Vermont CEM Requirements Revision 5

Appendix A
EPA Guidelines for Preparing Quality Assurance Project Plans

APPENDIX M

INTERIM GUIDELINES AND SPECIFICATIONS FOR PREPARING QUALITY ASSURANCE PROJECT PLANS

M.1 INTRODUCTION

Environmental Protection Agency (EPA) policy requires participation by all EPA regional offices, program offices, EPA laboratories and States in a centrally-managed QA program as stated in the Administrator's Memorandum of May 30, 1979. This requirement applies to all environmental monitoring and measurement efforts mandated or supported by EPA through regulations, grants, contracts, or other formalized means not currently covered by regulation. The responsibility for developing, coordinating and directing the implementation of this program has been delegated to the Office of Research and Development (ORD), which has established the Quality Assurance Management Staff (QAMS) for this purpose.

Each office or laboratory generating data has the responsibility to implement minimum procedures which assure that precision, accuracy, completeness, and representativeness of its data are known and documented. In addition, an organization should specify the quality levels which data must meet in order to be acceptable. To ensure that this responsibility is met uniformly across the Agency, each EPA Office or Laboratory must have a written QA Project Plan covering each monitoring or measurement activity within its purview.

M.2 DEFINITION, PURPOSE, AND SCOPE

M.2.1 Definition

QA Project Plans are written documents, one for each specific project or continuing operation (or group of similar

projects or continuing operations), to be prepared by the responsible Program Office, Regional Office, Laboratory, Contractor, Grantee, or other organization. The QA Project Plan presents, in specific terms, the policies, organization, objectives, functional activities, and specific QA and QC activities designed to achieve the data quality goals of the specific project(s) or continuing operation(s). Other terms useful in understanding this guideline are defined in Appendix A of this volume.

M.2.2 Purpose

This document (1) presents guidelines and specifications that describe the 16 essential elements of a QA Project Plan, (2) recommends the format to be followed, and (3) specifies how plans will be reviewed and approved.

M.2.3 Scope

The mandatory QA program covers all environmentally-related measurements. Environmentally-related measurements are defined as all field and laboratory investigations that generate data. These include (1) the measurement of chemical, physical, or biological parameters in the environment, (2) the determination of the presence or absence of pollutants in waste streams, (3) assessment of health and ecological effect studies, (4) conduct of clinical and epidemiological investigations, (5) performance of engineering and process evaluations, (6) study of laboratory simulation of environmental events, and (7) study or measurement on pollutant transport and fate, including diffusion models. Each project within these activities must have a written and approved QA Project Plan.

M.3 PLAN PREPARATION AND RESPONSIBILITIES

M.3.1 Document Control

All Quality Assurance Project Plans must be prepared using a document control format consisting of information placed in

the upper right-hand corner of each document page (Section 1.4.1 of this Volume):

1. Section number
2. Revision number
3. Date (of revision)
4. Page.

M.3.2 Elements of QA Project Plan

Each of the sixteen items listed below must be considered for inclusion in each QA Project Plan:

1. Title page with provision for approval signatures
2. Table of contents
3. Project description
4. Project organization and responsibility
5. QA objectives for measurement data in terms of precision, accuracy, completeness, representativeness and comparability
6. Sampling procedures
7. Sample custody
8. Calibration procedures and frequency
9. Analytical procedures
10. Data reduction, validation, and reporting
11. Internal quality control checks and frequency
12. Performance and system audits and frequency
13. Preventive maintenance procedures and schedules
14. Specific routine procedures to be used to assess data precision, accuracy and completeness of specific measurement parameters involved
15. Corrective action
16. Quality assurance reports to management.

It is Agency policy that precision and accuracy of data shall be assessed on all monitoring and measurement projects. Therefore, Item 14 must be described in all Quality Assurance Project Plans.

M.3.3 Responsibilities

M.3.3.1 Intramural Projects - Each Project Officer working in close coordination with the QA Officer is responsible for the preparation of a written QA Project Plan for each intramural project that involves environmental measurements. This written plan must be separate from any general plan normally prepared for the project (see caveat presented in Section M.6). The Project Officer and the QA Officer must ensure that each intramural project plan contains procedures to document and report precision, accuracy and completeness of all data generated.

M.3.3.2 Extramural Projects - Each Project Officer working in close coordination with the QA Officer has the responsibility to see that a written QA Project Plan is prepared by the extramural organization for each project involving environmental measurements. The elements of the QA Project Plan must be separately identified from any general plan normally prepared for the project (see caveat presented in Section M.6). The Project Officer and the QA Officer must ensure that each extramural project plan contains procedures to document and report precision, accuracy and completeness of all data generated.

M.4 PLAN REVIEW, APPROVAL, AND DISTRIBUTION

M.4.1 Intramural Projects

Each QA Project Plan must be approved by the Project Officer's immediate supervisor and the QA Officer. Completion of reviews and approvals is shown by signatures on the title page of the plan. Environmental measurements may not be initiated until the QA Project Plan has received the necessary approvals. A copy of the approved QA Project Plan will be distributed by the Project Officer to each person who has a major responsibility for the quality of measurement data.

M.4.2 Extramural Projects

Each QA Project Plan must be approved by the funding organization's Project Officer and the QA Officer. In addition, the

extramural organization's Project Manager and responsible QA official must review and approve the QA Project Plan. Completion of reviews and approvals is shown by signatures on the title page of the plan. Environmental measurements may not be initiated until the QA Project Plan has received the necessary approvals. A copy of the approved QA Project Plan will be distributed by the extramural organization's Project Director to each person who has a major responsibility for the quality of the measurement data.

M.5 PLAN CONTENT REQUIREMENTS

The sixteen (16) essential elements described in this section must be considered and addressed in each QA Project Plan. If a particular element is not relevant to the project under consideration, a brief explanation of why the element is not relevant must be included. EPA-approved reference, equivalent or alternative methods must be used and their corresponding Agency-approved guidelines must be applied wherever they are available and applicable.

It is Agency policy that precision and accuracy of data shall be assessed routinely and reported on all environmental monitoring and measurement data. Therefore, specific procedures to assess precision and accuracy on a routine basis during the project must be described in each QA Project Plan. Procedures to assess data quality are being developed by QAMS and the Environmental Monitoring Systems/Support Laboratories. Additional guidance can be obtained from QA handbooks for air, water biological, and radiation measurements (References 1, 2, 3, 12, 17, and 18).

