardization (H&S), the specialized harmonized worksheet must be used. Updates to a harmonized worksheet are performed after a Document Change Request (DCR) has been submitted, and the dedicated H&S reviewers have approved the request.
5. When harmonized worksheets are not available, locally made worksheet templates may be used. When there is a need to do so, these must be reviewed and approved by lab management prior to use.

C. It is recommended a new Form 431, harmonized worksheet, or equivalent used outside of ALIS (ALIS discussed in 6.1.A) be initiated when a check, different, or new analysis is performed. The worksheet shall be noted as a check or additional analysis with a clear reference to the original sample analyzed. Refer to section 6 for Check analysis worksheet requirements.

2.2. Abbreviated and Specialized Worksheets

A. Specialized programs and assignments may use alternative reporting procedures under agreement with the customer and with approval from appropriate organizational oversight. Refer to MAN-000044 ORA Lab Manual Vol. II - Reporting Laboratory Results (ORA-LAB.5.10) Section § 6.10.2 for approval requirements.

B. Some programs have specialized worksheets that may or may not fall within regulatory reporting; however, the documentation must still follow approved standardized reporting protocols. Some examples may be:

1. Surveillance
2. Shelf-Life Extension Program
3. Total Diet Study (TDS)
4. US Pharmacopeia (USP)
5. Cooperative Research and Development Agreement (CRADA)
6. Forensic analysis

3. Recording Analytical Information, Observations and Findings

3.1. General

The laboratory analyst records descriptive information pertaining to the sample, its handling in the laboratory, and analytical findings and observations on Analyst Worksheets and in web applications.

A. Use only common abbreviations. The United States Pharmacopeia, General Notices, and the Official Methods of Analysis of AOAC INTERNATIONAL, Definition of Terms and Explanatory Notes contain recognized scientific abbreviations. Clearly explain any abbreviations by defining them the first time they are used.

B. Measurements are made in metric units (e.g., cm, gm). Results can be reported in the English system (e.g., oz, lb.) when applicable for comparison to label declarations, or when it is the accepted convention for reporting the value.

C. All analysts who participate in the handling of the sample from preparation to analysis to calculations/interpretation will record data and observations directly to worksheets as they are performed, including their initials or equivalent identifier to denote who accomplished the activity and the date performed.

D. When handwriting worksheets, the writing will be in permanent black or blue ink, and must be legible, neat, and of adequate size to be easily read and photocopied.

   1. Do not record information in the margins of the handwritten Analyst Worksheet.

   2. Unused areas of handwritten worksheets are marked by lining out. A diagonal line is placed through the entire empty space, initialed, and dated.

E. Analysts may enter raw data and observations electronically using electronic worksheet templates or web applications in lieu of printed forms. When data and observations are recorded electronically, laboratories take additional measures to protect integrity.

   1. The files are protected (e.g., locked cells, password) from inadvertent change or loss.

   2. The files containing raw data entries are identified to link them to the sample to maintain traceability.

3. The analyst carefully reviews entries before saving and closing the file containing the entries. (Corrections made prior to peer review do not require annotation.)
4. Unused areas should be marked in some manner to clearly indicate that no data has been omitted.

3.2. Correcting Errors on Worksheets

Errors or corrections are clearly indicated, without obscuring any other data, and in a manner that avoids misinterpretation to include an explanation when discarding data.

A. The following information designations must be clear when making a correction:
   1. Original data
   2. Correction of original data
   3. Explanation (when reason for change is not obvious)
   4. Person accountable for making correction
   5. Date correction was made

C. For handwritten worksheets do not erase or overwrite to correct errors. Draw a single line through the incorrect entry, write the correct entry nearby, and include date and initials. Include the appropriate annotation and explanation when discarding data.

D. Web applications used for data capture and reporting automatically capture changes that are made after the file is signed and closed, with username, date, and time stamp stored internally. The audit log tracking record shall be produced upon request for any changes examined.

E. Once worksheets are signed, they become part of the final analytical package and therefore are an official record when submitted to the end user or customer through the appropriate application, such as CMS, SMART, Freedom, etc. If corrections are necessary after the record is submitted, a new amended file is generated, and the original file is retained to ensure traceability to corrections made. (Refer to MAN-000044 Reporting Laboratory Results, § 6.12)

3.3. Instrument-Generated Reports and Charts

When instrument-generated reports are included in an analytical package, the report should provide information needed to interpret its graphic, tabular, or computational output. This information should appear on each sheet of the

report. The report should provide traceability to the instrument used, user (analyst), and sample.

In situations where an instrument produces reports containing numerous pages and it is not practical to annotate them all, annotate those used to form analytical conclusions with the interpretive information contributing toward the final outcome.

3.4. Photographs, X-Rays, and Electronic Documentation

The analytical package may include photographs, x-rays, and electronic documentation to illustrate labeling, to assist in describing the product, or to show an analytical finding. Because the size of an object may not be evident from the photograph or photocopy, include a ruler along with the object in the picture. When providing a photocopy with an enlargement or reduction, indicate the percent enlargement or reduction on the photocopy or mounting sheet. Photographs, x-rays, and electronic documentation must include sample identification, date, and initials.

3.5. Analyst Notebooks

Analysts may keep bound notebooks to record non-sample specific data and observations. Sample-specific data and observations are recorded on the analyst worksheets.

Sample background and other supporting information that may be contained in a notebook can be used as evidence in litigation.

A. Analyst notebooks are not to contain data, observations, and results applicable to identified samples.

B. Analyst notebooks are bound, with numbered pages.

C. Analyst notebooks are considered as records and must be maintained within the laboratory.

3.6. Miscellaneous Data Entry

A. Where data is generated for a series of similar samples with different sample numbers, it is not necessary to include a copy of that data with every sample package. Instead, each package in the series will include reference to the lead sample package that contains the original data.

   Examples of such data include a standard curve, the standardization of a solution, or TLC-plate observations.

B. Violative sample packages must include a copy of the original data, and a reference to the sample number of the package containing the original data. In the case where all samples in the set are violative, a copy of the

original data is not required with each sample package. The location of the original data must be referenced in each package.

C. All reference materials, standards, reagents, critical equipment, and instrumentation used during the analysis must have a unique identifier: for traceability; to ensure identification of factors affecting the measurement result and its associated measurement uncertainty; and to enable the repetition of the laboratory activity under conditions as close as possible to the original.

   This includes, but is not limited to, traceability to NIST (e.g., Certificate of Analysis, calibration certificate), storage conditions, pertinent preparation details, and software version for instruments used to generate results.

