

STANDARD OPERATING PROCEDURE
Reviewing Contract Laboratory Methods

KEY WORDS

Quality Control, Chemistry Laboratory

APPROVALS

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Environmental Monitoring Branch organization and personnel, such as management, senior scientist, quality assurance officer, project leader, etc., are defined and discussed in SOP ADMN002.

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1 .0 INTRODUCTION

1 .1 Purpose

This Standard Operating Procedure (SOP) serves as a guide for reviewing an analytical method description or analytical SOP of a contract laboratory. This SOP does not describe the format of an analytical SOP, nor is a specific format required. This SOP is primarily a checklist of the descriptive elements that should be contained within an analytical SOP. This SOP applies to all laboratory methods, but primarily chemistry laboratory methods, developed under contract to the EHAP. This includes methods developed by the Department of Food and Agriculture for EHAP. Methods developed by EHAP personnel will follow the normal review procedure for EHAP SOPs.

1.2 Definitions

Quality control terminology, such as **reporting limit**, **method detection limit**, **method validation** and **storage stability** are defined and discussed in SOP QAQCOO1.

2.0 MATERIALS

none

3.0 PROCEDURES

3.1 Types of Review

Each analytical SOP should be reviewed by the following EHAP personnel: the quality assurance officer/laboratory liaison, the project leader and a senior scientist. A single person can perform more than one duty (e.g. one person can review as both the project leader and senior scientist). The quality assurance officer/laboratory liaison will review the method for adherence to the contract and laboratory specifications agreed upon.

The project leader will review the method for validity and applicability. The project leader should make sure that the method will meet the objectives of the study. Since the objectives of each study are different, there is no set procedure for this

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type of review. Generally, this will involve reviewing the specificity (equivocal or unequivocal identification of the analytes), reporting limit, precision and accuracy (as measured by the method validation data), turnaround time, and cost of the method.

The senior scientist will review the method for completeness and adherence to proper analytical principles. The senior scientist who reviews the method should be familiar with laboratory procedures and may or may not be the senior scientist assigned to the project. The senior scientist should use this SOP as a guideline for checking a method for completeness.

No field samples should be analyzed until the method has been reviewed and approved.

3.2 Elements of a Laboratory Method SOP

All laboratory method SOPs should be checked for the following elements, if applicable.

- 3.2.1 Name, address and phone number of the laboratory
- 3.2.2 Effective date of the method
- 3.2.3 Title of the method
- 3.2.4 Summary or principle of the method (including list of analytes and reporting limits)
- 3.2.5 List of materials, reagents, equipment and instruments
- 3.2.6 Description of the preparation, extraction and analytical procedures
- 3.2.7 Description of calibration procedure and calibration range
- 3.2.8 Description of the instrument operating conditions
- 3.2.9 Identification criteria for each analyte (e.g., chromatographic retention times, mass spectrometric ions detected)
- 3.2.10 Description and data of the method detection limit
- 3.2.11 Description of units
- 3.2.12 Description of the reporting limit
- 3.2.13 Description of calculations or data analysis
- 3.2.14 Description and data of the method validation
- 3.2.15 Description and data of the storage stability
- 3.2.16 List of references
- 3.2.17 Name of person who wrote the method
- 3.2.18 Name of person who approved the method

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If the study is conducted under Good Laboratory Practices, the following elements should also be included:

- 3.2.19 Name of the quality assurance officer
- 2.2.20 Procedure for corrective or remedial actions