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Agency

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Guidance for Preparing Standard Operating Procedures (SOPs)

EPA QA/G-6

FOREWORD

The U.S. Environmental Protection (EPA) Agency has developed an Agency-wide program of quality assurance for environmental data. EPA's Quality System requires documentation of both management and technical activities. This guidance document, *Guidance for Preparing Standard Operating Procedures (SOPs)* provides a standard working tool that can be used to document routine quality system management and technical activities. It replaces EPA's March 2001's *Guidance for Preparing Standard Operating Procedures (SOPs)* EPA/240/B-01-004 with minimal revisions in text and new examples of both technical and administrative SOPs.

This document is one of the U.S. Environmental Protection Agency Quality System Series documents. These documents describe the EPA policies and procedures for planning, implementing, and assessing the effectiveness of the Quality System. As required by EPA Manual 5360 A1 (May 2000), this document is valid for a period of up to five years from the official date of publication. After five years, this document will be reissued without change, revised, or withdrawn from the U.S. Environmental Protection Agency Quality System Series documents.

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GUIDANCE FOR PREPARING STANDARD OPERATING PROCEDURES

1.0 INTRODUCTION

1.1 Overview

A Standard Operating Procedure (SOP) is a set of written instructions that document a routine or repetitive activity followed by an organization. The development and use of SOPs are an integral part of a successful quality system as it provides individuals with the information to perform a job properly, and facilitates consistency in the quality and integrity of a product or end-result. The term "SOP" may not always be appropriate and terms such as protocols, instructions, worksheets, and laboratory operating procedures may also be used. For this document "SOP" will be used.

SOPs describe both technical and fundamental programmatic operational elements of an organization that would be managed under a work plan or a Quality Assurance (QA) Project Plan [EPA Requirements for QA Project Plans (QA/R-5) (EPA 2001a)], or Chapter 5 of the EPA Quality Manual for Environmental Programs, (EPA Manual 5360 A) and under an organization's Quality Management Plan [EPA Requirements for Quality Management Plans (QA/R-2) (EPA 2001b)], or Chapter 3 of the EPA Quality Manual. This document is designed to provide guidance in the preparation and use of an SOP within a quality system.

1.2 Purpose

SOPs detail the regularly recurring work processes that are to be conducted or followed within an organization. They document the way activities are to be performed to facilitate consistent conformance to technical and quality system requirements and to support data quality. They may describe, for example, fundamental programmatic actions and technical actions such as analytical processes, and processes for maintaining, calibrating, and using equipment. SOPs are intended to be specific to the organization or facility whose activities are described and assist that organization to maintain their quality control and quality assurance processes and ensure compliance with governmental regulations.

If not written correctly, SOPs are of limited value. In addition, the best written SOPs will fail if they are not followed. Therefore, the use of SOPs needs to be reviewed and re-enforced by management, preferably the direct supervisor. Current copies of the SOPs also need to be readily accessible for reference in the work areas of those individuals actually performing the activity, either in hard copy or electronic format, otherwise SOPs serve little purpose.

1.3 Benefits

The development and use of SOPs minimizes variation and promotes quality through consistent implementation of a process or procedure within the organization, even if there are temporary or permanent personnel changes. SOPs can indicate compliance with organizational

and governmental requirements and can be used as a part of a personnel training program, since they should provide detailed work instructions. It minimizes opportunities for miscommunication and can address safety concerns. When historical data are being evaluated for current use, SOPs can also be valuable for reconstructing project activities when no other references are available. In addition, SOPs are frequently used as checklists by inspectors when auditing procedures. Ultimately, the benefits of a valid SOP are reduced work effort, along with improved comparability, credibility, and legal defensibility.

SOPs are needed even when published methods are being utilized. For example, if an SOP is written for a standard analytical method, the SOP should specify the procedures to be followed in greater detail than appear in the published method. It also should detail how, if at all, the SOP differs from the standard method and any options that this organization follows. As noted in ASTM D5172-91 (2004), *Standard Guide for Documenting the Standard Operating Procedures Used for the Analysis of Water*, "a significant part of the variability of results generated by different laboratories analyzing the same samples and citing the same general reference is due to differences in the way the analytical test methods and procedures are actually performed in each laboratory. These differences are often caused by the slight changes or adjustments allowed by the general reference, but that can affect the final results." Using a correct well-written SOP can minimize such differences.

1.4 Writing Styles

SOPs should be written in a concise, step-by-step, easy-to-read format. The information presented should be unambiguous and not overly complicated. The active voice and present verb tense should be used. The term "you" should not be used, but implied. The document should not be wordy, redundant, or overly lengthy. Keep it simple and short. Information should be conveyed clearly and explicitly to remove any doubt as to what is required. Also, use a flow chart to illustrate the process being described. In addition, follow the style guide used by your organization, e.g., font size and margins.

2.0 SOP PROCESS

2.1 SOP Preparation

The organization should have a procedure in place for determining what procedures or processes need to be documented. Those SOPs should then be written by individuals knowledgeable with the activity and the organization's internal structure. These individuals are essentially subject-matter experts who actually perform the work or use the process. A team approach can be followed, especially for multi-tasked processes where the experiences of a number of individuals are critical, which also promotes "buy-in" from potential users of the SOP.

SOPs should be written with sufficient detail so that someone with limited experience with or knowledge of the procedure, but with a basic understanding, can successfully reproduce the procedure when unsupervised. The experience requirement for performing an activity should be noted in the section on personnel qualifications. For example, if a basic chemistry or biological course experience or additional training is required that requirement should be indicated.

2.2 SOP Review and Approval

SOPs should be reviewed (that is, validated) by one or more individuals with appropriate training and experience with the process. It is especially helpful if draft SOPs are actually tested by individuals other than the original writer before the SOPs are finalized.

The finalized SOPs should be approved as described in the organization's Quality Management Plan or its own SOP for preparation of SOPs. Generally the immediate supervisor, such as a section or branch chief, and the organization's quality assurance officer review and approve each SOP. Signature approval indicates that an SOP has been both reviewed and approved by management. As per the Government Paperwork Elimination Act of 1998, use of electronic signatures, as well as electronic maintenance and submission, is an acceptable substitution for paper, when practical.

2.3 Frequency of Revisions and Reviews

SOPs need to remain current to be useful. Therefore, whenever procedures are changed, SOPs should be updated and re-approved. If desired, modify only the pertinent section of an SOP and indicate the change date/revision number for that section in the Table of Contents and the document control notation.

SOPs should be also systematically reviewed on a periodic basis, e.g. every 1-2 years, to ensure that the policies and procedures remain current and appropriate, or to determine whether the SOPs are even needed. The review date should be added to each SOP that has been reviewed. If an SOP describes a process that is no longer followed, it should be withdrawn from the current file and archived.

The review process should not be overly cumbersome to encourage timely review. The frequency of review should be indicated by management in the organization's Quality

Management Plan. That plan should also indicate the individual(s) responsible for ensuring that SOPs are current.

2.4 Checklists

Many activities use checklists to ensure that steps are followed in order. Checklists are also used to document completed actions. Any checklists or forms included as part of an activity should be referenced at the points in the procedure where they are to be used and then attached to the SOP.

In some cases, detailed checklists are prepared specifically for a given activity. In those cases, the SOP should describe, at least generally, how the checklist is to be prepared, or on what it is to be based. Copies of specific checklists should be then maintained in the file with the activity results and/or with the SOP.

Remember that the checklist is not the SOP, but a part of the SOP.

2.5 Document Control

Each organization should develop a numbering system to systematically identify and label their SOPs, and the document control should be described in its Quality Management Plan. Generally, each page of an SOP should have control documentation notation, similar to that illustrated below. A short title and identification (ID) number can serve as a reference designation. The revision number and date are very useful in identifying the SOP in use when reviewing historical data and is critical when the need for evidentiary records is involved and when the activity is being reviewed. When the number of pages is indicated, the user can quickly check if the SOP is complete. Generally this type of document control notation is located in the upper right-hand corner of each document page following the title page.

Short Title/ID # Rev. #: Date: Page 1 of

2.6 SOP Document Tracking and Archival

The organization should maintain a master list of all SOPs. This file or database should indicate the SOP number, version number, date of issuance, title, author, status, organizational division, branch, section, and any historical information regarding past versions. The QA Manager (or designee) is generally the individual responsible for maintaining a file listing all current quality-related SOPs used within the organization. If an electronic database is used, automatic "Review SOP" notices can be sent. Note that this list may be used also when audits are being considered or when questions are raised as to practices being followed within the organization.

As noted above in Section 2.3, the Quality Management Plan should indicate the individual(s) responsible for assuring that only the current version is used. That plan should also designated where, and how, outdated versions are to be maintained or archived in a manner to prevent their continued use, as well as to be available for historical data review.

Electronic storage and retrieval mechanisms are usually easier to access than a hard-copy document format. For the user, electronic access can be limited to a read-only format, thereby protecting against unauthorized changes made to the document.

3.0 SOP GENERAL FORMAT

SOPs should be organized to ensure ease and efficiency in use and to be specific to the organization which develops it. There is no one "correct" format; and internal formatting will vary with each organization and with the type of SOP being written. Where possible break the information into a series of logical steps to avoid a long list. The level of detail provided in the SOP may differ based on, e.g., whether the process is critical, the frequency of that procedure being followed, the number of people who will use the SOP, and where training is not routinely available. A generalized format is discussed next.