4. Worksheet Sections

The analyst worksheet is completed as follows: (Supplemental to MAN-000044 ORA Lab Manual Vol. II - Reporting Laboratory Results (ORA-LAB.5.10))

When initiating the worksheet, the original analyst should complete information outlined in Blocks 1 through 8, and description of the container, labeling, codes, and product information in Block 10.

Flag: Indicate the appropriate “flag” in the top left margin of the worksheet to highlight the nature and significance of the sample for reviewers. The flag can indicate when other related reports are available or if the sample has a specific reporting need. This is an “optional” designation except when the report is a Check or Additional Analysis. Laboratories are to follow their local procedures for flags. A flag may be used to indicate the following:

A. Original, Check and Additional Analysis Sample
B. Compliance and Surveillance Sample
C. Complaint Sample
D. Follow-up to Consumer Complaint, often denoted "F/U to CC”.
E. Dealer Voluntarily Holding Sample
F. Audit Sample
G. Split Sample; and
H. NDA and ANDA Sample

Block 1. Product: Specify the common or usual name of the product received for examination. When a label accompanies the product, the name entered is consistent with the name used on the product label. The name should be consistent with information reported on the Collection Report (CR), unless obvious discrepancies are noted. If the product is a drug, include dosage form and strength. If the drug is a USP product, note this as part of the description.

Block 2. Sample Number: The assigned sample number.

Block 3. Sample Seals: Indicate the official seal (form FDA-415a) condition upon sample receipt as “Intact” or “Broken” if the sample is sealed; or “None” if the sample is not sealed.

Block 4. Date Received: The date the analyst initiating the worksheet received the sample from the laboratory’s Sample Evidence Specialist, other analyst, or secure storage.

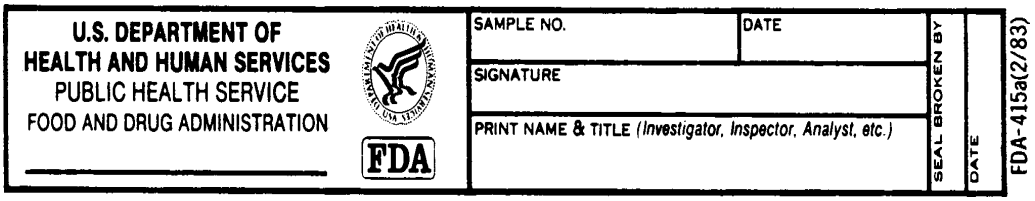
Block 5. Received From: The full name of person (first & last) from whom the sample was received, or location if the sample was obtained directly from secured storage.

Block 6. Laboratory: The common acronym for the laboratory.

Block 7. Description of Sample: The complete description of the sample received. Quote the seal inscription (see next paragraph) and describe the condition of the seal if damaged or broken (e.g., torn, cut). Quote the collector's identification on the sample, including sub-samples and sub-numbers as written (e.g., identified in part “X000001 1/1/00 SR” and numbered “sub 1”- “sub 8”). Specify the numbers and types of containers (e.g., clear plastic tray within a heat-sealed Mylar bag). Describe any abnormal sample conditions (e.g., torn, broken, not frozen). This section contains only the basics for sample accountability and is consistent with the information on the Collection Report; document any discrepancies between the two pertaining to the product name, collector’s identification on the package and on the seal, and the number of subs collected. Note: Analysts should notify their supervisor if the discrepancy is large enough to create doubt about whether the correct sample was received.

Quote the official seal (form FDA-415a) exactly as written, including any mistakes and corrections. The seal is quoted in this order: sample number, date, printed name, and title (e.g., "X000001 1/1/00 Sidney H. Rogers, Investigator"). When quoting a metal seal, quote both "U.S. Food and Drug" and the number on the seal. The seal quote is in quotation marks. The seal should be identical to that quoted on the CR, "Collector's Identification on Seal”. If a discrepancy exists, the seal should not be broken, and the analyst

should notify his or her supervisor. If a seal is completely illegible, the analyst should notify his or her supervisor and resolve seal problems with the investigator before proceeding.



Quote previously broken seal if present (e.g., from a previous analysis), and include "Seal(s) Broken By", initials and date. Do not remove any official seals from a sample unless necessary (e.g., to enter the sample or to maintain the chain of custody when there is no sample reserve).

If a seal is removed, mount it on a sheet of mounting paper and include with the analytical package as an attachment. For electronic analytical worksheets, attach a scan or digital photograph of the mounted label to the worksheet. Retain the mounted label in accordance with FDA records retention guidelines or until sample disposition is performed.

Note the fact that the seal (or digital copy) is attached and a brief description as to why the seal was removed on the worksheet in **Block 11**.

> **Other Information:** Describe all sample items down to the container in contact with the product. Additionally, describe any standards and reagents included with the sample. If there is insufficient space in **Block 7**, reference the location where information is continued. Note in **Block 7** any 702(b) portion received with the sample.

Block 8. Net Contents: Record label declaration of net contents. When the net contents are listed in multiple units (e.g., both fluid ounces and milliliters) record both declarations. If the label declares both a “net” and a “drained” weight, then record only the net weight.

When applicable, indicate the number of sub-samples examined for net contents in the space to the left of "Units Examined”. Also, report the average amount in units as declared on the label.

If there is no label or the label lacks a net contents declaration, check “Not Applicable.” If the sample contains a labeled net contents and net contents was not determined, check “Not Determined”.

Block 9. Labeling: Indicate the number of original labeling, sets, or copies submitted. Copies may be photocopies, photographs, handwritten copies "verified as true," etc. Copies are identified (e.g., sample number, date, initials

of collector or analyst) before copying or photo capture by the analyst. ALIS auto-generates the number of labels uploaded into the system as copies.

Check "None" if no product labeling is included with the analytical package. A “label” may be a single unit such as a label surrounding a can, or a set of separate units (e.g., Outer Product Labeling, Immediate Product Labeling, and Package Insert). A set collectively is considered as one original.

Select and submit labeling that includes the sample collector's identification if available. This reinforces sample integrity when original labeling cannot be submitted.

At least one unit with the original labeling is retained in the sample reserve for possible court use. The sample contents of the retained container may be removed for analysis. Only under exceptional circumstances and with supervisory approval may a labeling be removed from a single container that represents the sample and be submitted with the worksheet.

