## Sections in This Document



## 1. Purpose

This procedure defines the process for reporting analytical findings and conclusions as prescribed by the agency.

## 2. Scope

This procedure applies to all Office of Regulatory Science (ORS) laboratories and the release of information.

## 3. Responsibility

A. Laboratory Director:

1. Responsible for ensuring the timeliness, accuracy and completeness of all analytical information reported by the laboratory; and
2. Reviews, or designates review of violative worksheets prior to release by the laboratory.

B. Laboratory Management:

1. Responsible for ensuring the timeliness, accuracy and completeness of all analytical information reported by the analyst;
2. Responsible for ensuring that laboratory analysts comply with the data and information recording procedures; and
3. Review analytical findings and supporting records generated by analysts, enter related conclusions, and sample classification codes into web application, such as Field Accomplishments and Compliance Tracking System (FACTS), Automated Laboratory Information System (ALIS), or Laboratory Information Management Systems (LIMS).

C. Analysts:

1. Responsible for capturing and recording accurate and complete analytical information on analytical worksheets, continuation sheets, electronic lab notebooks, or other records in accordance with the instructions of this procedure; and
2. Complete worksheets and enter analytical observations and findings into web applications, such as FACTS or ALIS, in a timely manner.

## 4. Background

None

## 5. References

A. Food, Drug and Cosmetic Act, Section 704(d), Factory Inspection

B. DIR-000078 Field management directive No. 147, procedure for release of analytical results pursuant to section 704(d).

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

D. 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.

E. SOP-000529 FMD-147: Communicating Laboratory Analytical Findings for Food Products and Environmental Samples Standard Operating Procedure

## 6. Procedure

### 6.1. Introduction

The worksheets printed or electronic, and applicable supporting records (e.g., , packaging, promotional materials, instrument charts, exhibits, memorandums, controls) referred to in this section are used to provide the written or electronic account of analytical findings that either support regulatory action or serve to classify the sample as non-actionable. This documentation is prepared so the history of the sample can be reconstructed with confidence, including details on which the analyst may respond to queries or challenges months or years later. These records provide an accurate and objective description of the sample handling and analysis actions from the time of laboratory receipt to the time analysis and investigative efforts are concluded. There is no doubt about what was done, how it was done, who did it, and with what accuracy and precision the work was accomplished.

The worksheet package presents a complete picture that can be understood by reviewers, even those not technically or scientifically trained, and not a part of the analyzing science unit.

### 6.2. Results

Analytical findings are presented on worksheets and constructed using the requirements and structure of the FDA form FD-431(Analyst Worksheet) and FD-431a (General Continuation Sheet) templates. Data is recorded in a clear and concise manner to expedite interpretation of the results, especially by non-technical and non-scientific personnel. These forms and attachments make an

analytical package. Whenever possible, the analytical data should be tabulated.

When subsamples with differing codes are individually examined, the results are clearly recorded for each code because regulatory action may be based on the results of a particular code exclusive of other codes. The following are some components of the analytical package.

### 6.2.1. Analytical Worksheet

The following information is included on the analytical worksheet:

Note: For detailed description of all information required please see MAN-000047.

A. Title (i.e., ANALYST WORKSHEET),

B. Summary of Analysis;

C. Name of laboratory (e.g., DENLHAF);

D. Unique identification of the worksheet on each page (i.e. sample number and page numbering);

E. Identification of the method used.

F. Description of sample to include deviations, additions or exclusions from collector's report.

G. Date received.

H. Date(s) analysis performed.

I. Date reported.

J. Results.

*NOTE: Results include the unit of measurement and reflect the correct number of significant figures indicated by the analytical method. If computer generated results are included in the final report, a statement on the report indicating the correct number of significant figures suffices when the number of figures presented by the computer exceeds the capability of the method. Statistical or other data reflecting accuracy and precision are included.*

*Analytical results are compared with the label, labeling declarations, published tolerances and standards, regulatory action levels, manufacturer's specifications, or other applicable criteria.*

*When requested, a statement of compliance or non-compliance with requirements or specifications is recorded.*

*When discrepancies are found between analytical results and labeling statements or other criteria, these facts are set out clearly.*

K. Analyst and reviewer signatures.

### 6.2.2. Collection Report

The report includes, but is not limited to the following information:

A. Name of sampling office or entity.

B. Date of sampling.

C. Identification of the substance, material or product sampled.

D. Reason for collection.

E. Method of collection, how prepared; and

F. Analysis requested.

### 6.2.3. General Continuation Sheets

These sheets contain the raw data, calculations, standard preparation, dilution schemes, quality control data, equipment used, reagents, media, test conditions, deviations, additions or exclusions from the test method, and other sample related information.

### 6.2.4. Attachments

Attachments are supplemental information added to the analytical package to support laboratory findings and conclusions. These can consist of, but are not limited to:

A. Instrument generated reports and charts

B. Photographs

C. Memoranda

*Note: Analytical worksheet labels and labeling, while attached to the worksheet, should not be identified as attachments. Refer to MAN-000047 .