3.1 Title Page

The first page or cover page of each SOP should contain the following information: a title that clearly identifies the activity or procedure, an SOP identification (ID) number, date of issue and/or revision, the name of the applicable agency, division, and/or branch to which this SOP applies, and the signatures and signature dates of those individuals who prepared and approved the SOP. Electronic signatures are acceptable for SOPs maintained on a computerized database.

3.2 Table of Contents

A Table of Contents may be needed for quick reference, especially if the SOP is long, for locating information and to denote changes or revisions made only to certain sections of an SOP.

3.3 Text

Well-written SOPs should first briefly describe the purpose of the work or process, including any regulatory information or standards that are appropriate to the SOP process, and the scope to indicate what is covered. Define any specialized or unusual terms either in a separate definition section or in the appropriate discussion section. Denote what sequential procedures should be followed, divided into significant sections; e.g., possible interferences, equipment needed, personnel qualifications, and safety considerations (preferably listed in bold to capture the attention of the user). Finally, describe next all appropriate QA and quality control (QC) activities for that procedure, and list any cited or significant references.

As noted above, SOPs should be clearly worded so as to be readily understandable by a person knowledgeable with the general concept of the procedure, and the procedures should be written in a format that clearly describes the steps in order. Use of diagrams and flow charts help to break up long sections of text and to briefly summarize a series of steps for the reader.

Attach any appropriate information, e.g., an SOP may reference other SOPs. In such a case, the following should be included:

1. Cite the other SOP and attach a copy, or reference where it may be easily located.
2. If the referenced SOP is not to be followed exactly, the required modification should be specified in the SOP at the section where the other SOP is cited.

More information on text is contained in Section 4.1 for Technical SOPs and Section 4.2 for Administrative SOPs.

4.0 TYPES OF SOPs

SOPs may be written for any repetitive technical activity, as well as for any administrative or functional programmatic procedure, that is being followed within an organization. General guidance for preparing both technical and administrative SOPs follows and examples of each are located in the Appendix.

4.1 Guidelines for Technical SOP Text

Technical SOPs can be written for a wide variety of activities. Examples are SOPs instructing the user how to perform a specific analytical method to be followed in the laboratory or field (such as field testing using an immunoassay kit), or how to collect a sample in order to preserve the sample integrity and representativeness (such as collection of samples for future analysis of volatile organic compounds or trace metals), or how to conduct a bioassessment of a freshwater site. Technical SOPs are also needed to cover activities such as data processing and evaluation (including verification and validation), modeling, risk assessment, and auditing of equipment operation.

Citing published methods in SOPs is not always acceptable, because cited published methods may not contain pertinent information for conducting the procedure-in-house. Technical SOPs need to include the specific steps aimed at initiating, coordinating, and recording and/or reporting the results of the activity, and should be tailored only to that activity. Technical SOPs should fit within the framework presented here, but this format can be modified, reduced, or expanded as required. Examples of technical SOPs are located in the Appendices A, B, and C.

In general, technical SOPs will consist of five elements: Title page, Table of Contents, Procedures, Quality Assurance/Quality Control, and References:

1. Title Page - See Section 3.1.

2. Table of Contents - See Section 3.2.

3. Procedures - The following are topics that may be appropriate for inclusion in technical SOPs. Not all will apply to every procedure or work process being detailed.

    a. Scope and Applicability (describing the purpose of the process or procedure and any organization or regulatory requirements, as well as any limits to the use of the procedure),

    b. Summary of Method (briefly summarizing the procedure),

    c. Definitions (identifying any acronyms, abbreviations, or specialized terms used),

d. Health & Safety Warnings (indicating operations that could result in personal injury or loss of life and explaining what will happen if the procedure is not followed or is followed incorrectly; listed here and at the critical steps in the procedure),

e. Cautions (indicating activities that could result in equipment damage, degradation of sample, or possible invalidation of results; listed here and at the critical steps in the procedure),

f. Interferences (describing any component of the process that may interfere with the accuracy of the final product),

g. Personnel Qualifications/Responsibilities (denoting the minimal experience the user should have to complete the task satisfactorily, and citing any applicable requirements, like certification or "inherently governmental function"),

h. Equipment and Supplies (listing and specifying, where necessary, equipment, materials, reagents, chemical standards, and biological specimens),

i. Procedure (identifying all pertinent steps, in order, and the materials needed to accomplish the procedure such as:

- Instrument or Method Calibration and Standardization
- Sample Collection
- Sample Handling and Preservation
- Sample Preparation and Analysis (such as extraction, digestion, analysis, identification, and counting procedures)
- Troubleshooting
- Data Acquisition, Calculations & Data Reduction Requirements (such as listing any mathematical steps to be followed)
- Computer Hardware & Software (used to store field sampling records, manipulate analytical results, and/or report data), and

j. Data and Records Management (e.g., identifying any calculations to be performed, forms to be used, reports to be written, and data and record storage information).

4. Quality Control and Quality Assurance Section - QC activities are designed to allow self-verification of the quality and consistency of the work. Describe the preparation of appropriate QC procedures (self-checks, such as calibrations, recounting, reidentification) and QC material (such as blanks - rinsate, trip, field, or method; replicates; splits; spikes; and performance evaluation samples) that are required to demonstrate successful performance of the method. Specific criteria for each should be included. Describe the frequency of required calibration and QC checks and discuss the rationale for decisions. Describe the limits/criteria for QC data/results and actions required when QC data exceed

QC limits or appear in the warning zone. Describe the procedures for reporting QC data and results.

5. Reference Section - Documents or procedures that interface with the SOP should be fully referenced (including version), such as related SOPs, published literature, or methods manuals. Citations cannot substitute for the description of the method being followed in the organization. Attach any that are not readily available.

4.2 Guidelines for Administrative or Fundamental Programmatic SOP Text

As with the technical SOPs, these SOPs can be written for a wide variety of activities, e.g., reviewing documentation such as contracts, QA Project Plans and Quality Management Plans; inspecting (auditing) the work of others; determining organizational training needs; developing information on records maintenance; validating data packages; or describing office correspondence procedures. Administrative SOPs need to include a number of specific steps aimed at initiating the activity, coordinating the activity, and recording and/or reporting the results of the activity, tailored to that activity. For example, audit or assessment SOPs should specify the authority for the assessment, how auditees are to be selected, what will be done with the results, and who is responsible for corrective action. Administrative SOPs should fit within the framework presented here, but this format can be modified, reduced, or expanded. An example of administrative SOPs can be found in Appendix E.

In general, administrative/programmatic SOPs will consist of five elements: Title page, Table of Contents, Purpose, Procedures, Quality Assurance/Quality Control, and References.

1. Title Page - See Section 3.1.

2. Table of Contents - See Section 3.2.

3. Procedures -The following are topics that may be appropriate for inclusion in administrative SOPs:

a. Purpose – (identifying the intended use of the process)

b. Applicability/Scope (identifying when the procedure is to be followed),

c. Summary of Procedure,

d. Definitions (defining any words, phrases, or acronyms having special meaning or application),

e. Personnel Qualifications/Responsibilities (identifying any special qualifications users should have such as certification or training experience and/or any individual or positions having responsibility for the activity being described),

f. Procedure,

g. Criteria, checklists, or other standards that are to be applied during the procedure such as citing this document as guidance for reviewing SOPs), and

h. Records Management (specifically, e.g., as forms to be used and locations of files).

4. Quality Control and Quality Assurance Section - Describe any control steps and provisions for review or oversight prior to acceptance of the product or deliverable. This can include test plans such as verification and validation plans for software or running a "spell-check" program on the finished document.

5. Reference Section - Cite all references noted in the body of the SOP. A copy of any cited references not readily available should be attached to the SOP.

5.0 EXAMPLE SOPS

Example SOPS can be found in Appendices A-E. These examples are not purported to be perfect or complete in content, nor is their use endorsed or recommended. They are provided merely to illustrate application of SOP format to technical and administrative subjects. They should not be cited or followed as actual procedure specification or guidance. Attachments cited by the individual examples are not included.

6.0 REFERENCES

American Society for Quality. 2004. ANSI/ASQC E4-2004, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*. Milwaukee, WI.

American Society for Testing and Materials. ASTM D 5172-91 (2004), *Standard Guide for Documenting the Standard Operating Procedures Used for the Analysis of Water*. 2004. American Society for Testing and Materials, West Conshohocken, PA.

Code of Federal Regulations. July 1, 1999. 40 CFR Part 160. Good Laboratory Practice Standards.

Escoe, Adrienne. 1997. *Nimble Documentation. The Practical Guide for World-Class Organizations. Milwaukee*, Wisconsin: American Society for Quality, Quality Press.

Garner, Willa Y. and Maureen S. Barge, editors, "*Good Laboratory Practices. An Agrochemical Perspective*," ACS Symposium Series 369, American Chemical Society.

U.S. Environmental Protection Agency. 2000. *EPA Quality Manual for Environmental Programs (EPA Manual 5360 A1)*. Office of Environmental Information, Washington, DC.

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U.S. Environmental Protection Agency. 2001b. *EPA Requirements for Quality Management Plans (QA/R-2*), EPA/240/B-01/002, Office of Environmental Information, Washington, DC.