Analytical packages include one set of the original labeling, if available. When it is not feasible to include the actual labeling (e.g., pre-printed on the sample container or sample consists of one unit) a photocopy or photograph of the labeling is acceptable. These photocopies or photographs must be of high quality, legible, and include pictures of the entire product bottle/container labeling as well as all sides of any outer containers, including the outer container itself and its labeling.

In some cases, (e.g., survey samples and fresh produce submitted for pesticide residue analysis) submitting labels is not needed. This is at the discretion of the reviewing supervisor.

In rare instances when a photocopy or photograph is not available, handwritten or typed copies, which are “verified as true” by the original analyst and one additional analyst may be submitted. When quoting from labeling, use exact spelling, capitalization, punctuation, arrangement, etc., as found on the original labeling. Use asterisks to indicate any omissions. All originals and copies are identified with the FACTS sample number, date, and analyst’s initials.

When submitting original labeling with the worksheet, attach the physical labeling to a sheet of mounting paper. If labeling is on two sides of the submitted article, attach it to mounting paper in a manner that allows both sides to be reviewed (e.g., staple just the top or side to the mounting paper).

For non-ALIS Labeling requirements in the top right-hand corner of the mounting paper list the sample number, date, analyst’s initials, and the word “LABELING”. On the mounting paper describe what is being submitted (e.g., original cardboard box label, photocopy of bottle labeling, photograph of

original tube) and include identification for example as Outer Product Labeling, Immediate Product Labeling, Package Insert.

For ALIS Labeling requirements, all labels must be digitized and will be considered as an “Attachment”. Original physical labels should follow local procedures according to the established record file plan.

Block 10. Summary of Analysis: Summarize in concise and concrete language the following information under these headings and in the order listed:

A. Container
B. Labeling
C. Code
D. Product
E. Analysis (Purpose)
F. Method; and
G. Results.

Further clarification of directions for each of these items follows:

A. **Container:** Describe any commercial container in immediate contact with the product and any retail container(s) enclosing the immediate container. If a complete container or photo is submitted as labeling, do not describe it here, instead state that it is being submitted as labeling. Otherwise, record details as to the container’s type, size, color, and closure(s). Include a description of any commercial seals and their condition if present. Color and closure may not be pertinent for some products but are always needed for drugs. Describe any abnormalities or unusual conditions associated with the container, such as opened can, abnormal can, evidence of leakage, or broken commercial seal.

   Do not describe in detail containers furnished by FDA and used by the collector, such as “Inspector's glass vials”, “Whirl-Pak bag”, or “Mason jar”. For NDA and ANDA samples, describe only the primary product container. Secondary materials, such as standards and reagents, need not be described here, but should be referenced in Block 7: Description of Sample.

   Examples of container characteristics that should be described include the following:

   1. Shape (e.g., round, square).

2. Color and Transparency (e.g., “appears brown”, clear, transparent, translucent, opaque).
3. Material (e.g., glass, plastic, cardboard, Mylar).
4. Type (e.g., can, bag, vial, bottle, syringe).
5. Closure (e.g., screw cap, septum seal, heat sealed, intact clear plastic commercially sealed cap); and
6. Dimensions in metric units (e.g., 6.5 cm high x 3.2 cm diameter).

B. **Labeling:** Describe labeling associated with the sample, including that found on retail cartons, inserts, direct printing, and wrappers attached to sample units. If labeling is submitted with the Collection Report (e.g., copy of labeling from manufacturer’s box) or analyst worksheet, do not describe it here but state that this labeling has been submitted.

Carefully review the label and labeling for correlation between analytical results and labeling statements, and for compliance with applicable labeling regulations. Discrepancies should be noted on the worksheet, and the reviewing supervisor should reflect these in the summary report.

C. **Code:** Quote sample product codes and any product expiration date found on containers. Identify its type (e.g., embossed, ink stamped, perforated) and cite location. Do not record manufacturing codes (e.g., UPC, NDC). Timestamps do not need to be quoted unless they are the only code present. When there are units with differing codes in the sample, record all the codes, the number of units per code, and correlate these with the sample collector's sub-sample numbers. When there is a discrepancy between the observed code(s) and the code(s) cited on the FACTS Collection Report, record the discrepancy on the worksheet. For certain types of samples (e.g., devices) a warehouse storage number, serial number, or model number may serve the same function as a product code. If photographs or photocopies representing the code(s) are submitted with the analyst worksheet, do not describe it here but state that code has been submitted as labeling or as an attachment.

D. **Product:** Provide a complete and accurate description of the product. As applicable, include color, shape, odor, general appearance, and texture or consistency in lay language (e.g., frozen shrimp, whole frozen fish). When various sub-samples are raw materials, in-line products, finished products, and environmental samples, describe each in detail. Note any apparent abnormalities of the product (e.g., odor in aspirin

bottles, broken tablets, discoloration, biological growth). A picture may be submitted as an attachment to further clarify, but not substitute for, the product description.

Do not use the word “normal” to describe a product itself; however, it may be used to qualify a characteristic of that product, such as “normal appearance”.

In describing drugs in solid dosage form, the “Identification Guide for Solid Dosage Form”, Journal of the American Medical Association (JAMA) provides descriptive terminology that may be helpful.

Some products, such as devices, may be difficult to describe. In such cases one may supplement a written description with a drawing or photograph as an attachment whenever such an illustration will enhance the product description.

Identify and reference attachments in the written description.

E. **Analysis (Purpose):** Indicate the purpose of the analysis along with the number of units being tested. Refer to the FACTS Collection Report block entitled “Reason for Collection” if there are questions regarding the purpose. Remember that subsequent reviewers may not be familiar with the details of the case or analysis; therefore, the rationale for an analysis is important. Reference the compliance program, import alert, assignment, etc. when applicable.

F. **Method:** For standard and routine methods (e.g., United States Pharmacopeia, National Formulary, Official Methods of Analysis of AOAC INTERNATIONAL) or FDA “Official” methods (e.g., from compendia specified in the Food Drug and Cosmetic Act, Code of Federal Regulations and Compliance Programs, FDA manuals, SOPs) identify a complete method reference, including edition, revision, or date and page number(s). Ensure enough information is documented for traceability to method used. If applicable, record the section or chapter number, and date of any revision specific to section or chapter number. State any deviation and modifications made to the method here or reference where to find this information within the worksheet.

If selection and preparation of the analytical sample is not described in the method or applicable compliance program, describe this information in the analytical package.