The following subsections provide specific guidance pertinent to each of the 16 components which must be considered for inclusion in every QA Project Plan.

M.5.1 Title Page

At the bottom of the title page, provisions must be made for the signatures of approving personnel. As a minimum, the QA Project Plan must be approved by the following:

1. For intramural projects

   a. Project Officer's immediate supervisor
   b. QA Officer (QAO)

2. For extramural projects

   a. Organization's Project Manager
   b. Organization's responsible QA Official
   c. Funding organization's Project Officer
   d. Funding organization's QA Officer.

M.5.2 Table of Contents

The QA Project Plan Table of Contents will address each of the following items:

1. Introduction
2. A serial listing of each of the 16 quality assurance project plan components
3. A listing of any appendices which are required to augment the Quality Assurance Project Plan as presented (i.e., standard operating procedures, etc.).

At the end of the Table of Contents, list the QA official and all other individuals receiving official copies of the QA Project Plan and any subsequent revisions.

M.5.3 Project Description

Provide a general description of the project. This description may be brief but must have sufficient detail to allow those individuals responsible for review and approval of the QA Project Plan to perform their task. Where appropriate, include the following:

1. Flow diagrams, tables, and charts
2. Dates anticipated for start and completion
3. Intended end use of acquired data.

M.5.4 Project Organization and Responsibility

Include a table or chart showing the project organization and line authority. List the key individuals, including the QAO, who are responsible for ensuring the collection of valid measurement data and the routine assessment of measurement systems for precision and accuracy.

M.5.5 QA Objectives for Measurement Data in Terms of Precision, Accuracy, Completeness, Representativeness, and Comparability

For each major measurement parameter, including all pollutant measurement systems, list the QA objectives for precision, accuracy and completeness. These QA objectives will be summarized in a Table M.1.

TABLE M.1. EXAMPLE OF FORMAT TO SUMMARIZE PRECISION, ACCURACY AND COMPLETENESS OBJECTIVES

Measurement parameter (Method)	Reference	Experimental conditions	Precision, std. dev.	Accuracy	Completeness
NO_2 (Chemiluminescent)	EPA 650/4-75-011 February 1975	Atmospheric samples spiked with NO_2 as needed	<±10%	± 5%	90%
SO_2 (24 h) (Pararosaniline)	EPA 650/4-74-027 December 1973	Synthetic atmosphere	<±20%	±15%	90%

All measurements must be made so that results are representative of the media (air, water, biota, etc.) and conditions being measured. Unless otherwise specified, all data must be calculated and reported in units consistent with other organizations reporting similar data to allow comparability of data bases among organizations. Definitions for precision, accuracy and completeness are provided in Subsection M.10 and Appendix A.

Data quality objectives for accuracy and precision established for each measurement parameter will be based on prior knowledge of the measurement system employed, method validation studies using, for example, replicates, spikes, standards, calibrations, and recovery studies and on the requirements of the specific project.

M.5.6 Sampling Procedures

For each major measurement parameter(s), including all pollutant measurement systems, provide a description of the sampling procedures to be used. Where applicable, include the following:

1. Description of techniques or guidelines used to select sampling sites
2. Inclusion of specific sampling procedures to be used (by reference in the case of standard procedures and by actual description of the entire procedure in the case of nonstandard procedures)
3. Charts, flow diagrams or tables delineating sampling program operations
4. A description of containers, procedures, reagents, etcetera, used for sample collection, preservation, transport, and storage
5. Special conditions for the preparation of sampling equipment and containers to avoid sample contamination (e.g., containers for organics should be solvent-rinsed; containers for trace metals should be acid-rinsed)
6. Sample preservation methods and holding times
7. Time considerations for shipping samples promptly to the laboratory
8. Sample custody or chain-of-custory procedures
9. Forms, notebooks and procedures to be used to record sample history, sampling conditions and analyses to be performed.

M.5.7 Sample Custody

Sample custody is a part of any good laboratory or field operation. Where samples may be needed for legal purposes, "chain-of custody" procedures, as defined by the Office of Enforcement, will be used. However, as a minimum, the following sample custody procedures will be addressed in the QA Project Plans:

1. Field Sampling Operations:

a. Documentation of procedures for preparation of reagents or supplies which become an integral part of the sample (e.g., filters, and absorbing reagents)

b. Procedures and forms for recording the exact location and specific considerations associated with sample acquisition

c. Documentation of specific sample preservation method

d. Prepared sample labels containing all information necessary for effective sample tracking. Figure M.1 illustrates a typical sample label applicable to this purpose

e. Standardized field tracking reporting forms to establish sample custody in the field prior to shipment. Figure M.2 presents a typical sample of a field tracking report form.

2. Laboratory Operations:

a. Identification of responsible party to act as sample custodian at the laboratory facility authorized to sign for incoming field samples, obtain documents of shipment (e.g., bill of lading number or mail receipt), and verify the data entered onto the sample custody records

b. Provision for laboratory sample custody log consisting of serially numbered standard lab-tracking report forms. A typical sample of a standardized lab-tracking report form is shown in Figure M.3

(NAME OF SAMPLING ORGANIZATION)

Sample description _____

_____

Plant _____ Location _____
Date _____ _____
Time _____
Media _____ Station _____
Sample type _____ Preservative _____

Sampled by _____

Sample ID number _____

Lab number _____

Remarks _____

_____

_____

Figure M.1. Example of General Sample Label.

W/O number _____ Page ____

Field Tracking Report _____
(LOC-SN)

Field sample code (FSC)	Brief description	Date	Time(s)	Sampler

Figure M.2. Sample of Field Tracking Report form.

W/O number _____ Page ____

Lab-tracking report _____
(LOC-SN-FSC)

Fraction code	X	Prep/anal required	Responsible individual	Date delivered	Date completed

Figure M.3. Sample of lab-tracking report form.

c. Specification of laboratory sample custody procedures for sample handling, storage and dispersement for analysis.

Additional guidelines useful in establishing a sample custody procedure are given in Section 2.0.6 of Reference 2, and Section 3.0.3 of Reference 3, and References 13 and 14.