U.S. Environmental Protection Agency. 2005. *Manual for the Certification of Laboratories Analyzing Drinking Water. Criteria and Procedures/Quality Assurance*, fifth ed. EPA 815-R-05-004. Washington, DC. Office of Water, Cincinnati, OH.

APPENDIX A

PREPARATION OF FISH TISSUE FOR METAL ANALYSIS by ICP or FURNACE AA

LABORATORY OPERATING PROCEDURE
 # 54.0

September 5, 2006

By

Lisa Mathews

DRAFT EXAMPLE – DO NOT QUOTE OR CITE

APPROVED:
(Signature and date on file)
Inorganic Section Chief/date

(Signature and date on file)
Regional Laboratory Branch Chief/date

(Signature and date on file)
Laboratory QA Officer/date

A. SCOPE AND APPLICABILITY

This method is applicable to fish tissue samples ground with commercial meat processing equipment. It may be used for the graphite furnace atomic absorption (AA) analysis of As, Se, Sb, Cd, Pb, or the inductively coupled plasma (ICP) analysis for Ag, Al, Ba, Be, Cd, Cop, Cr, Cu, Fe, Mn, Mo, Ni, Pb, V, Zn, Mg, and Na. This method has not been evaluated for Ti, Ca, K, or Mg. This LOP is based on EPA Method 200.3.

B. SUMMARY OF METHOD

Fish tissue is dissolved in concentrated HNO_3 and concentrated HCl with gentle heating. Since all organic material is not removed, to insure acceptable precision and accuracy, all graphite furnace atomic absorption analyses must be performed utilizing a method of standard additions.

C. INTERFERENCES

There are no known interferences. All metals mentioned above have been found to produce acceptable precision and accuracy.

D. SAFETY

1. Care should be taken when doing the hot-acid digestion using concentrated nitric acid. Digestion is done in a block digester, in a fume hood. The analyst should wear protective clothing, safety glasses, and protective gloves. The hood sash should be lowered when samples are digesting. Solid samples sometimes bump.

2. EPA-RCRA regulations require the proper disposal of metal samples and wastes. In this laboratory, disposal operations are handled by the designated Laboratory Safety Coordinator. See LOP 32.3 for details.

E. APPARATUS AND MATERIALS

1. Digestion Containers:

100 mL polypropylene calibrated digestion containers with lids

2. Apparatus:

Block Digester-Technicon-BD-40, in a fume hood
Centrifuge or 10 mL syringes with PVDF filters

F. REAGENTS AND CHEMICALS

1. DI Water – DI water from the laboratory taps can be used after allowing it to run for several minutes before collection.

2. Acids and Bases

a. Concentrated Nitric Acid: Use "Baker Intra-Analyzed" reagent grade acid specifically for trace metal analysis, or equivalent.

b. Concentrated Hydrochloric Acid: Use reagent grade acid specially for trace metal analysis, or equivalent.

c. Thirty percent (30%) hydrogen peroxide.

3. Spiking Solutions

a. Spiking solutions 1 and 5 are made according to the spike solution log book in the metals digestion lab. Copies of the standards used and the initial run of the spikes will be kept in this log book. SPEX standards, or equivalent, should be used for the spiking solutions. Do not use the same standards used for the calibration standards as discussed in LOP #201.0 and 202.1. For AA analysis, 200 µL of solution 5 is added to a fish tissue sample. For ICP analysis, 500 µL of solution 1 is added.

4. Reference Standards

a. Samples, with known concentrations of the elements under analysis, obtained from the following external sources. They include, but are not limited to:

(1) NBS oyster tissue (SRM-1566)
(2) EPA trace metals in fish

Use only 1 gm of dried reference.

5. Calibration Standards

For preparation of instrument calibration standards, see LOP #201.0 and 202.1.

G. SAMPLE COLLECTION, PRESERVATION, AND HANDLING

Fish samples are collected by standard field procedures and, when received in the laboratory, are kept frozen until analysis. Samples are ground, using commercial meat processing equipment, and a portion of the ground sample is placed into an 8-oz glass jar for metals analysis.

H. QUALITY CONTROL

The following QC samples should be prepared and analyzed at the same time as unknown samples. They are to be done on a frequency of one per batch or one per every 20 samples, whichever is greater.

a. Method Blank. Digested blank carried through the entire process with all reagents but without sample. Deionized water is used for water matrices.

b. Laboratory Fortified Blank. This digested standard is prepared in the same manner as spiked samples except with no sample. For water, 100 mL of DI water is used. This quality control standard is required with water samples and may also be used with fish samples.

c. Laboratory Control Sample (LCS). This solid sample of known concentration is digested and analyzed along with the unknown solid samples as a measure of the analytical performance.

d. Matrix Spike (MS). An aliquot of standards added to the sample prior to digestion. The spiking procedure may be found in Section K or in the appropriate sample preparation method.

e. Matrix Spike Duplicate (MSD). A second aliquot of the same sample as *d*, spiked in the same way. It must be run at the same time as the matrix spike.

I. SAMPLE PREPARATION PROCEDURE

1. Sample Preparation

a. Weigh approximately 2 gm of fish tissue to the nearest 0.01 gm into 100 mL polypropylene digestion containers. Add 5 mL concentrated HNO_3. Heat in the block digester at 40 ^oC until tissue is dissolved or at room temperature overnight. Increase temperature to 110 ^oC and heat solution until it begins to turn brown – about 1 hour. Cool sample, and then add 2 mL of concentrated nitric acid and return solution to block digester at 110^oC and heat until the solution again begins to turn brown, about 30 minutes. Cool sample, then add 2 mL of 30% hydrogen peroxide to the sample, return to the block digester at 110^oC and reduce the solution volume to 5-10 mL. Allow sample to cool, then dilute to 100 mL volume with deionized water.

2. Sample Analysis

a. Refer to LOP # 312.3 for ICAP analysis and LOP # 311.2 for AA analysis.

J. CALCULATIONS AND DATA REPORTING

Refer to LOP #312.3 for ICAP analysis and LOP # 311.2 for AA analysis.

K. REFERENCES

1. EPA Method 200.3, "*Sample Preparation Procedure for Spectrochemical Determination of Total Recoverable Elements in Biological Tissues*", current version.

2. LOP #312.3, "*Analysis of Metals by PE Optima 4300 ICAP*", current version.

3. LOP # 311.2, "*Determination of Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption*", current revision.

4. LOP # 32.3, "*Sample Disposal*", current revision.

APPENDIX B

Jackson State Environmental Laboratory
Environmental Biology

JS NELAP Laboratory ID# 59867
NPDES Laboratory ID# JS 20849

Standard Operating Procedure JSEL-EB-103

Multiple Tube Fermentation (MTF) and Most Probable Number (MPN)

DRAFT EXAMPLE – DO NOT QUOTE OR CITE

Author: _____
Senior Microbiologist Nancy Morse

Approved: _____
Laboratory Director Ellen H. Bailey

Distribution

Ellen H. Bailey, Quality Assurance Officer and
Environmental Biology Laboratory Director

Laboratory Copy, maintained by Ellen H. Bailey

Paul Hines, Quality Assurance Officer
Jackson State Environmental Laboratory

Revision Record

Revision	Date	Responsible Person	Description of Change
1	June 2001	Ellen H Bailey	Initial Release
2	May 2003	Ellen H. Bailey	Additional description; minor typographical errors; QAO
3	December 2005	Ellen H. Bailey	Add 8.2.4; add clarification to 9.3.8, 10.0 and 10.1.
4	February 2007	Ellen H. Bailey	Change Lab Director

The following laboratory staff have read this Manual. A copy of this page will be distributed to the employee training record file.

Signature Title Date

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1. SCOPE AND APPLICATION. These methods are used to detect estimated numbers of total coliforms, and fecal coliforms or *E. coli* in 100 ml of potable (drinking) water or 100 ml source water samples, and in marine and wastewater samples. In addition, this method is used by public health officials to test shellfish and their overlying waters for evidence of recent contamination. The detection limits for this method range from less than 1.1 colony forming units (CFU) to infinite).

2. METHOD SUMMARY. A series of 5 to 10 tubes containing lauryl tryptose broth (LTB) are inoculated with aliquots of sample. If a five tube series is performed, at least three 10-fold dilutions of sample are inoculated into tubes containing LTB. The tubes are incubated at 35.0 ± 0.5 ^{o}C for 48 hours. If potable drinking water is being analyzed, 100 ml of water must be analyzed. The tubes are examined at 24 and 48 hours for presence of growth and gas. Tubes with growth and gas are considered presumptively positive for total coliform. Tubes are transferred to confirmatory broth (BGBL for total coliform and EC broth or EC/MUG broth for fecal coliform and/or *E. coli*) and incubated at the required temperature for a designated time.

3. DEFINITIONS. The coliform group comprises several genera of bacteria belonging to the family Enterobacteriaceae. The historical definition of the group is based on the method used for detection rather than on the tenets of systematic bacteriology.

3.1 MTF – Multiple Tube Fermentation

3.2 MPN (Most Probable Number) – when multiple tubes are used in the fermentation technique, results of the examination of replicate tubes and dilutions are reported in terms of the most probable number of organisms present. This number, based on certain probability formulas, is an estimate of the mean density of coliforms in the sample per 100ml.