For approved non-standard or non-routine laboratory developed methods, the method used is referenced and kept on file with the analyzing laboratory for non-violative samples. For violative samples,

the non-standard method will be included as an attachment to the analytical package as a memo of analysis referenced as “attached memo of...”. For a series of samples, each package in the series will include reference to the lead sample package that contains this memo. Experimental work for validation studies is kept on file with the analyzing laboratory and is available upon request.

G. **Results:** Present analytical findings in a clear and concise manner to expedite interpretation of the results, especially by non-technical, non-scientific personnel. Results are reported accurately with correct units based on factual findings.

Supply units (e.g., mg, oz, nm) for analytical data and express the data in the same units as those on the product label or applicable specifications. Whenever possible, tabulate the analytical data.

If sub-samples with differing codes were individually examined, separately report the results for each code because regulatory action may be based on the results for a particular code exclusive of other codes. Correlate results to the sub numbers and/or number of subs tested when applicable to the method or if not stated in sample preparation documentation.

Results must reflect the correct number of significant figures as indicated by the analytical method.

Compare the analytical results with the label declarations, published tolerances and standards, regulatory action levels, manufacturer's specifications, or other applicable criteria.

Record any discrepancies between analytical results and labeling statements or other criteria.

For analytical findings that are confirmed directly without a separate check analysis (e.g., confirmation of TLC spots that fade rapidly, identification of isolated filth elements, sensory confirmation) include a signed and dated statement as to what was confirmed and by whom.

Block 11. Reserve Sample: When a reserve sample is retained, provide a description, including location and storage conditions for accountability purposes. The amount of reserve remaining correlates with the difference between the amount received and the amount used in the analysis or provide an explanation for any discrepancy.

Quote the inscription on any new seal placed on the reserve sample. If the reserve sample is not returned to the sample evidence specialist, record the

place and condition of storage. When no reserve remains, state “NONE”, or “NO RESERVE”. Record the absence of a reserve in FACTS or in a LIMS.

When sending a portion of the sample to another party outside the laboratory, describe what was provided, how much, to whom, the date, how it was packaged and sealed, and a short explanation as to why the sample was sent.

If transferring all or a portion of the sample to an analyst within the laboratory indicate what was provided, to whom, the date, and a brief reason for the transfer. In cases where there are multiple transfers within the laboratory this information may be in an attachment and referenced in this block.

Return to the sample evidence specialist any developed x-rays or electronic media associated with the sample, which due to their bulk or storage-condition cannot be attached to the worksheet as part of the sample reserve. Otherwise submit such supporting documentation as attachments to the analytical report.

Block 12. Analyst Signature: If more than one analyst is involved in the analysis, the worksheet identifies the original analyst (who broke the seal) and everyone who assisted with the analytical process. It must be clear who did what activity within the work package.

Non-ALIS Generated Worksheets:

The Lead analyst signs and dates Block 12a upon completing the 431 and checks the “broke seal” box if applicable.

It should be the date the lead analyst completes pulling the package together and submits it for supervisory approval.

Other analysts or technicians participating in the analysis also sign in Block 12. Each analyst should identify, initial and date their work as it appears elsewhere in the package or specify their involvement with their signature in Block 12.

If more than three individuals are involved in the analysis, the signatures can be continued on the FORM FDA 431a.

When handwritten, everyone will print their full name adjacent to, above, or below their signature. PDF Adobe Certified Signatures using PIV card may replace wet signatures for electronic worksheets.

ALIS Generated Worksheets:

Upon completing the worksheet, the original analyst is identified in Block 12a and annotates having “Broke Seal” when applicable. Other analysts or technicians participating in the analysis are also identified in Block 12b with

their name and the date of their ALIS e-consent. The ASR will expand to fit all analysts who contributed to the analysis.

Block 13. Worksheet Check: A supervisor or designee fully knowledgeable of the type of analysis performed reviews the worksheets and supporting records for technical quality (e.g., method suitability, accuracy of calculations, accuracy of data transferred from one section of the worksheet or attachment to another, completeness).

Non-ALIS Generated Worksheets:

The person(s) who performs these checks signs and dates in this block. Worksheets that are maintained electronically may be signed using PDF Adobe Certified Signature using PIV card.

ALIS Generated Worksheets:

The person who performs these checks will apply final PDF Adobe Certified Signature using PIV card. This last and final certified signature attests the validity of all data captured in the report.

Block 14. Date Reported:

Non-ALIS Generated Worksheets:

Following completion of the final worksheet review, the supervisor or designee enters the date that the completed analytical package is classified.

ALIS Generated Worksheets:

Following completion of the final worksheet package by the analyst, ALIS automatically enters the date in which the system generated the report.

5. Continuation Worksheet

Use the FDA FORM 431a General Continuation Worksheet, approved ORS harmonized worksheets, or ALIS generated e431a or ACR to continue information from Block 7, Block 10, Block 11, and Block 12 of the initial worksheet when more room is necessary.

When information continues to another page, clearly indicate the block number, name and where it is continued (e.g., “continued on page 2”). Where the information is continued, reference where it is continued from (e.g., “continued from page 1 block 7”).

Complete the blocks of the continuation worksheet as follows:

A. **Product:** Enter product name identical to that found on the first page of the of the worksheet.

B. **Sample No.:** The FACTS assigned sample number. This number should be identical to that on the FORM FDA 431 or ASR.

C. **Body:** The body of the continuation worksheet can be used for the following:

1. To record other data and observations that will not fit on the first page of the worksheet.
2. To record raw analytical data, calculations, quality controls, calibrations, standardization, instrument operating parameters, and identification of instruments or equipment used to complete the analysis.
3. Use the following guidelines:
    a. Clearly annotate entries.
    b. Enter data in a clear, logical sequence. It is permissible to abbreviate, but there should be sufficient detail and identification for complete reconstruction and understanding of the data.
    c. When showing calculations, use the formulas given in the method whenever possible and explain any factors used in the calculation that are not evident in the method or from common knowledge.
4. Provide traceability for the equipment, instruments, materials, standards, and reagents used. At a minimum, record unique identification number to facilitate identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. If this data is in an attachment, then reference the location of this information (e.g., refer to Attachment #).

D. **Analyst:** The “lead” analyst signs his or her name in this block for paper generated forms. The “lead” analyst is identified in this block when the form is generated electronically, and final ink or PDF certified signature is applied to the 431 for the entire work package. This is the original analyst for the ALIS - generated ACR.