M.5.8 Calibration Procedures and Frequency

Include calibration procedures and information:

1. For each major measurement parameter, including all pollutant measurement systems, reference the applicable standard operating procedure (SOP) or provide a written description of the calibration procedure(s) to be used

2. List the frequency planned for recalibration

3. List the calibration standards to be used and their source(s), including traceability procedures.

M.5.9 Analytical Procedures

For each measurement parameter, including all pollutant measurement systems, reference the applicable standard operating procedure (SOP) or provide a written description of the analytical procedure(s) to be used. Officially approved EPA procedures will be used when available. For convenience in preparing the QA Project Plan, Elements 6, 8, and 9 may be combined (e.g., Subsections M.5.6, M.5.8, and M.5.9).

M.5.10 Data Reduction, Validation, and Reporting

For each major measurement parameter, including all pollutant measurement systems, briefly describe the following:

1. The data reduction scheme planned on collected data, including all equations used to calculate the concentration or value of the measured parameter and reporting units
2. The principal criteria that will be used to validate data integrity during collection and reporting of data
3. The methods used to identify and treat outliers
4. The data flow or reporting scheme from collection of raw data through storage of validated concentrations. A flowchart will usually be needed
5. Key individuals who will handle the data in this reporting scheme (if this has already been described under project organization and responsibilities, it need not be repeated here).

M.5.11 Internal Quality Control Checks

Describe and/or reference all specific internal quality control ("internal" refers to both laboratory and field activities) methods to be followed. Examples of items to be considered include:

1. Replicates
2. Spiked samples

3. Split samples
4. Control charts
5. Blanks
6. Internal standards
7. Zero and span gases
8. Quality control samples
9. Surrogate samples
10. Calibration standards and devices
11. Reagent checks.

Additional information and specific guidance can be found in References 17 and 18.

M.5.12 Performance and System Audits

Each project plan must describe the internal and external performance and system audits which will be required to monitor the capability and performance of the total measurement system(s).

The system audit consists of evaluation of all components of the measurement systems to determine their proper selection and use. This audit includes a careful evaluation of both field and laboratory quality control procedures. System audits are normally performed prior to or shortly after systems are operational; however, such audits should be performed on a regularly scheduled basis during the lifetime of the project or continuing operation. The on-site system audit may be a requirement for formal laboratory certification programs such as laboratories analyzing public drinking water systems. Specific references pertinent to system audits for formal laboratory certification programs can be found in References 19 and 20.

After systems are operational and generating data, performance audits are conducted periodically to determine the accuracy of the total measurement system(s) or component parts thereof. The plan should include a schedule for conducting performance audits for each measurement parameter, including a performance audit for all measurement systems. As part of the performance

audit process, laboratories may be required to participate in analysis of performance evaluation samples related to specific projects. Project plans should also indicate, where applicable, scheduled participation in all other interlaboratory performance evaluation studies.

In support of performance audits, the Environmental Monitoring Systems/Support Laboratories provide necessary audit materials and devices and technical assistance. Also, these laboratories conduct regularly scheduled interlaboratory performance tests and provide guidance and assistance in the conduct of system audits. To make arrangements for assistance in the above areas, these laboratories should be contacted directly:

Environmental Monitoring Systems Laboratory
Research Triangle Park, NC 27711
Attention: Director

Environmental Monitoring and Support Laboratory
26 W. St. Clair Street
Cincinnati, Ohio 45268
Attention: Director

Environmental Monitoring Systems Laboratory
P. O. Box 15027
Las Vegas, NV 89114
Attention: Director

M.5.13 Preventive Maintenance

The following types of preventive maintenance items should be considered and addressed in the QA Project Plan:

1. A schedule of important preventive maintenance tasks that must be carried out to minimize downtime of the measurement systems

2. A list of any critical spare parts that should be on hand to minimize downtime.

M.5.14 Specific Routine Procedures Used to Assess Data Precision, Accuracy and Completeness

It is Agency policy that precision and accuracy of data must be routinely assessed for all environmental monitoring and measurement data. Therefore, specific procedures to assess precision and accuracy on a routine basis on the project must be described in each QA Project Plan.

For each major measurement parameter, including all pollutant measurement systems, the QA Project Plan must describe the routine procedures used to assess the precision, accuracy and completeness of the measurement data. These procedures should include the equations to calculate precision, accuracy and completeness, and the methods used to gather data for the precision and accuracy calculations.

Statistical procedures applicable to environmental projects are found in Appendices A through L of this Volume and in References 2, 3, 12, 17, and 18. Examples of these procedures include:

1. Central tendency and dispersion (e.g., arithmetic mean, range, standard deviation, relative standard deviation, pooled standard deviation, and geoemtric mean)
2. Measures of variability (e.g., accuracy, bias, precision; within laboratory and between laboratories)
3. Significance test (e.g., u-test, t-test, F-test, and Chi-square test
4. Confidence limits
5. Testing for outliers.

Recommended guidelines and procedures to assess data precision, accuracy and completeness are being developed.

M.5.15 Corrective Action

Corrective action procedures must be described for each project which include the following elements:

1. The predetermined limits for data acceptability beyond which corrective action is required
2. Procedures for corrective action
3. For each measurement system, identify the responsible individual for initiating the corrective action and also the individual responsible for approving the corrective action, if necessary.

Corrective actions may also be initiated as a result of other QA activities, including:

1. Performance audits
2. System audits
3. Laboratory/field comparison studies
4. QA Program audits conducted by QAMS.

A formal corrective action program is more difficult to define for these QA activities in advance and may be defined as the need arises.

M.5.16 Quality Assurance Reports to Management

QA Project Plans should provide a mechanism for periodic reporting to management on the performance of measurement systems and data quality. As a minimum, these reports should include:

1. Periodic assessment of measurement data accuracy, precision and completeness
2. Results of performance audits
3. Results of system audits
4. Significant QA problems and recommended solutions.

The individual(s) responsible for preparing the periodic reports should be identified. The final report for each project must include a separate QA section which summarizes data quality information contained in the periodic reports.

M.6 QUALITY ASSURANCE PROJECT PLANS VERSUS PROJECT WORK PLANS

This document provides guidance for the preparation of QA Project Plans and describes 16 components which must be included. Historically, most project managers have routinely included the majority of these 16 elements in their project work plans. In practice, it is frequently difficult to separate important quality assurance and quality control functions and to isolate these functions from technical performance activities. For those projects where this is the case, it is not deemed necessary to replicate the narrative in the Quality Assurance Project Plan section.

In instances where specific QA/QC protocols are addressed as an integral part of the technical work plan, it is only necessary to cite the page number and location in the work plan in the specific subsection designated for this purpose.