4. HEALTH AND SAFETY WARNINGS.

4.1 Microbiological analyses involve the culturing of potentially pathogenic organisms. Standard biosafety level 2 precautions should be followed.

4.2 Observe all safety procedures discussed in the "JSEL Chemical Hygiene Plan".

4.3 All microbiologically contaminated media in the laboratory shall be autoclaved prior to disposal.

4.4 Laboratory equipment and benches shall be disinfected at least twice daily.

4.5 Mouth pipetting is prohibited.

4.6 All accidents, particularly those which may result in infection, shall be reported to the Laboratory Supervisor.

4.7 MSDS sheets detailing the hazards of media and reagents are available in the laboratory.

5. INTERFERENCES. High concentrations of chlorine can interfere with growth of coliform organisms. For this reason, if chlorine is expected, sodium thiosulfate shall be added to sample bottle prior to autoclaving.

6. HANDLING AND PRESERVATION.

6.1 Samples for microbiological analysis shall be collected in approved sample bottles in accordance with procedures set forth in Doc No. JSEL-QA-101, "Jackson State Environmental Laboratory Quality Manual."

6.2 A completed Request for Analysis form should accompany each sample submitted for analysis.

6.3 Sample bottles that contain thiosulfate to neutralize chlorine and shall not be washed out of the sample bottles prior to sample collection.

6.4 Sample collectors are encouraged to hold samples at <10 ^{o}C during transit to the laboratory.

6.5 Analysis of potable waters shall begin within 30 hours of sample collection. Analysis of samples from all other waters sources shall begin within 8 hours of sample collection.

7. EQUIPMENT AND SUPPLIES

7.1. Laboratory Apparatus

7.1.1 Air-jacketed fan circulating air incubator set at 35.0 ± 0.5^{o}C

7.1.2 Circulating water bath set at 44.5 ± 0.2^{o}C

7.1.3 Disposable (plastic/borosilicate) 10, 5, 1mL serological pipets (sterile)

7.1.4 Hardwood applicator sticks, sterilized by hot air oven.

7.1.5 Cotton-tipped applicator sticks, sterile

7.1.6 Fischer-Scientific 99mL sterile PBS blanks (or equivalent brand)

7.1.7. Borosilicate culture tubes, 150 x 20mm and 150 x 18mm containing inverted fermentation vials 75 x 10mm

7.1.8 Loose fitting/screw cap tops

7.1.9 Pyrex 100mL graduated cylinders

7.1.10 Culture tube racks

7.2. Preparation of Medium

Use media commercially available. Avoid preparing media from initial ingredients.

7.2.1 Presumptive test – Lauryl tryptose broth.

Make up lx, 2x, 3x and/or 6x broth so that final concentration (after sample addition) is not less than the standard medium. Follow manufacturer's recommendations for preparation. Final pH should be 6.8 ±0.2.

7.2.2 Confirmed test – Brilliant green bile lactose (BGBL) broth (2%) and EC/MUG medium

Prepare media following manufacturer's recommendation. Final pH for BGBL is 7.2 ±0.2 and for EC/MUG, 6.9 ±0.2.

8. QUALITY CONTROL

8.1. Calibration and standardization. Check and record temperatures in incubator twice daily, separated by at least 4 hours. Thermometers must be checked at least annually against a NIST-certified thermometer using the protocol specified in SOP JSEL-EB-111. For calibration of laboratory equipment, check JSEL Quality Manual appendix G for list of equipment and their SOP numbers.

8.2. Quality Control.

8.2.1 Analyze a minimum of one known positive sample per quarter using this method, if no positive samples have been processed.

8.2.2 Media – each lot of prepared media is checked for the following parameters:

8.2.1 Sterility – each lot is incubated for 24 hours at 35.0±0.5°C and examined for presence of growth and gas. If a tube is positive for growth or gas, the entire lot is discarded.

8.2.2 pH – pH of the media is measured prior to, and after, autoclaving. If the pH is outside the manufacturer's specifications prior to autoclaving it can be adjusted by addition of NaOH or HCl. If the pH exceeds these specifications after autoclaving, the entire prepared batch must be discarded.

8.2.3 Proper reactions using standard culture controls that include a total coliform, fecal coliform and/or *E coli* and a non-coliform will be used to evaluate the results with each set of samples.

8.2.3 Successfully analyze a set of commercially available performance samples twice a year. In lieu of measurement of uncertainty studies for the presence/absence format, the method performance is demonstrated by acceptable analysis of a set of performance test unknowns semi-annually. Method performance for the quantitative format has been established at this laboratory through a measurement of uncertainty study performed March 2005.

8.2.4 For general quality assurance/quality control procedures associated with this method and the associated laboratory procedures see Appendix J of the JSEL Quality Manual.

9. PROCEDURES

9.1. General Testing Procedures

9.1.1. Disinfect work area before and after analysis.

9.1.2.. Ensure that sample complies with Sample Acceptance Policy (see JSEL-A 609.3).

9.1.3. All samples shall be numbered, opened and handled individually to avoid mixing of samples.

9.2. Sample Preparation

9.2.1 Water samples with high solids – blending of sediments, primary effluents, sludge, and highly turbid waters is essential for representative subsampling. Blend the entire water sample containing in a laboratory scientific blender. Use only autoclavable borosilicate glass, stainless steel, or plastic blender containers with safety screw covers to prevent release of aerosols. Limit blending to no more than 30 seconds at about 5000 RPM to avoid overheating or shearing damage. Dilute sediments or soils containing limited amounts of water at a 1:1, 1:2 ratio or more with dilution water to ensure good blending action and to reduce heat generation. Use of a smaller blender container rather than smaller blender units will also reduce heat production.

9.2.2 Analysis of shellfish samples performed similarly to section 9.1, except that the shellfish are aseptically shucked prior to blending. A minimum of 6 - 8 shellfish are used to provide statistically reliable data. See reference "Recommended Procedures for the Examination of Sea Water and Shellfish" 1970 for details.

9.3. Analysis

9.3.1 Presumptive phase– arrange tubes in rows with the number of dilutions dependent upon the quality and character of the samples. For potable water use ten 10mL portions or a single bottle of 100mL portion. If a single bottle of 100 mL is used, the color indicator, bromocresol purple is added. For non-potable waters use five tubes per dilution with a minimum of three 10 fold serial dilutions.

9.3.2 Shake sample and sample-containing dilution bottles vigorously about 25 times over an arc of 12 inches in less than 7 seconds. Remove cap from sample bottle. Inoculate each tube in a set of five with replicate sample volumes in decreasing volumes. If necessary, mix test portions in the medium by gentle agitation.

9.2.3 After incubating inoculated tubes or bottles at 35 ±0.5^{o}C for 24 ± 2 hours, gently agitate the bottles and tubes in the rack and examine for gas production or effervescence, growth and acidic reaction. If no gas or acid production has occurred, re-incubate and re-examine at the end of 48 ± 3 hours. Record presence or absence of heavy growth, gas and/or acid production. Since the fecal coliform test can be run in parallel, transfer to EC/MUG and BGBL at the same time. At the end of 48 hours, if there is heavy growth, but no gas, follow through with the confirmation phase.

9.4 Interpretation

9.4.1 Production of gas and growth formation in the tubes or bottles after the required incubation time constitutes a positive presumptive reaction. Submit tubes with a positive presumptive reaction to the confirmed phase. The absence of growth or gas at the end of the required incubation period constitutes a negative test.

9.4.2 Confirmed phase – Submit all primary tubes/bottles showing heavy growth, any amount of gas, or acidic growth within 24 hours incubation to the confirmed phase. If additional primary tubes/bottles show active fermentation or growth at the end of a 48-hour incubation period, submit these to the confirmation phase. Gently shake the primary tubes or bottles showing gas/growth to resuspend the organisms. With a set of two sterile wood sticks held side-by-side, transfer some liquid from each presumptive tube to a tube containing EC/MUG, first, and then a tube containing BGBL. Remove the wooden sticks and discard. Repeat this for all presumptive tubes/bottles. Incubate the inoculated EC/MUG broth tube 24 hours at 44.5 ±0.2°C and the inoculated BGBL tubes for 24-48 hours at 35.0 ±0.5°C. Examine the BGBL at 24 and 48 hours for the presence of growth/gas. The formation of any amount of gas in this tube within the 48-hour incubation constitutes a positive confirmed phase. The EC/MUG tube is examined at 24 hours as prescribed by "For detection of *E coli* in drinking water."

9.4.3 Completed phase – Not required for potable drinking water samples. Streak one LES Endo agar or MacConkey agar plate from each positive BGBL tube so that single colonies can be isolated. Incubate plates at 35.0 ±0.5°C for 24 ± 2 hours. Typical colonies are pink to dark red with a green metallic surface sheen. Select one or more isolated colonies and streak onto nutrient agar slant and inoculate one or more LTB tubes. Incubate broth tubes at 35.0 ±0.5°C for 24 -48 hours and observe for gas production. In addition, develop a Gram-stain preparation from the agar slant incubated at the same temperature and time sequence and look for the presence of gram negative rods.

9.4.4. Record results on appropriate record sheet (JSEL-EB-103A). Call in positive results, or if requested by submitting agency.