E. **Page Number:** Consecutively number all the pages (e.g., Page X of Y).

6. Check Analysis

The check analysis is performed to confirm a finding. The check analysis is performed by a standard method, validated, or FDA "Official" method. When such a procedure is not available, or is unsuitable for the analysis being performed, recovery data will be obtained to support validity of the results.

Requirements for check analyses are discussed below. These are not all-inclusive. There will be circumstances when the check is not required or, conversely, when it is judged necessary on a sample usually exempt from check analysis. Individual compliance programs and Compliance Policy Guides must be consulted for special requirements. When unusual circumstances exist, the appropriate center(s) must be consulted about the need for check analysis.

6.1. Check or Additional Analysis Requirements

The check analysis is necessary to confirm results on domestic and import violative regulatory samples, and those that will be referred to a local, State, or Federal agency, and that may form the basis for action by that agency.

A. When a Check or Additional Analysis is performed:

1. Using the FDA FORM 431 or approved ORS harmonized worksheet, clearly indicate the work as a check or additional analysis.
    a. When a new worksheet is generated flag this new worksheet per part 4 of this document, with the following exceptions:
        i. Blocks 8 and 9 need not be repeated, and can be left blank, or include the statement "see original analysis".
        ii. Under Block 10 for items that remain the same, such as the description of the container, labeling, codes, and product, enter the statement "see original analysis".
    b. When not generating a new worksheet, provide information on a continuation sheet that clearly indicates what was received as a sample, and what activity was performed on the sample. Indicate Check or Additional analysis. List what was done differently than the original analysis. In Block 11 of the 431, state where reserve sample is located.
2. When a Check or Additional Analysis is performed using ALIS, the automatically generated ASR/ALIS e431 and ACR/ALIS e431a must have clear indication of the type of analysis that is performed on each page. A new ASR is not required while using ALIS.

B. The check analysis will be conducted by a second competent and qualified analyst and, when available, on a separate, intact portion of the product (e.g., intact food product, intact tablets, unopened vials, or bottles of liquid products). In practice, there may be reasons for exceptions to this requirement:

   1. When sample preparation instructions require compositing and comminuting or blending the entire sample (e.g., some pesticide or metal samples), the check analyst will analyze a second portion of the prepared composite. When comminution is not required for the entire composited sample, the check analyst will take a representative portion of the uncomminuted composite and subject it to the required additional preparation.
   2. When program requirements do not provide an FDA reserve portion (e.g., certain medical devices, radiological health samples), where feasible, a second analyst may observe the original analyst's work or duplicate selected segments of the analysis on the same sample.
   3. When the examination is for isolated filth and extraneous material, the check analyst need only examine elements isolated by the original analyst from enough sub samples to be assured that the original analyst has reliably identified the elements.
   4. When visual examinations for defective units of foods, drugs, or devices are conducted by an analyst, another analyst (usually one who is more experienced) confirms the defects.
   5. For samples that traditionally do not have separate portions analyzed, this is not truly a check analysis, but is a confirmation of the original results. Such analyses include moisture and fat determinations on dairy product sub samples prepared by the original analyst, mold counts on sub samples prepared by the analyst if no FDA reserve portion is available, or organoleptic examination of sub samples analyzed by the original analyst if no FDA reserve is available and there are no instructions directing analysis of a separate intact portion.
   6. When reagents, standards, and equipment are required in the analysis, the check analysis will be conducted independently of the original analysis. The check analyst must prepare the reagents and standards used or must demonstrate by reanalysis (e.g., volumetric solution), controls (e.g., media), or other objective evidence that those prepared by others have been prepared properly. When traceable reference standards exist (e.g., National Institute of

Standards and Technology (NIST), USP), a reference standard from the current lot(s) must be used in the check analysis. When physical examinations are the issue and the same equipment must be used by the check analyst, the analyst must check the equipment to assure that it is calibrated and operating properly.

C. The check analysis of a sample may be requested by another FDA laboratory for a specific reason. Reasons for such a request include:

1. Availability of a specialized analyst who is familiar with the method or the range of analytical responses exhibited by the commodity;
2. Availability of specialized instrumentation; or
3. A Compliance program which specifies which FDA laboratory must perform this work.

6.2. Check Analysis Not Required

A check analysis is not necessary in the following instances:

A. When certain types of samples are specifically exempted from the requirement for a check analysis by a compliance program or by the Compliance Policy Guides.

B. When check analysis of specific samples is waived by the Center.

C. When the original analysis is performed by a national or international expert, unless specifically called for by a program or by the Compliance Policy Guides or when the method of analysis, instrumentation, or circumstances require check analysis by other experts. For field laboratories, this decision will be made by the Director, Office of Regulatory Science, in consultation with the laboratory director, and the appropriate Center compliance unit. Expert status shall be recorded on the analyst worksheet.

D. When the original analysis using a standard or FDA “Official” analytical method confirms the result of another government laboratory and personnel from that laboratory will so attest to the results.

E. The following types of out-of-compliance samples do not require check analysis:

1. Microbiological samples. Devices for sterility and samples analyzed for antibiotic potency using microbiological techniques do not require check analysis.
2. Samples originally examined for filth and extraneous material by an analyst recognized as a national or international expert in the

microanalytical identification. Isolated material must be maintained with the reserve sample.

3. Exhibits of filth and extraneous material that have been isolated and submitted by the investigator or inspector and confirmed by a qualified analyst.
4. Samples for net weight determinations when initial weight was measured by the investigator or inspector and confirmed by a qualified analyst.
5. Samples proposed for regulatory action based on labeling and the original analysis confirms the label declaration of ingredients.
6. Samples proposed for regulatory action where the violation is based on the qualitative identification by the laboratory of a prohibited substance which is present at “macro” (e.g., non-trace) level, using a highly specific method such as mass spectrometry or infrared spectroscopy.
7. Samples of surveying, leveling, or alignment laser products that are labeled as Class IIIb or IV (or the IEC equivalent Class 3B or 4).

7. FACTS (Field Accomplishments and Compliance Tracking System)

Laboratory analysts enter analytical findings and observations following the analysis. Individuals performing laboratory activities associated with the sample (e.g., preparation, sample analyses, peer worksheet review, and completion) are also recorded. The supervisor or designee enters final conclusions and sample classification codes. Laboratory personnel make every effort possible to ensure that they accurately enter data and errors are corrected as quickly as possible.

8. Assembling the Analytical Package

The lead analyst is responsible for assembling the worksheet package.