## 6.3. Field Accomplishments and Compliance Tracking System (FACTS)

Analytical findings and observations are entered into FACTS by laboratory analysts. Supervisors enter conclusions and laboratory classification. The individuals performing the laboratory activities are recorded in FACTS. The data is obtained by internal clients (FDA) through FACTS or electronic file transmission. Laboratory personnel are to make every effort possible to ensure the sample information, analytical findings and conclusions entered are correct and that any errors are corrected as quickly as possible.

### 6.4. Other

The following information is found at the laboratory, but not necessarily provided in the analytical packet or web application:

A. Address of the analyzing laboratory.

B. Address and contact information of the sampling district.

C. Statement to the effect that the results relate only to the item tested; and

D. Estimated uncertainty of measurement

### 6.5. Deviations and modifications

Whenever there is a need to (a) deviate from or add to an official method, (b) use an entirely new method for a sample analysis or (c) modify test conditions such that it may affect the integrity of the analysis and interpretation of results, these deviations or new methods are comprehensively described by the analyst. Depending upon the magnitude of the deviation or change, this can be a relatively short entry in Block 10 Summary of Analysis. Clearly describe the deviations and new methods employed and how the proper performance of the new or modified method was demonstrated in terms of accuracy, precision, specificity for the product being analyzed, and the estimated uncertainty of the measurements when this is needed for the validity or application of the examination. The validation techniques used will vary depending upon the situation.

### 6.6. Check or Additional analysis

Whenever a check or additional analysis is performed, a new FDA-431 typically started. Refer to ORA LM Volume III, Section 3 MAN-000047 . The worksheet shall be noted as a check or additional analysis with a clear reference to the original sample analyzed. Blocks 8 and 9 need not be repeated, and can be left blank, or include the statement “see original analysis” on these second worksheets. In addition, the description of the container, labeling, codes, and product in block 10 on the second worksheet need not be repeated if they are the same unless requested or instructed to do so. For those items remaining the same on the second worksheet, enter the statement “see original analysis”, and under the analysis category enter the subsample numbers retested whenever applicable. The information entered in block 7 is complete in description to demonstrate continuity of sample handling.

When not generating a new FDA-431 or approved harmonized 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 or harmonized worksheet and state where reserve sample is located.

When a Check or Additional Analysis is performed using ALIS, the automatically generated ALIS Summary Report (ASR) and ALIS Continuation Report (ACR) must have clear indication of the type of analysis that is performed on each page. A new ASR is not required while using ALIS.

Refer to the Glossary for an explanation of various types of analysis.

### 6.7. Opinions and Interpretations

The laboratory management interprets the analytical findings and assigns a sample classification in FACTS or LIMS. The laboratory classifications are defined in MAN-000047 ORA Laboratory Manual Volume III Section 3. Other opinions and interpretations by laboratory management may be included in the analytical package. These may be comprised of, but not limited to the following records:

A. Opinion on the conformity of the results with regulatory requirements;

B. Recommendations on how to use the results; and

C. Guidance to be used for improvements, when needed and applicable.

### 6.8. Reviewing Analytical Results

A. Worksheet Check –A second qualified analyst or supervisor will review the package prior to it being forwarded to final reviewing official. 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. Supervisor Review – Following the worksheet check, a supervisor reviews it for accuracy and completeness.

### 6.9. Authorizing Analytical Results Prior to Release

Analytical packages for non-actionable samples will be approved by the responsible Supervisor or designee. Analytical packages for actionable samples are approved by the laboratory director or designee. The responsible Supervisor or Laboratory Director enters their conclusion(s) and sample classification code(s) into FACTS.

### 6.10. Reporting

#### 6.10.1. Reports issued to internal (within FDA) offices

Reporting laboratory findings to compliance and other internal FDA offices is accomplished using the FACTS application, LIMS, or, when requested, via

distribution of an analytical package to the division responsible for the sample. Each laboratory maintains a record of package distributions.

### 6.10.2. Abbreviated reporting

Analytical findings and conclusions may also be reported using abbreviated procedures designed to minimize laboratory resources when such is authorized by the Office of Regulatory Science (ORS) Headquarters and/or Program management (e.g. ORS Director, Associate Director, and/or Program Manager) The exact way abbreviated reporting is accomplished is determined on a case-by-case basis to meet client needs.

### 6.10.3. Reports issued to agents responsible for food products tested by an ORS laboratory

A. Section 704(d) of the Food, Drug and Cosmetic Act requires that the results of an analysis be reported promptly to the owner, operator, packer, or agent in charge when a sample of food is collected during an inspection of an establishment where food is manufactured, processed, or packaged and the sample of food was collected to ascertain whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food.

B. . Form FDA 1551 is issued to the responsible firm within two (2) working days of approval of the Sample Summary Report preferably via email. The sample description includes the following:

1. The nature of the sample, number and size of the units examined, and the code marks of the subdivisions examined.

2. The results of analysis described in simple (lay) terms whenever possible, and restricted to addressing filth, decomposition or other factors causing the food to be unfit for food. Details should be given regarding any factors in the analysis that are significant in terms of the possible violation. A general summary should be provided on factors that are not significant.