10. DATA ANALYSIS AND CALCULATIONS

10.1 The results of the confirmed or completed test may be obtained from an MPN table based on the number of positive tubes in each dilution. See attachment A or reference noted in section 12 below. Note that 100mL sample aliquots of potable water are reported as presence/absence only.

10.2. Positive results are immediately called in to local health departments. Phone calls are recorded on the result sheet, including the date and time of call, and on the Request for Analysis form including the date, time, person to whom the information was reported, results reported, and caller. Negative results are called in only if a request to do so is made on the Request for Analysis form OR any time the sample is related to an illness (this data is supplied on the Request for Analysis form.) A list containing salient phone numbers is posted in the laboratory.

10.3. Worksheets are compared against reported results and the Request for Analysis form to ensure the lack of transcription errors. Worksheets and reports are signed or initialed and dated by the supervisor or the deputy after accuracy has been ascertained. If mistakes in transcription have occurred, the report is re-submitted to data entry for immediate correction.

11. WASTE MANAGEMENT. All infectious waste shall be autoclaved prior to disposal. Glassware is reused. Follow "Pollution Prevention Plan for the Jackson State Environmental Laboratory" located in the JSEL Quality Manual.

12. REFERENCES

Method 9221 – Multiple-Tube Fermentation Technique for Members of the Coliform Group. *In*: *Standard Methods for the Examination of Water and Wastewater*, 21st edition or most current EPA approved version. American Public Health Association. Washington, D.C.

Recommended Procedures for the Examination of Sea Water and Shellfish. 1970. American Public Health Association, Washington, D.C.

Chemical Hygiene Plan. Jackson State Environmental Laboratory. Current version.

Pollution Prevention Plan. Jackson State Environmental Laboratory. Current version.

Jackson State Environmental Laboratory Quality Manual, Doc No. JSEL-QA-101. Current version.

APPENDIX C

WASTEWATER SAMPLE COLLECTION

November 18, 2006

Janice Bland
EMB/ESAD

DRAFT EXAMPLE – DO NOT QUOTE OR CITE

APPROVED:

_____	_____
Author	Date
_____	_____
Manager, Environmental Monitoring Branch	Date
_____	_____
Quality Assurance Officer Environmental Science and Assessment Division	Date

Annual Reviewer				
Date				

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Attachments:

1. Equipment List (2 pages).

A. PURPOSE AND APPLICABILITY

The purpose of this Standard Operation Procedure (SOP) is to establish a uniform procedure for collecting wastewater samples for the analysis of non-organic parameters specified in National Pollutant Discharge Elimination System (NPDES) permits and in pretreatment agreements. The procedures outlined in this SOP are applicable to all Regional inspectors who collect samples of wastewater at federal, municipal and industrial facilities in support of water compliance regulations.

B. SUMMARY OF THE METHOD

Compliance samples of a wastewater stream are collected in accordance with permit requirements. They can be instantaneous (grab) samples, and/or composites. A composite sample is a sample in which, over a period of time, representative aliquots of a wastewater stream are collected manually or automatically using a portable compositor. Normally, the aliquots are combined into one sample in the compositor. At the end of sampling, the sample is divided among one or more containers and preserved, if needed. The sample is then packed in ice and shipped to the EPA Region 21's Laboratory (RLAB). The resultant data are then compared to permit limits to determine compliance or are used to establish new permit limits.

C. DEFINITIONS

1. Non-organic parameters. Parameters that: 1) require analysis off site; and 2) are not identified as "organics" in SOP 2334.20 1. Examples include: nutrients, metals, cyanide, oxygen demand parameters, oil and grease, residues, chlorides, sulfides, sulfates, hardness, alkalinity, specific conductance, total organic carbon, acute and chronic toxicity and others listed in 40 CFR 136.3.

2. Permittee. The holder of an NPDES permit or a pretreatment agreement.

3. Facility. A wastewater treatment plant (WWTP) or an industry that generates a regulated process wastewater that discharges directly to the environment or to a WWTP.

D. HEALTH AND SAFETY WARNINGS

Wastewater can be classified as sanitary, process, or combined (sanitary plus process). Some process wastewaters that do not come in contact with product, such as non-contact cooling or boiler blow-down, may appear innocuous. However, the sampler should treat all sources of wastewater as though each contained a chemical and/or a biological agent that could cause illness. The sampler should wear protective gloves, and the sample containers should be handled with care. The sampler should also wear safety gear such as steel-toed boots, a hard hat, safety glasses and earplugs to protect him or her from other environmental hazards. In the winter time, the sampler should take extra precautions when working outside in the cold. The sampler should test surfaces for slipperiness and pay particular attention to conditions when working at the edge of cavernous basins. Also, pay particular attention to icy roads when traveling.

E. CAUTIONS

Concentrated strong acids (nitric, sulfuric) are used to preserve metals and nutrient samples and sodium hydroxide is used to preserve cyanide samples. All three preservatives are corrosive and toxic. Care must be taken when handling them.

F. INTERFERENCES

The purpose of representative sampling is to characterize the true picture of the wastewater at the time of sampling. Contaminants introduced into the sample containers through careless handling, or by using "dirty" preservatives can bias the true picture.

G. PERSONNEL QUALIFICATIONS

This SOP is written specifically for NDPES inspectors. All personnel who perform activities with this SOP must have the Basic Inspector Training and the Hazardous Waster Operations Training (including the 8 hour refresher). Additional training could include NPDES permitting and regulations as well as on-the-job training.

H. EQUIPMENT AND SUPPLIES

The reader is referred to Attachment 1. This attachment lists equipment, sample containers, preservatives and other paraphernalia the sampler will need to consider when conducting a sampling inspection. SOP 2334.20 addresses equipment and supplies needed for organics sample collection.

I. PROCEDURAL STEPS

1. As a rule, wastewater sampling is associated with a compliance inspection of a facility that discharges a regulated wastewater. In addition to this SOP, SOP 2332.2 2 covers aspects of sampling inspections that the inspector should be familiar with. Included are facility selection, sample planning, analytical requests, field sheets, chain of custody, label and equipment preparation, inspection protocol and data management. This SOP focuses on the collection of wastewater samples that best represent the effluent stream during the period of sampling. Other helpful SOPs include SOP 2334.20 and SOP 2333.1 3.

2. Conditions encountered in the field can be quite variable. The sampler will find himself, or herself, in situations in which he must make decisions based on common sense and a few fundamentals. Instead of hard-and-fast rules, the procedures listed in this SOP are guidelines meant to provide the fundamentals on which to make good decisions.

3. The objectives of the sampling activity will dictate which wastewater streams should be sampled and where they should be sampled at any particular facility. In most cases, the actual sampling point for compliance monitoring has been previously established. However, for good reason (brought to light in his or her inspection report) the sampler may elect to pick a new sampling point in lieu of the traditional one. Guidelines to consider when picking a sampling point include:

a. Sample where the wastewater is well mixed.

b. Sample in the center of the channel at about half depth where the velocity of flow is average or above average and the chances of solids settling are minimal.

c. Sample where flow is measured.

d. If sampling from a faucet, valve or other line tap device, allow sufficient flushing before collecting.

4. Wastewater Treatment Plants

Influent samples at wastewater treatment plants should be collected upstream of any recirculation flows such as supernatant, filtrate, sludge and filter backwash, or any treatment. In many cases, an influent sampling point has already been established. The sampler should check to see if that point is upstream of any of the above flow sources before selecting it. The following are preferred influent sampling points:

a. At the throat of a Parshall flume or other flow measuring device.

b. Downstream of a comminutor, bar screen or other screening device.

c. Inlet to the distribution box or channel following a raw wastewater pumping station or force main from a main lift station.

d. Inlet to a grit chamber.

e. Wet well of a raw wastewater pumping station.

Effluent samples at wastewater treatment plants should be collected at the most representative site downstream of all entering waste streams and treatment prior to being discharged to the receiving water body. The most desirable location may not be accessible. Therefore, the sampler must select the next best location to obtain a representative sample. The preferred effluent sampling points include:

a. At the end of the outfall pipe (e.g., Outfall 001).

b. At the throat of a Parshall flume or similar flow measuring device if it is downstream of the last treatment unit.

c. At the outlet from the last treatment unit such as the final clarifier or disinfection system.

5. Industries

Unless specified otherwise in the pre-treatment agreement, sample discharges at the end of process wastewater pre-treatment (or no treatment, as the case may be) before mixing with other wastewater from the facility.

6. Sample types (grabs or composites):

a. Collect the type of sample specified in the permit of the facility being inspected, unless directed otherwise by the client.

b. When the permit requires collecting a composite sample for pH, dissolved oxygen, chlorine, purgeable organics, oil and grease, cyanide, hexavalent chromium and/or coliform bacteria, the sampler should sample according to the permit. However, because of holding time or preservation requirements, the sample should be collected as a grab sample, and the sampler should note this under Findings in his or her inspection report. The sampler may wish to collect both grabs and composites to demonstrate differences.

7. Sample Collection

a. Composite Sampling - Use an automatic composite sampler that is clean and contains new pump tubing. Pumping tubing will have been checked for contamination by following the SOP 2334.14 4 “Tubing Blanks”. The sample collection container used in the automated sampler will have adequate capacity to hold all of the sample used to perform anticipated analysis. In most cases, the sample collection container may be plastic but samples for organic analysis will only be collected in glass. Pump intake tubing can be plastic except all organic samples shall be collected using Teflon intake tubing. The Teflon tubing will have been checked for organic contamination by following SOP 2334.14.