The composition of the analytical package varies depending upon how the sample is handled or treated by the laboratory. Different classifications of the sample may result in a package lacking one or more of the records. Examples of this include samples that are classified as Class 5 which are ones collected for analytical purposes but not examined or held for further action, and perishables that have arrived at the laboratory decomposed and cannot be analyzed. In this case, there will be no worksheets or analytical package; the sample will be closed in FACTS or LIMS.

Once the analysis is complete, records related to the sample are assembled for review as follows:

A. **Worksheets, Continuation Sheets (FORM FDA 431 and 431a), and Attachments** – Worksheets, continuation sheets, and attachments are assembled in a manner that effectively organizes and displays the analyst's findings.

B. **Page Numbering and Identification** – Worksheets and continuation sheets compose the main sections of the analytical package and are numbered in consecutive order using a format showing the total number of pages (e.g., 1 of 6, 2 of 6. . .6 of 6.)

C. **Attachments** – Additional analytical records (e.g., instrument or computer-generated charts and data sheets, photographs, negatives, developed x-rays, electronic media, or photocopies) accumulated during the analytical phase of the sample examination attached as needed to support laboratory findings and conclusions.

   1. Each page of each hardcopy package attachment will be directly identified with the sample number, unique attachment number or letter, date, and initials of the analyst.
   2. The first page of each attachment is also titled, and attachments with multiple pages are numbered (e.g., 1 of 4, 2 of 4. . . 4 of 4).
   3. If the attachment is less than the size of a page or of awkward shape, the item may be mounted securely on mounting paper. If mounting paper is used, it is also identified with the sample number, date, and the analyst's initials.
   4. The number of attachments included with the analytical package is listed as "Attachments A to ZZ" or "Attachments 1 to 999" in the bottom of block ten or in the bottom margin of the first page worksheet (FORM FDA 431). In situations where an instrument produces many reports (e.g., GC/MS and FTIR/MS) and it is not practical to attach them all to the package only those used to form analytical conclusions need be attached.
   5. ALIS identifies attachments in the upper right corner of the page.

D. **Labels and Labeling** – For paper-based documentation, although attached to the analytical worksheet labels and labeling should not be identified as "attachments". (Refer to Glossary for definition of "attachment" vs. "Labels and labeling"). The number and types of labels and labeling included with a package are identified in Block 9 of the basic worksheet.

ALIS labels are digitized and will be considered as a “Digital Attachment” in the system.

E. **Other Documents** – Optional (e.g., Collection Report, FDA 525, documents submitted with the sample, emails regarding sample)

F. **Digital Attachments** – documents are required to be digitized to include in the Analytical Work Package.

Refer to WI-000127 Upload of Analytical Work Packages and Lab Documents to the Compliance Management System and WI-000184 Converting Analytical Work Packages from Paper to Digital Format for detailed instructions.

9. Review of the Analytical Worksheet Package

After assembling the analytical package, the package is forwarded for review and approval.

A. Unless necessary, analysts who worked on the analysis should not review the final package. If a participant needs to be a reviewer, a brief justification should be provided on the bottom of the worksheet.

B. Refer to the ALIS User Manual for appropriate electronic worksheet check and review process for ALIS Generated Packages.

C. For non ALIS generated packages:

1. The worksheet check reviewer inspects the package for accuracy and completeness and for errors or omissions. If issues are identified, the worksheet is returned for correction. Once the worksheet and supporting documentation is satisfactory, the reviewer signs and dates in Block 13 on the first page of the worksheet. If the worksheet check is not performed by the supervisor, the package is forwarded to the responsible supervisor for further review and classification.

2. A supervisor reviews the package for accuracy and completeness. If errors or omissions are discovered, it will be returned to the analyst for correction. Once the reviewing supervisor determines that the worksheet and supporting documentation are satisfactory, he or she completes Block 13 (if it is not already completed because of an analyst review), enters the date reported in Block 14 and enters their

conclusions, related program assignment, and sample classification codes into FACTS or a LIMS.

3. Follow-Up Actions – If the data compiled by the analyst is insufficient or inadequate to determine the sample's compliance status, the responsible supervisor will contact the client (e.g., compliance officer, investigator, Center) to discuss and identify additional actions to resolve this situation.

10. Approval of the Analytical Package

Sample classifications are defined in the Glossary/Definitions section.

A. Approval for non-actionable samples (Class 1, 2, 4, and 5 Samples) – will be performed by the responsible supervisor or designee.

1. If found unsatisfactory, the supervisor or designee will return the package to the Analyst for corrections, changes, or additional testing.
2. To indicate approval, the supervisor or designee will set the sample status in FACTS or a LIMS to "Completed".

B. Approval of Class 3 Samples – Analytical packages for actionable samples are approved by the laboratory director or designee.

1. The responsible supervisor enters their conclusion(s) and sample classification code(s) into FACTS application when they find the package to be satisfactory. This supervisor then sets the status in FACTS to "Ready for the Laboratory Director's Review" and forwards the package to the director or designee.
2. The laboratory director or designee reviews both the analytical package and recommended conclusions in FACTS to apply final approval.
    a. If the director or designee is not satisfied with the package or the FACTS summary, the package is returned to the responsible supervisor for corrections, changes, or additional testing.
    b. Once the director or designee finds the analytical package and FACTS input satisfactory, they indicate their approval by setting the sample status in FACTS to "Completed".

11. Reporting Results

11.1. Reporting Microbiological Results

Report microbiological results in sample summary as indicated below:

NOTE: In the applied method section for Salmonella, Listeria, and Shigella testing, record “not speciated” under the Spcs Code.

A. Salmonella – No Salmonella spp. was detected in two composites analyzed.

B. Salmonella – Salmonella sp. was detected in one of two composites analyzed.

C. EHEC – No Enterohaemorrhagic Escherichia coli (EHEC) or STEC was detected in ten subs analyzed individually.

D. Listeria – No Listeria spp. was detected in two composites analyzed.

E. Listeria monocytogenes was detected in one of two composites analyzed.

F. Shigella – No Shigella spp. was detected in two composites analyzed.

11.2. Reporting Chemical Results

Report Chemical results as indicated below:

A. Results less than the Limit of Detection (LOD) or Method Detection Limit (MDL) – report as less than LOD or MDL and include the detection limit concentration.

B. Results between the LOD or MDL and the Limit of Quantitation (LOQ) – report the concentration and include the detection limit and quantitation limit concentration.

C. Results above the LOQ, report the sample concentration.

11.3. Reporting presumptive positive results or Cannot Rule Out (CRO)

When initial testing or screening indicate the possibility that the analyte or organism in question is present. Additional analysis is required to confirm the presence, absence, or concentration.