It must be stressed, however, that whenever this approach is used a "QA Project Plan locator page" must be inserted into the project work plan immediately following the table of contents. This locator page must list each of the items required for the QA Project Plan and state the section and pages in the project plan where the item is described. If a QA Project Plan item is not applicable to the work plan in question, the words "not applicable" should be inserted next to the appropriate component on the locator page and the reason why this component is not applicable should be briefly stated in the appropriate subsection in the QA Project Plan.

M.7 STANDARD OPERATING PROCEDURES

A large number of laboratory and field operations can be standardized and written as SOP. When such procedures are applicable and available, they may be incorporated into the QA Project Plan by reference.

QA Project Plans should provide for the review of all activities which could directly or indirectly influence data quality and the determination of those operations which must be covered by SOP's. Examples are:

1. General network design
2. Specific sampling site selection
3. Sampling and analytical methodology
4. Probes, collection devices, storage containers, and sample additives or preservatives
5. Special precautions, such as heat, light, reactivity, combustibility, and holding times
6. Federal reference, equivalent or alternative test procedures
7. Instrumentation selection and use
8. Calibration and standardization
9. Preventive and remedial maintenance
10. Replicate sampling
11. Blind and spiked samples
12. Collocated samplers
13. QC procedures such as intralaboratory and intrafield activities, and interlaboratory and interfield activities
14. Documentation
15. Sample custody
16. Transportation
17. Safety
18. Data handling procedures
19. Service contracts
20. Measurement of precision, accuracy, completeness, representativeness, and comparability
21. Document control.

M.8 SUMMARY

Each intramural and extramural project that involves environmental measurements must have a written and approved QA Project Plan. All 16 items described previously must be considered and addressed. Where an item is not relevant, a brief explanation of why it is not relevant must be included. It is Agency policy that precision and accuracy of data must be routinely assessed and reported on all environmental monitoring and

measurement data. Therefore, specific procedures to assess precision and accuracy on a routine basis during the project must be described in each QA Project Plan.

M.9 EXAMPLE OF PROJECT PLAN

For the convenience of the reader the following pages of this section contains an example of a QA project plan for ambient air monitoring. The format is retained as one would prepare a plan and hence not necessarily consistent with the Handbook format. The only exception is that the documentation is given on each page consistent with the Handbook.

M.9.1 Project Plan for Ambient Air Monitoring

A MODEL QA PROJECT PLAN

AMBIENT AIR MONITORING STUDY AROUND THE WEPCO POWER PLANT

QA PROJECT PLAN FOR IN-HOUSE PROJECT

APPROVAL:

EPA Project Officer: Thomas Swift Date 5/1/80

EPA Supervisor: Thomas Smith Date 5/5/80

EPA QA Officer: Harold Tuff Date 5/10/80

TABLE OF CONTENTS

Distribution of Approved QA Project Plan:

1. Harold Smooth, QAD, EMSL/RTP
2. Thomas Swift, EMD, EMSL/RTP
3. Thomas Tuff, EMD, EMSL/RTP
4. Mary Pickford, EMD, EMSL/RTP
5. Mike Evans, EMD, EMSL/RTP
6. Gregory Thomas, QAD, EMSL/RTP
7. Ralph Niceguy, WEPCO

1. Project Description

The WEPCO power plant, located at Somewhere, Virginia, initiated a 12-mo ambient air monitoring project on April 1, 1980, to collect air quality data necessary for a construction permit for a new 200 meg-watt coal-fired boiler. WEPCO has established a monitoring network for total suspended particulates (TSP), SO_2 and NO_2 around the existing location where the new boiler will be constructed. EPA has received permission from WEPCO to monitor for TSP, SO_2 and NO_2 at WEPCO monitoring sites 2 and 5 for six mo starting July 1, 1980. Both WEPCO and EPA monitoring complies with monitoring and quality assurance requirements for Prevention of Significant Deterioration (PSD) monitoring. The purpose of the EPA study is to compare EPA and WEPCO results. In addition, EPA plans to compare the results from their continuous SO_2 monitors to results obtained by running the manual EPA Reference Method (pararosaniline method) every six days.

2. Project Organization and Responsibility

All EPA air monitoring and quality assurance will be performed by EPA personnel from the Environmental Monitoring Systems Laboratory, Research Triangle Park, North Carolina. The air monitoring will be performed by the Environmental Measurement Division (EMD) and the quality assurance by the Quality Assurance Division (QAD). The key personnel involved in the project, their project responsibility and line authority within EMSL are shown in Figure 1.

3. QA Objectives in Terms of Precision, Accuracy, Completeness, Representativeness and Comparability

All WEPCO sampling sites, including sites 2 and 5, were inspected by The State of Virginia Air Pollution Control Division and found to be valid and representative sampling sites. All 24-h integrated samples for TSP and SO_2 (by the Reference