The sampler should collect aliquots of sample at an adequate volume and frequency that provides a representative sample with enough volume to perform the intended analysis. Another consideration is the variability of the flow both in volume and content. Where flow characteristics are not highly variable, the sampler should collect an aliquot each hour or less time intervals. As a general rule, where the flow appears more variable, the time interval between aliquots collected should be reduced to account for the variability. If the variability cannot be determined, the sampler should collect aliquots at a more frequent time interval. For a highly variable flow, the interval might be as short as five or 10 minutes.

Another consideration would be the collection of samples over less than 24 hours. If a sample is to be collected for a discharge of 12 hours or less, the frequency of sample collection should be at shorter intervals and a high volume to help assure a representative sample of adequate volume.

b. Grab sampling - Insert the sample container directly into the wastewater with the mouth of the container facing upstream.

1. If direct insertion is impractical, then use a pre-cleaned plastic or stainless steel bucket on a rope to dip into the waste stream, and then pour the wastewater into the sample container(s).

2. For oil and grease, use a single length or double length pole sampler for immersing the glass bottle into the wastewater.

3. If access to the wastewater is a manhole, and the manhole cover is permanently attached but with a port for accepting the intake line for a composite sampler, use a composite sampler for collecting the grab sample.

c. Field measurements - For on-site measurements of pH, temperature, dissolved oxygen, or conductivity, immerse the probe of the meter directly into the waste stream. Otherwise, collect a grab sample for these measurements and preserve the sample immediately with the correct preservative.

8. Using the facility's sampling equipment.

If conditions preclude the use of the inspector's sampling equipment, he, or she, may use the facility's equipment provided the equipment meets the inspector's approval. Considerations should include the: 1) security of the sampler; 2) location of the sampler intake with respect to the wastewater flow stream; 3) cleanliness of the intake tubing and collection bottle(s); 4) ambient temperature around the collection bottle; 5) aliquot volumes; and 6) sampling intervals (if time driven) or sample volumes (if flow driven).

9. Parameters to be analyzed:

a. When sampling facilities for permit compliance, the permit parameters that have limits should be sampled, as a minimum.

b. Exclude parameters that the laboratory cannot analyze and/or the holding times cannot be met.

10. Preparing samples for shipment to the laboratory.

a. Secure the sample label to the container with 2-inch, clear, adhesive tape. Wrap the tape around the container at least one time. This will insure that the label will not separate from the container as water accumulates from the melting ice in the ice chest.

b. Samples received by RLAB are required to be at 4-6° Centigrade. When the inspector ships samples to RLAB in a cooler (ice chest), he or she should place the samples in a large, heavy duty plastic bag that does not leak water. Enough ice should be packed

around the samples in the bag in the ice chest to ensure their arrival at the right temperature.

The samples must be accompanied by the sample field sheets and a chain-of-custody record placed in the ice chest, but outside the bag. A custody seal, signed and dated, should be placed on the ice chest between the lid and the body of the ice chest. A practical method is to place in a zip lock bag the documents and tape the bag to the inside lid of the ice chest.

J. DATA AND RECORDS MANAGEMENT

A data summary will be provided by RLAB and will be attached to the facility inspection report or trip report. A hard copy and an electronic copy of the data will also be kept by RLAB along with all bench data. The NPDES and Facilities Branch (NFB) maintains the inspection reports in the Regional Records Center (RRC) located on the ground floor of the EPA Region 21's main office. NFB maintains four types of record filing which follow EPA Records Series 211A. These include NPDES Compliance files, Performance Audit Inspection Compliance files, Pretreatment Compliance files and Tribal Compliance files. The File Break for compliance files occurs annually with any active material identified and brought forward by program personnel. The inactive material remains in the RRC for one year after the File Break and is then transferred to the Federal Records Center five years after the File Break the material is destroyed.

K. QUALITY ASSURANCE AND QUALITY CONTROL

1. A field blank is prepared for each parameter requiring a preservative. If the parameter of interest is detected in a sample and also in the field blank, the inspector is to ignore it's presence in the sample unless it is found at a concentration 10 times, or more, than that found in the blank. If, indeed, the concentration in the sample is 10 times that found in the field blank, the inspector is to accept the reported sample value as is.

2. Other inspection and sampling procedures not covered in this SOP will be done in accordance with SOPs 2332.2 and 2334.20.

L. REFERENCES

1. SOP 2334.20 Organics Sampling Collection.
2. SOP 2332.2 NPDES Compliance Sampling Inspection.
3. SOP 2333.1 Field Equipment Calibration and Maintenance.
4. SOP 2334.14 Tubing Blanks.

M. ATTACHMENTS / CHECKLISTS

Equipment List (2 pages).

NOTE: Appendices, Checklists, and Attachments are not added to this example SOP.

APPENDIX D

JOINT AIR COMPLIANCE OVERVIEW INSPECTION

December 20, 2006

By

Paul Hershey,
ACB/ESAD/EPA Region XXI

DRAFT EXAMPLE – DO NOT QUOTE OR CITE

APPROVED:

___*electronic signature and date*_____
Author, Paul Hershey, Air Compliance Branch

___*electronic signature and date* _____
Peer Reviewer, Air Compliance Branch

___*electronic signature and date* _____
Chief, Air Compliance Branch

____*electronic signature and date* _____
Independent Quality Assurance Reviewer, EPA Region XXI

Recertified:

initials				
date	/ /2008	/ /2009	/ /2010	/ /2011

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Attachments

A. Joint Overview Inspection Checklist, 3 pages.

B. Joint Overview Inspection Report Checklist, 1 page.

C. Example Report Format, 2 pages.

A. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to establish uniform procedures pertaining to the preparation for, the performance of, and the reporting of joint (State/EPA) air compliance overview inspections (JOIs) as performed by the Air Compliance Branch (ACM), Environmental Science and Assessment Division (ESAD). The JOIs are performed as a means of evaluating the effectiveness, reliability, and completeness of the state/local agency's inspection procedures in the administration and enforcement of its air compliance inspection program established pursuant to Section 114 of the Clean Air Act (CAA). The SOP will aid in ensuring credibility, accuracy, and completeness of all joint overview air compliance inspections and reports completed by ACB.

Specifically, the JOIs are designed to provide a critique of individual state inspector-conducted air compliance monitoring inspections as a mechanism for assessing the quality of the field activities for obtaining and documenting information.

The inspector may deviate from these procedures when necessary due to unexpected or unique problems that may occur in the field. Any deviation must be discussed in the report.

B. APPLICABILITY

The policies and procedures of the SOP are applicable to all personnel involved in the planning, coordination, preparation, conducting, and reporting of joint air compliance overview inspections.

C. SUMMARY OF METHOD

The JOIs are performed as part of the EPA's quality assurance function in assessing the state's air compliance inspection program. An important objective is to evaluate inspection procedures to ensure continuing compliance of the sources. The JOI provides EPA the opportunity to overview the effectiveness and the level of the state/local agency's on-site compliance assurance activities for all stationary sources. The JOI will be conducted as a Compliance Evaluation Report (CER), unless otherwise indicated by the Air Permitting and Compliance Division (APCD). A CER is defined in SOP #231.1C, Air Compliance Monitoring Inspections.

During the JOI, the state/local agency inspector assumes the lead role while the EPA inspector evaluates their performance with no interruption. After the inspection, the EPA inspector completes the Joint Air Compliance Overview Inspection Checklist (Attachment A) which is reviewed, discussed, and signed by both inspectors. The Joint Air Compliance Overview Inspection Report Checklist (Attachment B) is completed after the state/local inspector's inspection report is received by the EPA inspector. The completed JOI report is sent to the APC Division.

D. DEFINITIONS

1. Compliance Evaluation Report (CER): A comprehensive evaluation of the compliance status of the entire facility. It addresses all regulated pollutants at all regulated emission points.

2. EPA Inspector: The EPA Inspector who is assigned to perform the JOI.

E. PERSONNEL QUALIFICATIONS

Certain duties and responsibilities have been assigned to specific Regional personnel as follows:

1. Branch Manager: The person responsible for assigning an EPA Inspector to perform the necessary coordination and/or to conduct and complete the JOI in a timely manner and to ensure that the personnel within their area of responsibility adhere to the policies and procedures outlined in this SOP.

2. EPA Inspector: The EPA Inspector assigned to conduct the JOI. The personnel performing JOIs should have completed all required training to be a lead inspector as defined in EPA Order 3500.1, Training and Development of Lead Compliance Inspectors/Field Investigators. Personnel should also be a senior level inspector, with adequate experience to evaluate the state/local inspector. Have the responsibility of conducting JOI activities in accordance with the SOP and references.

F. PROCEDURAL STEPS

Joint Air Compliance Overview Inspections involve the selection of the candidates, the preparation for the field procedures, the field procedures and the documentation of findings in the report.