3. Form FDA 1551 shall not list the methods employed, conclusions drawn from the analysis, any details regarding the way the sample was handled prior to the analysis, explanation of the type of examination made, or the results of examinations for factors other than filth, decomposition, or those causing the food to be unfit for food. These forms shall only be communicated to the, responsible party, (retailer, distributor wholesaler, agent in charge, owner, manufacturer, processor, packer) from whom the sample was collected.

**Note**: For complaint samples and consumer complaint letters there is a different process, please refer to Section 11.5 of MAN-000047 .

6.10.4. Reports issued in cooperation with industry and other Federal and State agencies

A. Unsolicited requests for analytical results on any product may be sent to any firm, individual or cooperating agency that, in the judgment of the responsible program, has a legitimate interest in the results and when a useful purpose will be served.

B. Specific guidance regarding when and how laboratory information is to be shared will be provided by the Collecting Office responsible for the products involved on a case-by-case basis or the Compliance Branch.

C. On occasions where a laboratory enters into an interagency agreement with an external agency (i.e. State or local agency) to share analytical test results on the food, drug, cosmetic or medical device products being tested, this data is shared in compliance with the established agreement. As a minimum, this agreement includes terms and limitations designed to protect the privacy of the clients whose products have been tested.

## 6.11. Format of Reports

The general format of the analyst worksheet consists of three parts:

A. Heading which includes these items:

1. Product,
2. Sample number,
3. Seals,
4. Date received,
5. Received from,
6. Lab,
7. Description of sample,
8. Net Contents, and
9. Labeling.

B. Body or Summary of Analysis which includes these subparts:

1. Container,
2. Labeling,
3. Code,

4. Product,
5. Analysis,
6. Method, and
7. Results.

C. Closing which includes vital information:

1. Reserve sample location or disposition,
2. Conclusion
3. Signatures (worksheet check)
4. Date reviewed, and
5. Date reported.

### 6.12. Issuing Modifications or Amendments to Reported Findings (Completed Documents)

Material amendments to analytical results that have already been reported are made only in the form of an additional record or data transfer. These reports are flagged at top left corner on FDA 431 or ASR as Additional Analysis or Amended Report with the sample identification (unique package or sample number). These amendments are to clearly identify the sample or samples involved and describe the changes, additions and corrections being made and the rationale for why they are needed. The requesting official must also be contacted with notification of the amended report.

Transcription errors that do not affect the data, i.e. incorrect dates, are changed on the original analyst worksheet or if applicable, in FACTS or LIMS.

## 7. Glossary/Definitions

A. **ACR** – ALIS Continuation Report

B. **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.

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. **ASR** – Alis Summary Report

F. **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.

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

K. **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.)

L. **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.

M. **Original Analysis**: Initial examination conducted on a representative portion of sample.

N. **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.

O. **Check Analysis** – a separate and different analysis than the original analysis and used to confirm a finding. Refer to MAN-000047 for Check analysis requirements.

P. **Amended report** – corrected report due to error or change that affects data and/or its interpretation. (See Completed Document)

Q. **Sample classifications** – Samples are assigned to different regulatory decision-making classes (1-5) by laboratory supervisors based upon the results of the laboratory's examination. An explanation of each sample class can be found in MAN-000047 .

## 8. Records

A. FACTS data

B. ALIS data

C. LIMS data

D. Analytical package

E. Abbreviated packages

F. Form FDA 1551

G. Reports to industry

H. Modifications and amendments to reported findings

## 9. Supporting Documents

A. Regulatory Procedures Manual (RPM)

B. FACTS Reference Guides

C. LIMS Reference Guides

D. SOP-000529 FMD-147: Communicating Laboratory Analytical Findings for Food Products and Environmental Samples Standard Operating Procedure

E. ALIS Manual

F. MAN-000047 ORA Lab Manual Vol. III Section 3 - Recording of Results Analyst Worksheet (III-03).

## 10. Document History

| Revision # | Status* (D, I, R) | Date | Author Name and Title | Approving Official Name and Title |
|---|---|---|---|---|
| 1.2 | R | 11/16/05 | LMEB | LMEB |
| 1.3 | R | 08/15/08 | LMEB | LMEB |
| 1.4 | R | 01/22/13 | LMEB | LMEB |
| 1.5 | R | 05/08/14 | LMEB | LMEB |
| 02 | R | 06/06/2019 | LMEB | LMEB |
| 03 | R | REFER TO QMIS | LMEB | LMEB |

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

## 11. Change History

| Revision # | Change |
|---|---|
| 02 | 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. |
| 03 | Added use of ALIS. Updated entire document to align with recent revision to MAN-000047 ORA Lab Manual Vol. III Section 3 - Recording of Results Analyst Worksheet (III-03). |

## 12. Attachments

None