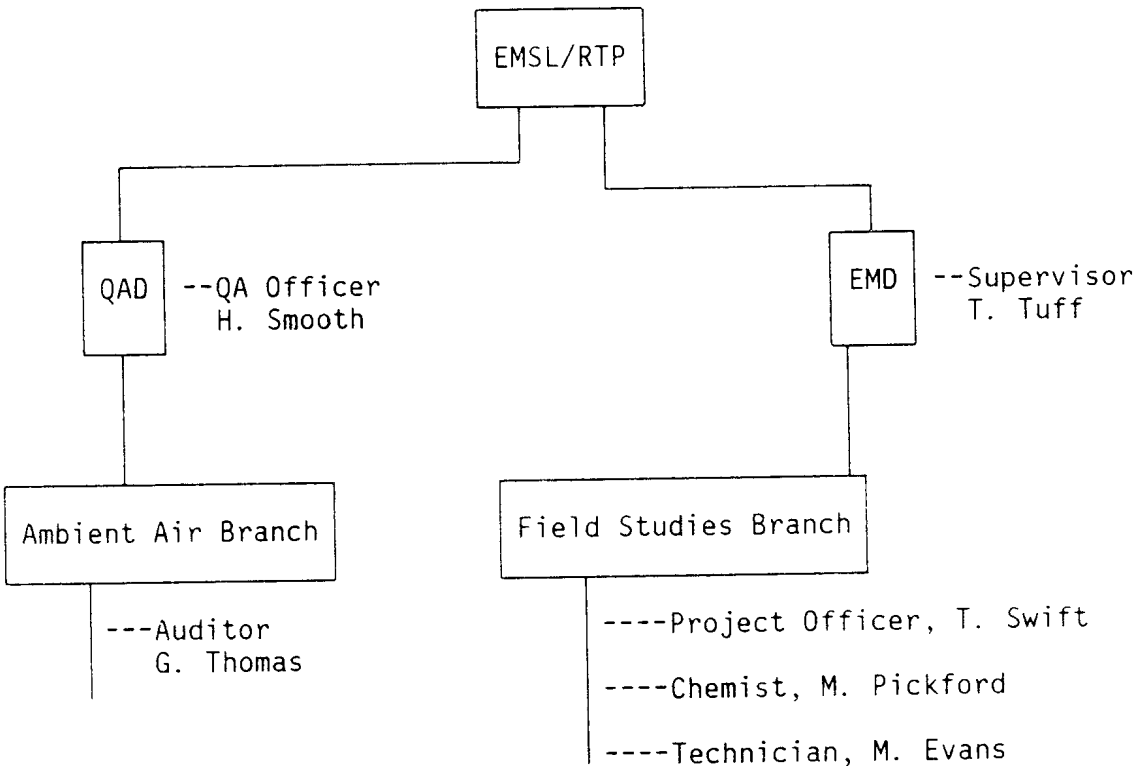

Figure 1. Project organization and responsibility.

Method) will be collected from midnight to midnight to correspond to calendar days. All results for TSP, SO_2 and NO_2 are calculated in $\mu g/m^3$ corrected to 25°C and 760 mm Hg so that results are comparable with WEPCO's data base.

The following QA objectives for precision, accuracy, and completeness have been used in the design of this study.

a. Completeness - Seventy-five (75) percent of all possible measurement data should be valid.

b. Accuracy - Each SO_2 and NO_2 continuous monitor results should agree within ±15 percent of audit concentration during each audit. Each SO_2 sample analysis audit for the SO_2 Reference Method should agree within the 90 percentile limits described in Section 2.1.8 of Volume II of this Handbook (EPA-600/

4-77-027a). Each TSP sampler flow audit should be within ±7 percent of the audit flow value.

c. Precision - Current data are insufficient to give a good estimate for precision based on the quality assurance procedures required in Appendix B, 40 CFR 58 for PSD monitoring.

4. Sampling and Analysis Procedures

All measurement methods used are EPA reference or equivalent methods. The following measurement methods will be used in this study.

a. Continuous SO_2 by Meloy SA185-2A flame photometric detector analyzers

b. Continuous NO_2 by Monitor Lab 8840 chemiluminescence analyzers

c. EPA Reference Method for SO_2 (pararosaniline method)

d. EPA Reference Method for TSP (Hi-Vol Method).

5. Sample Custody

Since this is a research project, sample custody is not planned on this project.

6. Calibration Procedures

All continuous monitors for SO_2 and NO_2 will be calibrated according to the manufacturer's recommended procedures and the recommendations in Section 2.0.9 of Volume II of this Handbook. Namely, each calibration shall include:

a. A zero concentration and three upscale concentrations equally spaced over the measurement range of 0 to 0.5 ppm

b. A daily Level 1 zero and span to be used to determine when recalibration is needed as per guidelines in Section 2.0.9 of Volume II of this Handbook.

Calibration and span gases for all continuous monitors for SO_2 and NO_2 shall be traceable to NBS, Standard Reference Materials using EPA Protocol No. 1 (Traceability Protocol for Establishing True Concentrations of Gases Used for Calibration

and Audits of Air Pollution Analyzers, Section 2.0.7 of Volume II). Specifically, cylinder gases of NO in N_2 at 50 ppm will be used for NO_2 monitors and SO_2 permeation tubes will be used for SO_2 monitors.

The calibration procedures described in the Reference Methods for TSP and SO_2 (pararosaniline method) will be followed. Recalibration shall be performed consistent with the guidance of Section 2.0.9 of Volume II of this Handbook.

7. Data Analysis, Validation, and Reporting

The analysis and flow of data from the point of collection (raw data) through calculation and storage of validated concentrations (in $\mu g/m^3$) is shown in Figure 2.

The SO_2 and NO_2 analyzers are calibrated in ppm. To convert ppm to $\mu g/m^3$ use the following equations:

$$SO_2\ \mu g/m^3 = SO_2\ ppm \times 2620$$
$$NO_2\ \mu g/m^3 = NO_2\ ppm \times 1880.$$

The equations for the calculation of SO_2 (pararosaniline bubbler method) and TSP concentrations are in the Reference Methods in Sections 2.1.6 and 2.2.6 of Volume II of this Handbook.

The principal criteria used to validate data are described in Subsection 9.1.4 of Section 2.0.9 for continuous methods (SO_2 and NO_2 analyzers) and Subsection 9.2.5 of Section 2.0.9 of Volume II of this Handbook for manual methods (TSP and SO_2 bubbler method).

8. Internal Quality Control Checks and Frequency

The operational checks recommended in Section 2.0.9 of Volume II will be used in this project for internal quality control. A listing of the operational checks, the control limits for initiating corrective action, the planned corrective action, and the reference for more detailed description are shown in Figure 3.