1. INSPECTION SELECTION
At the beginning of each fiscal year, APCB will provide ACB with a target number of joint inspections and the selected State inspectors. The EPA Inspector will coordinate with the selected State Inspector on an appropriate inspection candidate and schedule. The facility to be inspected will be chosen based on its difficulty and the state/local inspector's schedule. More difficult facilities are preferred to better evaluate the inspector's abilities. When the specific JOI has been chosen, it will be communicated to APCD.

To schedule a JOI:

a. Contact appropriate state/local inspector and explain JOIs.
b. Determine if any of his/her prospective inspections might be candidates for a JOI.
c. Choose the JOI source and schedule tentative inspection date with state/local inspector.
d. Contact APCD and discuss tentative JOI.

2. PREPARATION FOR INSPECTION

After the EPA inspector has scheduled a JOI with the appropriate state/local inspector, preparation for the inspection should commence. The EPA inspector should be familiar with the facility to be inspected in order to objectively evaluate the state/local inspector's performance. In preparation for the JOI, the EPA inspector will:

a. Contact the APCD state coordinator to discuss the proposed inspection and any special issues related to the source or the JOI.

b. Contact the appropriate state/local agency personnel where the inspection is to be performed to:

(1) Make arrangements to review state/local agency files, if practical, or request copies of pertinent information from it.
(2) Coordinate participation in the inspection.

c. Initiate a search of the APCD files, state/local agency files and data systems for the following information:

(1) List and description of each process or unit.
(2) List and description of each emission point and attendant air pollution control equipment.
(3) List of all applicable regulations for each emission point.
(4) Baseline operational parameters for each air pollution source, where available.
(5) Potential and/or real problems.
(6) Citizen complaints.
(7) Compliance status history.

d. Initiate a search of other files which may contain pertinent information, e.g., Aerometric Informational Retrieval System (AIRS), Water Compliance, RCRA Compliance, etc.

e. Review the regulations for each emission point, e.g., State Implementation Plan (SIP), New Source Performance Standards (NSPS), National Emission Standards for Hazardous Air Pollutants (NESHAP), Prevention of Significant Deterioration (PSD), construction and operating permits, etc.

f. Review appropriate references, e.g., inspection manuals, guidelines, etc.

g. Prepare a file for the inspection which contains the following:
(1) Applicable JOI inspection forms.
(2) Process Summary Sheets, completed with the point source information compiled during the inspection preparation.
(3) Visible Emissions Data Evaluation Sheets.
(4) Background information from pre-inspection file reviews.

h. Since safety is of utmost concern during a JOI, the procedures outlined in publication number EPA-340/1-85-002a, Air Pollution Source Inspection Safety Procedures, should be understood before and utilized during the inspection.

i. Assemble and prepare appropriate inspection and safety equipment.

3. FIELD PROCEDURES

The JOI consists of an EPA inspector accompanying a state/local agency inspector on an actual Compliance Evaluation Report (CER) inspection of a regulated facility. The state/local agency inspector will take the lead role in the performance of the inspection. The EPA inspector will observe, with no interference, and evaluate the state/local agency inspector's procedures.

a. Preliminary Procedures (prior to site entry):
(1) Meet with the state/local agency inspector to finalize the conduct of the inspection,
(2) Complete the Inspection Preparation Activities and Pre-entry Procedures sections of the Joint Air Compliance Overview Inspection Checklist (Attachment A).

b. Site Entry:
(1) Upon obtaining access to the facility and presenting the appropriate credentials to the responsible official in charge of the facility, the official shall be informed that the state/local agency inspector has the lead role in SOP No. 2312.11C conducting the inspection and that the EPA inspector is observing the state/local agency inspector. The EPA inspector should not take an active role in conducting the inspection.

(2) Sign-in. The EPA inspector need only provide identification and must not sign a release of liability. If the facility requires sign-in for safety/security reasons, make sure that it is not a waiver of any rights. If unsure, do not sign anything.

c. Facility Tour:

(1) Follow the state/local agency inspector through the conduct of the inspection.
(2) Take notes regarding the inspection procedures of the state/local agency inspector.
(3) Complete the Joint Air Compliance Overview Inspection Checklist during and/or immediately after the inspection.
(4) Take notes regarding unusual occurrences of operation and problems at the facility.

d. Exit Interview: During the exit interview, the state/local inspector should discuss inspection findings with the authorized facility personnel.

e. Post-Inspection Procedures: When the facility inspection has been completed, conduct a review of the Joint Air Compliance Overview Inspection Checklist with the state/local agency inspector.

(1) Complete the Joint Air Compliance Overview Inspection Checklist.
(2) Discuss the inspection findings with the state/local agency inspector.
(3) Provide immediate feedback, positive and negative, to the state/local inspector regarding the quality of the inspection using the Joint Air Compliance Overview Inspection Checklist.
(4) Discuss and record in the comment section of the Joint Air Compliance Overview Inspection Checklist any clarifications, additions and differences of opinion raised by you or the state/local inspector.
(5) If, after the post-inspection discussion, the state/local inspector suggests returning to the source, ACB will recommend that the state/local inspector indicate this in the state/local inspection report.
(6) Obtain the signature of state/local inspector attesting to the fact that he/she has reviewed and discussed the JOI checklist findings.
(7) Request that a copy of the state/local agency inspection report be submitted to the EPA inspector within fifteen (15) days of completion of the JOI.
(8) Upon receipt of inspection report, review and complete the Joint Air Compliance Overview Inspection Report Checklist (Section G).

4. INSPECTION REPORT

The EPA inspector will prepare a formal report to document the inspection findings. This report will consist of the completed checklist.

All inspection reports will contain the information and be presented in the format described as follows. (See Attachment C for an example report format):

a. Heading - This indicates the type of inspection performed, e.g., JOINT AIR COMPLIANCE OVERVIEW INSPECTION REPORT

b. Facility Identification - This includes the name, location, telephone number, AIRS Facility Subsystem (AFS) Plant I.D., the date of the inspection and the regional office conducting the inspection.

c. Introduction - This section describes the purpose and objectives of the inspection. This section also includes the date and time of the inspection and the weather conditions during the inspection.

d. Participants - This section includes the name, title and affiliation of each participant.

e. Inspection Procedures - This section briefly describes the activities conducted during the inspection.

f. Process/Facility Description - This section should contain a description of the process including the Standard Industrial Classification (SIC) number and a description of the facility, its process and air pollution control equipment. The detail included will depend on the facility inspected and the extent to which information is current and available in the files from previous inspections. Applicable previous inspection information should be referenced.

g. Discussion of Inspection Procedures - This section contains discussion of the specific inspection procedures used by the state/local inspector. This section should include specific procedures used by the state/local inspector and comments on those procedures. Any problems, discrepancies and deficiencies, as well as positive aspects should be discussed. The discussion should be based on observations of the inspector's activities and the information contained on the Joint Overview Air Compliance Inspection and Report Checklists.

h. Summary/Recommendations - This is based upon the previous sections and should include conclusions which can be made about the state/local agency inspector's activities and state/local agency inspection policies. Both positive and negative comments should be included. Also discuss any influence your actions might have had on the state/local inspector's inspection. This section should be oriented toward improving the state/local agency's air compliance inspections.

i. Signatures - The inspector will sign the report. The date signed will be included, e.g.: (Inspector's Name) Environmental Engineer and Date:

j. Attachments - These are identified by a number (e.g., Attachment 1) and placed in numerical sequence in the report. They may include:

(1) Joint Air Compliance Overview Inspection Checklist.
(2) Joint Air Compliance Overview Inspection Report Checklist.
(3) State/local Agency Inspection Report.
(4) Other appropriate documents, i.e., photographs and any documents obtained during the inspection.

G. RECORDS MANAGEMENT

The original, signed final report is transmitted to APCD.

H. QUALITY CONTROL AND QUALITY ASSURANCE

After the field portion of the inspection, the EPA Inspector documents the inspection in a written report. The draft of the written report is first peer-reviewed for technical content by the Team Leader or by a member of the inspection staff. The draft is then reviewed by the Branch Manager for final approval. The final report is completed and transmitted to the Air Permitting and Compliance Division (APCD).

I. REFERENCES

1. Training and Development of Lead Compliance Inspectors/Field Investigators, EPA Order 3500.1.

2. Air Pollution Source Inspection Safety Procedures, EPA-340/1-85-002a.

3. US EPA, Region XXI, Air Compliance Monitoring Inspections, SOP #232.1C.

NOTE: Appendices, Checklists, and Attachments are not added to this example SOP.

APPENDIX E

PREPARING, NUMBERING, RETAINING, INDEXING, REVISING, and USING STANDARD OPERATING PROCEDURES

June 7, 2007

Halifax Environmental Laboratory

DRAFT EXAMPLE - DO NOT QUOTE OR CITE

AUTHOR:

_____ _____
Date

APPROVED:

_____ _____
Manager Date

_____ _____
Quality Assurance Manager Date

Reviewed

Initials				
Date				

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A. PURPOSE AND APPLICABILITY:

The purpose of this document is to establish a uniform process for the preparation and review of Halifax Environmental Laboratory standard operating procedures (SOPs). This SOP is applicable to this laboratory only.

B. SUMMARY OF METHOD

Standard operating procedures (SOPs) are written to describe study methods or processes in sufficient detail so as to ensure the quality and integrity of the data, and serve the following functions:

1. Document established procedures that lead to quality data;
2. Provide the technical staff with references for specific tasks;
3. Construct checklists and quality controls for inspections and audits;
4. Help management evaluate the adequacy of the procedures; and
5. Provide an historical record of the procedures in use for a given study at a given time, thus allowing for the reconstruction of the study at a later date.