11.4. Abbreviated Recording and Reporting of Findings

MAN-000044 ORA Laboratory Manual, Volume II, ORA-LAB.5.10, provides information on abbreviated reporting.

11.5. Consumer Complaint Letters

A complainant is to be informed of FDA's findings when a sample is examined as requested by the complaint coordinator.

When the examination is completed (or if no examination is made), the complaint coordinator is responsible to determine if the consumer wishes the sample returned.

If the complainant requests the sample, the sample is returned, and an appropriate record maintained. Complaint samples are held for at least thirty days from the time of analysis. If sample return is not requested by the complaint coordinator during this period, the sample may be destroyed.

There may be rare occasions when an intact complaint sample serves as the basis for legal actions. On these occasions, the compliance branch is responsible for the release of the remaining sample to the customer.

Upon request from the complaint coordinator, the lab will create a letter for the coordinator to send to the complainant advising the individual of the general nature of the findings. When additional interpretation is indicated, an explanation of the findings is included. If an examination has not been made, the complainant is informed by the coordinator and given the reason(s). The letter to the complainant is sent by the complaint coordinator.

Cosmetic injury complaint reports will be handled by the Center for Food Safety and Applied Nutrition.

12. Glossary/Definitions

A. **ALIS (Automated Laboratory Information System) –** A laboratory information system defined as computer software that processes, stores, and manages data related to laboratory processes and tests.

B. **Additional Analyst:** Conducts additional tests on a sample, performs determinations not covered by the original analyst, or resolves discrepancies in reported analytical results.

C. **Analyst Worksheet** - the document(s) used for recording observations and results pertaining to the scientific analysis performed for data reporting. This document may be in paper format, PDF, or other electronic format, or be system generated.

D. **Analytical Package** – A collection of records designed to provide a complete account of analytical findings, conclusions, labels, and attachments.

E. **Attachments**– Supplemental information added to the analytical package including, but not limited to broken seals, instrument generated data or results, photographs, x-rays, exhibits, and photocopies to support laboratory findings and conclusions.

F. **Check Analyst**: Conducts additional analysis to confirm an original finding.

G. **Completed Document** - A document is considered complete once the analytical package has been submitted to the end user or customer.

H. **Labels or Labeling** – Commercially printed material that describes the contents of a sample package and is found in association with the product. Labels or labeling include carton labeling, bottle labels, all inserts, product packaging, promotional materials, photographs, or photocopies of original label, or verified handwritten copies. Labels or labeling components are often identified as Outer Container Labeling, Immediate Container Labeling, and Package Insert. Labels or labeling is comprehensively defined in the FD&C Act, Sections 201(k) and 201(m).

I. **Laboratory Information Management System (LIMS)**: system(s) which includes the management of data and information contained in both computerized and non-computerized systems.

J. Lead Analyst: May or may not be the same person as the original analyst, dependent upon workflow for various types of analysis within each individual laboratory. The Lead Analyst is responsible for assembling the analytical package.

K. Non-Regulatory Samples: Samples for which no regulatory action is planned by the agency from the point of collection.

L. Original Analyst: Conducts the initial examination on a representative portion of the sample. This analyst will break the official seal, when present, and initiate an analytical package.

M. **Parent Document**: Intermediary records or documents created or used in the process of creating a subsequent record. Refer to WI-000458 Intermediary Electronic Laboratory Record Determination and Disposition

N. **Regulatory Samples** – Evidence collected and analyzed to either support regulatory action or serve to classify the evidence as non-actionable.

O. **Reserve Sample** – Any remaining intact sample, sample composite(s), 702(b) portions, and exhibits associated with an Official Sample (e.g., Investigator/Inspector filth exhibits, Analyst filth analysis plates, and microbiological isolates.)

P. **Sample Classifications** – Samples are assigned by laboratory supervisors to classes based upon whether they are considered "regulatory (classes 1, 2, 3, & 5)" or "non-regulatory (class 4)" in nature, and the results of the laboratory's examination.

1. **Class #1** (In Compliance) – The sample meets established standards (CFR, USP, etc.) or policy guides in the absence of standards.
2. **Class #2** (Regulatory Action Not Established/Defined):
    a. The sample fails to meet established standards but may meet policy guides.
    b. In the absence of standard guides, results may or may not be applicable for regulatory actions because of the level or significance of the results but may still have implications for public health; for example, detection of Listeria species other than Listeria monocytogenes; acidified canned foods (ACD) where the process is not known; detection of Shiga Toxin E. coli (STEC)s; other examples include Potency Results that are borderline and the product is not close to expiration date; and Health Hazard Evaluations performed by the Center.
    c. Sample results may indicate the need for investigatory, compliance, and/or policy follow-up or further laboratory analysis. For example, 1) the laboratory identified a color which was permitted as a dye and not as a "lake" and the difference between the two forms could not be determined analytically or 2) Whole Genome Sequencing (WGS) for further pathogen characterization, data analysis and epidemiological considerations.
3. **Class #3** (Adverse Findings) – The sample fails to meet established standards and policy guides; or the results, in the absence of standards and guides, are of a level or significance to support a recommendation for regulatory action. This classification is also used for documentary samples, exhibits or other types of samples which are being held without analysis for evidence in regulatory proceedings.

4. **Class #4** (No Classification Needed) – The sample is not classified because of the type of examination or reason for analysis makes classification meaningless. Examples include survey samples where one sample consists of multiple products or where there is no documentation to support regulatory action. These include “Total Diet Samples”; samples examined for another regulatory agency that has responsibility for classifying the sample; samples used in research or collaborative studies; response to consumer complaints or petition validation projects.

   Note: As noted in Section 12, the distinctions between Lab Classifications 1, 2, 4 and 5 samples and Lab Class 3 samples center around whether the analytical packages relate to non-actionable versus actionable packages. Since WGS result is generally supportive to previous actionable results, it is counter-intuitive to continue to use LC4 for these types of analytical packages.

5. **Class #5** (Sample Shipping and Collection Problems) – The sample is rendered unusable for analysis due to shipping of collection reasons, such as broken containers, improper collection, or sample not collected. For other reasons, such as PAC codes, incorrect servicing laboratory, laboratory problems, the sample information is corrected in FACTS or a LIMS and/or the sample is properly transferred to another servicing laboratory.