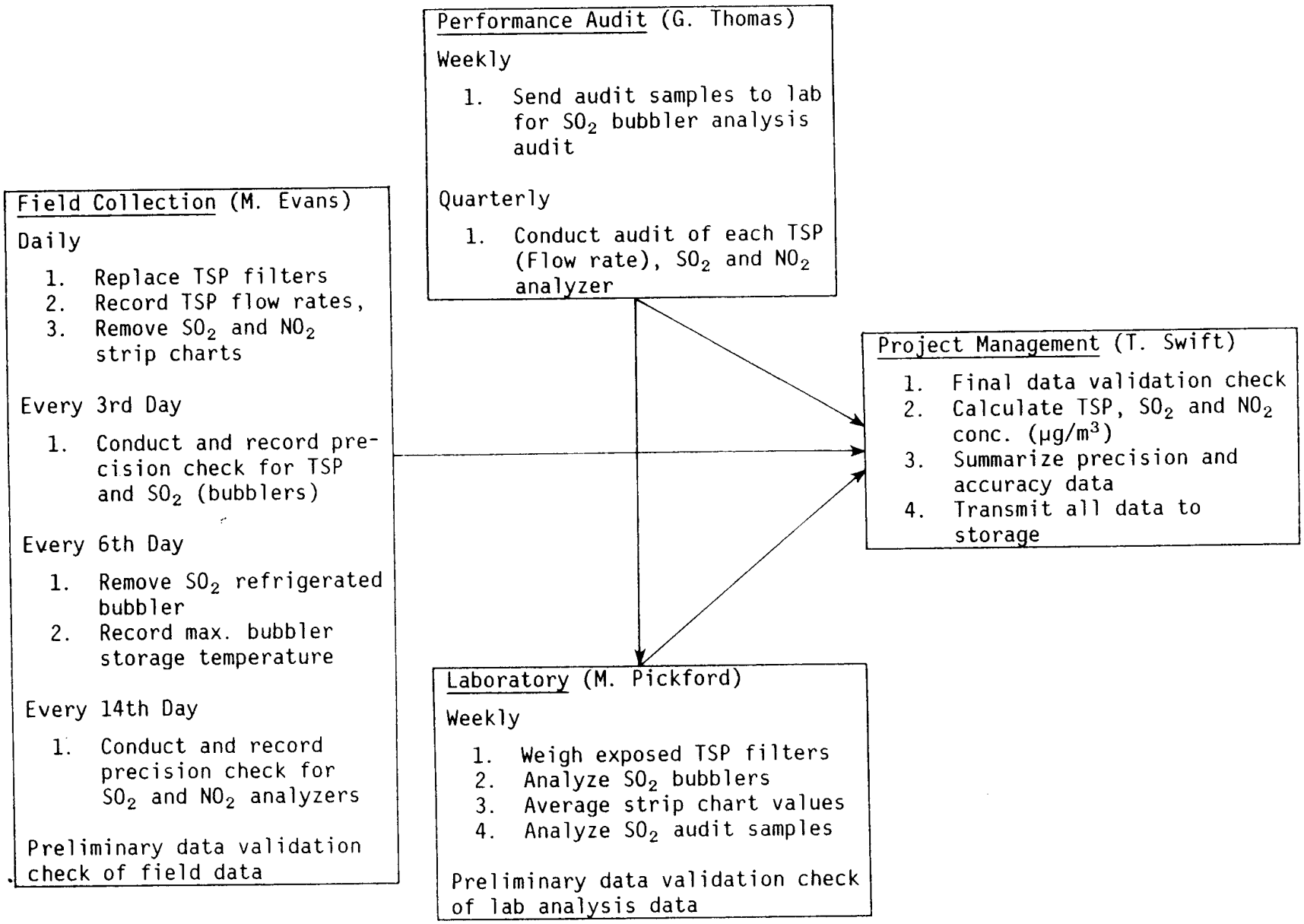

Figure 2. Data flow and analysis.

Measurement	Operation check	Control limit	Corrective action planned
Continuous SO_2 and NO_2	daily level 1 span and zero drift check[1]	1. 3 std deviations 2. zero ±0.025 ppm 3. span ±15% 4. span ±25%	1. adjust analyzer 2. recalibrate 3. recalibrate 4. invalidate data
Manual SO_2 (Pararosaniline)	record bubbler temp during sampling and maintain low temp during shipment/ storage[1]	temp must be between 5 and 25°C	invalidate sample
	sampling flow rate check each sample day[1,2]	±10%	invalidate sample
	blank and standard solution each analysis day after every 10th sample[1,2]	1. blank absorbance ±0.03 units 2. std solution ±0.07 μg/ml	1. reanalyze previous 10 samples 2. reanalyze previous 10 samples
TSP	sampling flow rate check each sample day[1,3]	±10%	recalibrate hi-vol sampler
	monthly reweigh a portion of exposed filters[1,4]	±5 mg	reweigh all exposed filters

[1]Section 2.0.9 of Volume II of QA Handbook.
[2]Section 2.1.5 of Volume II of QA Handbook.
[3]Section 2.2.4 of Volume II of QA Handbook.
[4]Section 2.2.8 of Volume II of QA Handbook.

Figure 3. Internal quality control checks.

9. Performance and System Audits

Ambient air pollution measurements are scheduled to be initiated on July 1, 1980. A system audit is scheduled to be conducted during the week of June 23, 1980.

Performance audits to be conducted are the same type and on the same schedule as shown in Appendix B, 40 CFR 58 for PSD monitoring. Appendix B should be referred to for details. Briefly, the following performance audits and frequency will be conducted (based on Appendix B).

a. Each continuous SO_2 and NO_2 analyzer will be audited quarterly with cylinder gases.

b. For TSP, each hi-vol sampler will be audited quarterly at one flow rate between 40 and 60 cfm.

c. For SO_2 bubbler samples, laboratory analyses will be audited each analysis day with one audit sample each in the range of 0.2 - 0.3, 0.5 - 0.6, and 0.8 - 09 μg SO_2/ml. Note: This audit is described in Appendix A, not B, of 40 CFR 58.

10. Preventive Maintenance

The preventive maintenance tasks and schedules recommended by the manufacturers of the SO_2 and NO_2 analyzers will be followed. The preventive maintenance recommended for TSP and the SO_2 Reference Method (bubblers) will be the same tasks and schedules described in Section 2.2.7 (for TSP) and Section 2.1.7 (for SO_2) of Volume II of this Handbook.

The following spare materials will always be maintained on-hand during the project for daily checks and recalibrations:

a. two extra SO_2 permeation tubes

b. one extra zero cylinder gas

c. one extra 50 ppm NO cylinder gas

11. Specific Procedures to be Used to Routinely Assess Data Precision, Accuracy and Completeness

The results from performance audits described in Section 9 of this QA Project Plan are used to calculate accuracy for each measurement device. The audit frequency for each measurement device is also described in Section 9. The equations used to calculate accuracy are shown in: Appendix B of 40 CFR 58, for continuous SO_2 and NO_2, and TSP; and Appendix A of 40 CFR 58 for

the SO_2 Reference Method. Example calculations for accuracy for each measurement device are shown in Section 2.0.8 of Volume II of this Handbook.