To achieve these functions, SOPs must be written by an individual experienced in the process to be described; the completed SOPs then must be reviewed and approved by peer reviewers, the QA Manager, and appropriate management prior to the use of the SOP. A set format in styling, information required, and a numbering system is needed, as well as biannual or annual review to ensure that the procedure is up-to-date. An archival system is needed to ensure that an historical record can be maintained and only current SOPs are available for staff use.

C. DEFINTIONS

a. Addendum: an addendum is written when the scope of the procedure is expanded.
b. Administrative SOP: a standard operating procedure which does not involve environmental data manipulation activities, e.g., how to conduct an inspection.
c. Clarification: a clarification is written when one or more of the procedural steps lack sufficient detail or when additional steps are added to ensure the quality/integrity of the data.
d. Technical SOP: a standard operating procedure which involves environmental data generation, manipulation, or compilation, e.g., an analytical process.

D. RESPONSIBLITIES

1. It is the responsibility of staff to identify the need for development or revision of a standard operating procedure (SOP) and to convey that need to their immediate supervisor and/or the QA Manager (QAM).

2. It is the responsibility of the author of an individual SOP to include sufficient detail that the process or procedure can be followed by another person when needed.

3. It is the responsibility of the author to request peers to review the SOP to determine whether it contains sufficient detail.

4. It is the responsibility of the immediate supervisor and the QA Manager to review and approve the SOP prior to its use.

5. It is the responsibility of both the staff, and the QAM, to ensure that the procedure or process follows the details noted in the individual SOP and to detail in writing when the SOP or a component of that SOP has not been followed.

6. It is the responsibility of the manager to ensure that all routine operations and activities in their area are documented by SOPs.

7. It is the responsibility of the QAM to oversee the appropriate preparation, numbering, retention, indexing, revision, and use of SOPs.

E. PROCEDURAL STEPS

PREPARING SOPS

1. Identify the need for an SOP or the revision of an existing one by informing the appropriate supervisor.

2. Once the need for a particular SOP is established, it should be drafted immediately.

3. SOPs are drafted by laboratory or supervisory staff qualified to perform the procedure. Next the SOP is reviewed by other staff, where possible, and then approved by the QA Manager (QAM) and management, such as immediate supervisor. Circulation to staff members for review/comment is advisable prior to acquiring management approval.

4. The SOPs should be written to describe study methods or processes in sufficient detail so as to ensure the quality and integrity of the data or procedure to be followed.

5. When writing SOPs, the detail used may include both procedural requirements (exact instructions) and guidance information (general information) on the procedure.

6. Procedural requirements must be followed exactly, while guidance information is used to help perform the procedure; it is not a mandatory requirement and, therefore, it does not have to be followed exactly.

7. Procedural requirements can be distinguished from guidance elements, based on the context they are used (e.g., MUST or SHALL indicates the action as a procedural requirement and command statements, such as "Remove the animal from its cage").

8. Follow office standard format for margins, font, and font size.

9. Official SOPs will have a colored header and footer on each page, dated signatures on the front title page, and be printed on ivory colored paper with a watermark.

10. Use an outline format and include alpha and/or numeric characters to indicate levels of information.

11. The SOP must include the following information where applicable:
    a) Header and footer, detailing:
        1) SOP No. (assigned by QAM and established based on defined categories, e.g., A is used for administrative processes, and B and C are used for biological chemical procedures, respectively
        2) Page X (current page) of Y (total number of pages)
        3) Revision No. (new SOPs will be indicated by the use of a zero after the procedure number and subsequent revisions will be marked as 1, 2, 3…..etc.)
        4) Effective date (date when procedure has been approved by all parties for use)
    b) Title Page
        1) Identifier: Standard Operating Procedure for …….
        2) Signature lines minimally for author, QAM, and immediate supervisor
    c) Table of Contents (not needed if SOP is three pages or less)
    d) Purpose and Applicability
    e) Summary of Method
    f) Definitions (if any terms need to be defined)
    g) Personnel Responsibilities/Qualifications (applying primarily to administrative and technical SOPs respectively)

h) Health and Safety Warnings (primarily for technical SOPs)
i) Cautions (primarily for technical SOPs)
j) Interferences (primarily for technical SOPs)
j) Equipment and Supplies (primarily for technical SOPs)
k) Procedural Steps
l) Data and Records Management
m) Quality Assurance and Quality Control
n) References

NUMBERING SOPS

1. SOPs are numbered sequentially based on assignment to a specific category, such as:

100-199	General Information and Quality Assurance
200-299	Instrument and Equipment Calibration, Maintenance, and Testing
300-399	Routine Procedures
400-499	Specialized Procedures
500-599	Data and Records Management
600-	Miscellaneous or unassigned.

2. The QAM is responsible for assigning SOP numbers and determining category. Numbers are assigned sequentially and may only be used once, i.e., numbers cannot be reused even if a procedure is eliminated or incorporated into another SOP.

SOP INDEXING

1. Each SOP will be listed numerically in the "Table of Contents" and "Alphabetical Index" in the laboratory Quality Manual.

2. The QAM is responsible for maintaining both the "Table of Contents" and the "Alphabetical Index".

3. The author of the SOP is responsible for providing up to 3 keywords to the QAM for indexing the SOP.

REVISING SOPS

1. If the SOP does not accurately describe the procedure, then the SOP must be revised. Any change in the procedure must be incorporated into the SOP. However, prior to any change to the SOP, management must be advised of, and approve, the change.

2. Finalized SOPs, containing typographical errors, printing errors, e.g., wrong page numbers or misaligned sentences) or any errors that do not affect the scope of the procedure may be correctly immediately and reprinted. These types of errors do not require full SOP revision, thus a revision number will not be generated and management approval is not needed. If the error occurs on the signature page then the signature page will be resigned. These types of corrections will be traceable since the historical file will reflect all corrections including typographical errors. Specifically, the historical SOP file will contain both the SOP with the correct page(s) as well as the page(s) containing the error. The page with the error will not be removed from the historical file.

3. Additions can be made to an SOP via a clarification or an addendum.

4. Clarifications and addenda must be attached to the applicable SOP until such time that the SOP can be revised. Generally, the revision will be incorporated during the biannual review process.

5. When the SOP is revised, the revision number is updated. Revisions, clarifications, and addenda are prepared by appropriate personnel, but must be approved by management.

6. An SOP can be eliminated when it is no longer applicable. Management must approve the elimination of an SOP. Two or more SOPs can be consolidated; in this case one SOP supersedes the other, but management approval is required for consolidation of procedures.

7. The signed revised SOP must be sent to the historical file for archiving.

USING SOPS

1. Prior to performing a procedure for the first time, the individual must document in writing that they have read and reviewed the specific SOP.

2. In addition, the staff should review all SOPs at least once every two years to ensure that each SOP accurately describes the procedure in use. The biannual review will be documented in writing. SOP review signature logs will be maintained the company's archives.

3. All procedures must be performed in accordance with the written SOPs.

4. If a given procedure is not performed in accordance with the pertinent SOP, the all SOP deviations must be written to document the change in the procedure.

5. The laboratory section chief must be informed and must acknowledge in writing the occurrence of the SOP deviation and must determine the effect, if any, the deviation may have on the integrity of the data.

6. All deviations must be filed with the study information.

F. RECORDS MANAGEMENT

ACCESS AND LOCATION OF SOPS

1. Appropriate SOPs will be placed in green binders to be found in a designated spot in each work area, e.g., laboratory, equipment rooms, the library, etc., and shall be available to staff and managers. These binders will not be located in the supervisor's office. Removal of an individual SOP requires completion of the sign-out located on the insider of the binder. The binder must not be removed from its designated spot by anyone other than the QAM or laboratory director.

2. It is the responsibility of the QAM to update each binder as individual SOPs are revised.

3. The staff is required to read any revised SOP within 7 working days of issuance if the SOP is applicable to their work.

4. Reading of the updated SOP requires signature on the SOP review sheet.

SOP RETENTION

1. An historical file is created for each SOP that is approved by management and will be maintained in the company's archives by the QAM.

2. The historical file will consist of the original signed SOP and all subsequent modifications thereof.

3. Official SOPs will have both colored header and footer lines, and be printed on watermarked ivory colored paper. All copies of the original will be black and white, initialed, numbered, and placed in the appropriate binder located in each office.

4. If a procedure is incorporated into another SOP (superseded), a copy of the superseded version is placed in the historical file of both SOPs.

G. QUALITY ASSURANCE AND QUALITY CONTROL

1. All SOPs are reviewed by the applicable supervisor at least every two years in order to maintain their relevancy.

2. Before January 31st of each calendar year, a list of all SOPs which are at more than one year old is provided by the QAM to each supervisor.

3. For those SOPs which do not require a revision, documentation attesting to that fact must be submitted to the QAM who in turn initials and dates the table located at the bottom of the title page of the original SOP.

H. REFERENCES

1. Quality Manual. Halifax Environmental Laboratory. Current version.
2. Guidance for the Preparation of Standard Operating Procedures. U.S. EPA. Current Version.