Q. **Standard Method and FDA “Official” Method** – Standard methods are those published by international, regional, or national standards-writing bodies; by reputable technical organizations; in legal references; and FDA published methods. FDA “official” methods are those in compendia specified in the FD&C Act and prescribed in the CFR and methods in applications and petitions that have official status are included. These methods include those in the United States Pharmacopeia, National Formulary, Homeopathic Pharmacopeia of the United States, Official Methods of Analysis of AOAC INTERNATIONAL or any supplement of any of them, American Public Health Association (APHA) Compendium of Methods for the Microbiological Examination of Foods, FDA compliance programs, the Pesticide Analytical Manual (PAM), the Food Additives Analytical Manual, the Food Chemicals Codex, FDA Bacteriological Analytical Manual (BAM), FDA Macroanalytical Procedures Manual (MPM), and ORA Laboratory

Information Bulletins (LIBs) that are included in compliance programs and special assignments.

R. **Template:** A document or file with a preset format, so that the format does not have to be recreated each time it is used for specific information.

S. **Types of Analyses:** Different types of analyses may be conducted on samples. The type of analysis required is usually defined in the Compliance Program or Assignment. The types of analyses that are addressed in individual Compliance Programs and Assignments include the following:

1. **Original Analysis**: Initial examination conducted on a representative portion of sample.
2. **Screening** – used to detect the presence of a substance or class of substances at the level of interest and to filter large numbers of samples for potential non-compliant results. Results from a screening are usually considered estimates.
3. **Determinative (or Quantitative) analysis** – used to determine the presence or concentration of an identified organism or analyte.
4. **Confirmatory** – used to provide full or complementary information enabling the substance to be unequivocally identified and if necessary quantified. Methods that provide information on the chemical or DNA structure of the analyte or organism are considered confirmatory and do not always require a second determinative or check analysis.
5. **Additional Analysis**: Additional tests on a sample, determinations not included in the original analysis, or tests to resolve discrepancies in reported analytical results. These tests are not the same method or analysis repeated, which would be a check analysis.
6. **Check Analysis** – a separate and different analysis than the original analysis and used to confirm a finding.

13. Supporting Documents

A. ALIS User Manual

B. AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food, Dietary Supplements,

and Pharmaceuticals – An Aid to Interpretation of ISO/IEC 17025:2017; August 2018.

C. Investigations Operations Manual (IOM), Chapter 4 – Sampling.

D. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories. Section 7.8.

E. LIMS User Manual

F. WI-000458 Intermediary Electronic Laboratory Record Determination and Disposition

G. WI-000127 Upload of Analytical Work Packages and Lab Documents to the Compliance Management System

H. WI-0000184 Converting Analytical Work Packages from Paper to Digital Format

I. MAN-000044 ORA Lab Manual Vol. II - Reporting Laboratory Results (ORA-LAB.5.10)

14. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.4	R	12/06/06	LMEB	LMEB
1.5	R	08/15/08	LMEB	LMEB
1.6	R	02/02/10	LMEB	LMEB
1.7	R	07/20/10	LMEB	LMEB
1.8	R	02/06/12	LMEB	LMEB
1.9	R	01/29/13	LMEB	LMEB
2.0	R	05/02/14	LMEB	LMEB
03	R	06/06/2019	LMEB	LMEB
04	R	REFER TO QMIS	LMEB	LMEB

* - D: Draft, I: Initial, R: Revision

15. Change History

Revision #	Change
1.4	3.3.2, **Block 9. Labeling**: - added term “set”; defined “label” and set in first paragraph; added identification examples and assembly of labeling sets to last paragraph. 3.3.2 **Block 10. Summary of Analysis**: - moved second sentence from **Container:** to first paragraph of **Labeling:** 3.9 Changed from Document History to Document/Change History
1.5	3.4.2.2 Added f.
1.6	3.2.1 b. – corrected reference from 3.2.2.2 to 3.2.2.3 3.2.2.3 d. – corrected reference from 3.2.1 c. to 3.2.1 d. 3.2.5 – deleted reference to ORA Laboratory Manual, Volume V 3.5.3 – added “designee” to paragraph 3.6 – added reference to ORA-LAB.5.10, Section H.2. Footer - updated

Revision #	Change
1.7	3.3.3 Added “to complete the analysis, or reference to attachments, logbooks, or appropriate worksheets containing this information” to first paragraph. 3.5.1 and 3.8 Added “photocopies” as examples of attachments
1.8	3.3.2 Block 7 – added “from the Collection Report: in last sentence 3.3.2 Labeling – revised second sentence in second paragraph 3.4 – Title changed to Types of Analysis 3.4.1 – heading changed to Types; added bullets on Screening, Confirmatory, and Determinative 3.5.3 – added last section on reporting results 3.8 – revised Class #5 definition
1.9	Header – Division of Field Science changed to Office of Regulatory Science 3.4.2.2 c. – Division of Field Science changed to Office of Regulatory Science
2.0	Contents: 3.2.5 – added Laboratory Information System Contents: 3.9 – changed to References Contents: 3.10 – now Document Change History 3.1 – changed FACTS system to “web application, such as FACTS or LIMS” 3.2.1 – revised first paragraph 3.2.1 a. – added “Handwritten” 3.2.1 b. – added “or web application” 3.2.2.1 – added last sentence 3.2.2.3 – added “or web application” 3.2.2.3 c. – added “or electronically” 3.2.2.3 d. – added “or LIMS generated PDF file” 3.2.3 – revised second paragraph 3.2.5 – added references to LIMS 3.3.1 – added “or enters information into the web application” 3.3.2 – minor changes made to grammar 3.3.2 Block 6 – deleted District 3.3.2 Block 7 – added to last sentence 3.3.2 Block 9 – added to last sentence of first bullet on retaining original label 3.3.2 Block 10 Containers – added “or photo” 3.3.2 Block 10 Labeling – revised 3.3.2 Block 11 – added “or LIMS” 3.3.4 – added “handwritten” to first bullet 3.5.1 – added reference to LIMS at end of first paragraph & Attachments first bullet 3.5.2 – added reference to LIMS to Supervisor Review 3.5.3 – added reference to LIMS 3.8 – added reference to LIMS in definition of Lab Class 5 3.9 – added references
03	Revisions made as needed to align this procedure with new ISO/IEC 17025 and AOAC requirements. Revision to formatting and policy clarifications were also made.
04	Clarified existing requirements throughout for interpretation clarity and standardization. Updated Glossary. Added requirements when using new ALIS electronic worksheets.

16. Attachments

None