Precision check description and frequency for each measurement device is the same as shown in: Appendix B of 40 CFR 58 for continuous SO_2 and NO_2, and TSP; and Appendix A of 40 CFR 58 for the SO_2 Reference Method. The results from these precision checks are used to calculate precision for each measurement device. The equations used to calculate precision are also shown in Appendices A and B. Example calculations for precision for each measurement device are shown in Section 2.0.8 of Volume II. A summary of the precision checks follows:

a. Each continuous SO_2 and NO_2 analyzer will be checked by the field operator every two weeks for span drift at a concentration between 0.08 and 0.09 ppm. Calculation of precision for each analyzer is based on a quarterly results.

b. The calculation of TSP precision is based on the operation of a second hi-vol sampler collocated at one of the two sites. This collocated sampler will be operated every third sampling day along with the regular hi-vol sampler. Calculation of TSP data precision is based on quarterly results and applies to both sampling sites.

c. The calculation of SO_2 precision for the Reference Method (bubbler technique) is based on the operation of a second bubbler system at one of the two sites. This collocated bubbler system will be operated every sixth day along with the regular bubbler system. Calculation of SO_2 data precision is based on quarterly results and applies to both sampling sites.

Data completeness will be calculated for each measurement device and is based on quarterly results. Completeness will be calculated as a percentage of valid data compared to the amount of data expected to be obtained under normal operations.

12. Corrective Action

Figure 3 describes internal quality control checks planned for each measurement. Control limits and planned corrective actions are also shown in Figure 3. The authority to conduct the planned corrective action when the control limits are exceeded is given to M. Evans for field operations and M. Pickford for laboratory operations.

13. Quality Assurance Reports to Management

Within 15 days following the end of the calendar quarter, precision, accuracy and completeness will be reported on each measurement system to: T. Tuff, Supervisor, EMD, EMSL/RTP; H. Smooth, EPA Project Officer; and R. Niceguy, WEPCO.

M.10 GLOSSARY OF TERMS

This glossary is specialized for the needs of developing QA project plans. The definitions do not agree precisely with those in Appendix A of this volume of the Handbook; however, they do agree in substance. One should refer to Appendix A for additional definitions or further information concerning the following definitions.

Audit - A systematic check to determine the quality of operation of some function or activity. Audits may be of two basic types: (1) performance audits in which quantitative data are independently obtained for comparison with routinely obtained data in a measurement system, or (2) system audits of a qualitative nature that consist of an on-site review of a laboratory's quality assurance system and physical facilities for sampling, calibration, and measurement.

Data Quality - The totality of features and characteristics of data that bears on their ability to satisfy a given purpose. The characteristics of major importance are accuracy, precision, completeness, representativeness, and comparability. These five characteristics are defined as follows:

1. Accuracy - the degree of agreement of a measurement X with an accepted reference or true value, T, usually expressed as the difference between the two values, X-T, or the difference as a percentage of the reference or true value, 100 (X-T)/T, and sometimes expressed as a ratio, X/T.

2. Precision - a measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions. Precision is best expressed in terms of the standard deviation. Various measures of precision exist depending upon the "prescribed similar conditions."

3. Completeness - a measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct normal conditions.

4. Representativeness - expresses the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition.

5. Comparability - expresses the confidence with which one data set can be compared to another.

Data Validation - A systematic process for reviewing a body of data against a set of criteria to provide assurance that the data are adequate for their intended use. Data validation consists of data editing, screening, checking, auditing, verification, certification, and review.

Environmentally Related Measurements - A term used to describe essentially all field and laboratory investigations that generate data involving (1) the measurement of chemical, physical, or biological parameters in the environment, (2) the determination of the presence or absence of criteria or priority pollutants in waste streams, (3) assessment of health and ecological effect studies, (4) conduct of clinical and epidemiological investigations, (5) performance of engineering and process evaluations, (6) study of laboratory simulation of environmental events, and

(7) study or measurement on pollutant transport and fate, including diffusion models.

Performance Audits - Procedures used to determine quantitatively the accuracy of the total measurement system or component parts thereof.

Quality Assurance - The total integrated program for assuring the reliability of monitoring and measurement data. A system for integrating the quality planning, quality assessment, and quality improvement efforts to meet user requirements.

Quality Assurance Program Plan - An orderly assemblage of management policies, objectives, principles, and general procedures by which an agency or laboratory outlines how it intends to produce data of known and accepted quality.

Quality Assurance Project Plan - An orderly assembly of detailed and specific procedures which delineates how data of known and accepted quality are produced for a specific project. (A given agency or laboratory would have only one quality assurance program plan, but would have a quality assurance project plan for each of its projects.)

Quality Control - The routine application of procedures for obtaining prescribed standards of performance in the monitoring and measurement process.

Standard Operating Procedure (SOP) - A written document which details an operation, analysis or action whose mechanisms are thoroughly prescribed and which is commonly accepted as the method for performing certain routine or repetitive tasks.

M.11 REFERENCES

1. Quality Assurance Handbook for Air Pollution Measurement Systems. Vol. I - Principles. EPA-600/9-76-005, March 1976.

2. Quality Assurance Handbook for Air Pollution Measurement Systems. Vol. II - Ambient Air Specific Methods. EPA-600/4-77-027a. May 1977.

3. Quality Assurance Handbook for Air Pollution Measurement Systems. Vol. III - Stationary Source Specific Methods. EPA-600/4-77-027b. August 1977.

4. Systems Audit Criteria and Procedures for Ambient Air Monitoring Programs. Section 2.0.11, Vol. II, QA Handbook. Currently under development and available from address shown in Reference 1 after July 1, 1980.

5. Techniques to Evaluate Laboratory Capability to Conduct Stack Testing.

6. Performance Audit Procedures for Ambient Air Monitoring Programs. Section 2.0.12, Vol. II.

7. Appendix A - Quality Assurance Requirements for State and Local Air Monitoring Stations (SLAMS). Federal Register, Vol. 44, No. 92, pp. 27574-81. May 10, 1979.

8. Appendix B - Quality Assurance Requirements for Prevention of Significant Deterioration (PSD) Air Monitoring. Federal Register, Vol. 44, No. 92, pp. 27582-84. May 10, 1979.

9. Appendix F - Procedure 1 - Quality Assurance Requirements for Gas Continuous Emission Monitoring Systems (CEMS) for Compliance. To be submitted as a proposed regulation to amend 40 CFR 60.

10. Test Methods for Evaluating Solid Waste - Physical/Chemical Methods. EPA SW-846. 1980.

11. Quality Assurance Guidelines for IERL-CI Project Officers. EPA-600/9-79-046. December 1979.

12. Handbook for Analytical Quality Control in Water and Wastewater Laboratories. EPA-600/4-79-019. March 1979.

13. NEIC Policies and Procedures Manual. Office of Enforcement. EPA-330-9-78-001, May 1978.

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19. Procedure for the Evaluation of Environmental Monitoring Laboratories. EPA 600/4-78-78-017. March 1978.

