

OPI: SCI/CD

ANALYTICAL METHOD INTRODUCTION

I. PURPOSE

This directive prescribes FSIS policy concerning the adoption and use of new chemistry analytical methods by FSLD laboratories.

II. (RESERVED)

III. REASON FOR ISSUANCE

To prescribe how new chemistry analytical methods will be introduced into FSLD laboratories and to identify organizational responsibilities.

IV. (RESERVED)

V. FORMS AND ABBREVIATIONS

The following will appear as abbreviated in this Directive:

CD	Chemistry Division
EPA	Environmental Protection Agency
EP	Exploratory Program
FDA	Food and Drug Administration
FSL	Field Service Laboratory
FSLD	Field Service Laboratories Division
MSD	Mathematics and Statistics Division
PREB	Planning, Review and Evaluation Branch
REPD	Residue Evaluation and Planning Division
SCI	Science Program
PMB	Program Management Branch

VI. POLICY

This directive identifies the system used within SCI for authorizing the use of new chemistry analytical methods by FSLD laboratories, either methods developed and/or evaluated within a FSL, or methods from other sources. This Directive standardizes that process.

VII. PROCEDURES/RESPONSIBILITIES

This section describes procedures to follow and identifies responsibilities for carrying out the prescribed procedures.

A. Source of Methods. Analytical methods may originate from sources such as CD, FDA, New Animal Drug Applications, EPA, FSLD laboratories, literature, etc. The need to introduce a new analytical method to a FSLD laboratory may be suggested by any FSIS program area having

responsibilities for product testing. The decision to introduce a method will be the responsibility of the Deputy Administrator, SCI.

B. Introduction Process. The following major activities are required in the analytical method introduction process. To meet unusual, emergency program needs or exploratory program sampling, the CD will authorize the use of non validated chemical methods referenced in FSIS Directive 10,110.1, Data Reporting for Nonvalidated Chemical Methods (NVCM).

1. A decision to recommend to the Deputy Administrator, SCI, introduction of an analytical method will be made jointly by the Directors of CD, FSLD, and REPD if it is a chemistry residue method, during the program planning process. The approval of the Deputy Administrator, SCI, is required prior to the method's introduction.

2. CD responsibilities are to:

a. Identify and recommend purchase of instrumentation, equipment and special chemical requirements according to Science policy.

b. Conduct a technical review of the method.

c. Provide leadership and technical guidance in initial laboratory evaluations, if needed.

d. Prepare project schedule charts for method introduction in conjunction with FSLD.

e. Prepare, update, and distribute a method information sheet to involved laboratories and staffs. (See Attachment 1.)

f. Identify critical analytical operations and conduct a safety hazard analysis in conjunction with FSLD.

g. Publish the method in the chemistry guidebook in conjunction with FSLD.

h. Prepare a quality assurance plan, including analyte sensitivity, stability and tissue preservation requirements, in conjunction with FSLD.

i. Design and coordinate a method evaluation study (validation or collaborative). (See Attachment 2 for protocol format.)

j. Design in cooperation with FSLD, an analyst familiarization protocol.

k. Make a recommendation to the Deputy Administrator, SCI, to conduct EP or pilot study in a FSLD laboratory (ies).

3. FSLD responsibilities are to:

a. Identify the laboratory(ies) that will receive the analytical method.

b. Participate with CD in the preparation of project

charts.

- c. Schedule time for training, introduction, etc.
 - d. Acquire equipment and supplies.

 - e. Participate with CD in identifying critical analytical operations and in conducting a hazard analysis.

 - f. Participate in design of studies for, and conducting familiarization, validation and collaborative studies.

 - g. Participate with CD in writing the method in guidebook format.

 - h. Participate with CD in preparing the quality assurance plan.
4. MSD responsibilities are to:
- a. Participate in design of method evaluation study.
 - b. Perform or review statistical analysis of results.
5. REPD responsibilities are to (for residue methods):
- a. Recommend method introduction following successful evaluation based on sampling program requirements.
 - b. Schedule required times in the residue sampling program for training, method evaluation, analyst familiarization, etc.
 - c. Schedule sampling programs.

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Attachments (See hard copy of the directive.)

- 1 Science Project Schedule
- 2 Method Information Sheet
- 3 Protocol Format