20. Manual for the Interim Certification of Laboratories Involved in Analyzing Public Drinking Water Supplies - Criteria and Procedures. EPA 600/8-78-008. August 1978.

U.S. GOVERNMENT PRINTING OFFICE 1985 - 559-111/10741

Vermont CEM Requirements Revision 5

Appendix B
40 CFR Part 52, Appendix E, Performance Specifications and SpecificationTest
Procedures for Monitoring Systems for Effluent Stream Gas Volumetric Flow Rate

Percent deviation from slowest time=average upscale−average downscale×100%/slower time

[40 FR 5517, Feb. 6, 1975]

APPENDIX E TO PART 52—PERFORMANCE SPECIFICATIONS AND, SPECIFICATION TEST PROCEDURES FOR MONITORING SYSTEMS FOR EFFLUENT STREAM GAS VOLUMETRIC FLOW RATE

1. *Principle and applicability.*

1.1 *Principle.* Effluent stream gas volumetric flow rates are sampled and analyzed by a continuous measurement system. To verify the measurement system performance, values obtained from the measurement system are compared against simultaneous values obtained using the reference method. These comparison tests will be performed to determine the relative accuracy, and drift of the measurement system over the range of operating conditions expected to occur during normal operation of the source. If the measurement system is such that the specified tests in section 5.1 for drift do not apply, those test procedures shall be disregarded.

1.2 *Applicability.* This method is applicable to subparts which require continuous gas volumetric flow rate measurement. Specifications are given in terms of performance. Test procedures are given for determining compliance with performance specifications.

2. *Apparatus.*

2.1 Continuous measurement system for determining stack gas volumetric flow rate.

2.2 Equipment for measurement of stack gas volumetric flow rate as specified in the reference method.

3. *Definitions.*

3.1 *Measurement system.* The total equipment required for the determination of the gas volumetric flow rate in a duct or stack. The system consists of three major subsystems:

3.1.1 *Sampling interface.* That portion of the measurement system that performs one or more of the following operations: Delineation, acquisition, transportation, and conditioning of a signal from the stack gas and protection of the analyzer from any hostile aspects of the source environment.

3.1.2 *Analyzer.* That portion of the measurement system which senses the stack gas flow rate or velocity pressure and generates a signal output that is a function of the flow rate or velocity of the gases.

3.1.3 *Data presentation.* That portion of the measurement system that provides a display of the output signal in terms of volumetric flow rate units, or other units which are convertible to volumetric flow rate units.

3.2 *Span.* The value of gas volumetric flow rate at which the measurement system is set to produce the maximum data display output. For the purposes of this method, the span shall be set at 1.5 times the maximum volumetric flow rate expected under varying operating conditions of the source.

3.3 *Zero drift.* The change in measurement system output over a stated period of time of normal continuous operation when gas volumetric flow rate at the time of the measurements is zero.

3.4 *Calibration drift.* The change in measurement system output over a stated time period of normal continuous operation when the gas volumetric flow rate at the time of the measurement is 67 percent of the span value.

3.5 *Operation period.* A minimum period of time over which a measurement system is expected to operate within certain performance specifications without unscheduled maintenance, repair, or adjustment.

3.6 *Orientation sensitivity.* The angular tolerance to which the sensor can be misaligned from its correct orientation to measure the flow rate vector before a specified error occurs in the indicated flow rate compared to the reference flow rate.

3.7 *Reference method.* Method 2 as delineated in 40 CFR Part 60.

4. *Measurement system performance specifications.* A measurement system must meet the performance specifications in Table E–1 to be considered acceptable under this method.

TABLE E–1

Parameter	Specifications
Accuracy (relative)	<10 percent of mean reference value (paragraph 6.3.1).
Zero drift (24 hours)	<3 percent of span (paragraph 6.3.2).
Calibration drift (24 hours)	<3 percent of span (paragraph 6.3.3).
Operational period	<168 hours minimum.

5. *Test procedures.*

5.1 Field test for accuracy, zero drift, calibration drift, and operation period.

5.1.1 *System conditioning.* Set up and operate the measurement system in accordance with the manufacturer's written instructions and drawings. Offset the zero point of the chart recorder so that negative values up to 5 percent of the span value may be registered. Operate the system for an initial 168-hour conditioning period. During this initial period, the system should measure the gas

stream volumetric flow rate in a normal operational manner. After completion of this conditioning period, the formal 168-hour performance and operational test period shall begin.

5.1.2 *Field test for accuracy and operational period.* During the 168-hour test period, the system should be continuously measuring gas volumetric flow rate at all times. During this period make a series of 14 volumetric flow rate determinations simultaneously using the reference method and the measurement system. The 14 determinations can be made at any time interval at least one hour apart during the 168-hour period except that at least one determination on five different days must be made with one determination on the last day of such period. The determinations shall be conducted over the range of volumetric flow rates expected to occur during normal operation of the source. The measurement system volumetric flow rate reading corresponding to the period of time during which each reference method run was made may be obtained by continuous integration of the measurement system signal over the test interval. Integration may be by use of mechanical integration of electrical units on the chart recorder or use of a planimeter on the strip chart recorder. The location and orientation of the reference method measurement device and the measurement system should be as close as practical without interference, but no closer than 1.3 cm (0.5 inch) to each other and shall be such that dilution air or other interferences cannot be interjected into the stack or duct between the pitot tube and the measurement system. Be careful not to locate the reference method pitot tube directly up or down stream of the measurement system sensor.

5.1.3 *Field test for calibration drift and zero drift.* At 24-hour intervals, but more frequently if recommended by the manufacturer, subject the measurement system to the manufacturer's specified zero and calibration procedures, if appropriate. Record the measurement system output readings before and after adjustment. Automatic corrections made by the system without operator intervention are allowable at anytime.

5.1.4 *Field test for orientation sensitivity.* If a velocity measurement system is either a single point measurement device or a pressure sensor or any other device such as pitot tube which uses the flow direction of the test gas, then the following test shall be followed and a performance specification of ±10 degrees device orientation sensitivity for ±4 percent flow rate determination accuracy must be met in order for the measurement system to be considered acceptable under this method. This is in addition to the performance specifications given in paragraph 4 of this appendix. During a period of relatively steady state gas flow, perform the following orientation test using the measurement system. The system should be continuously measuring gas velocity at all times. Rotate the measurement 10° on each side of the direction of flow in increments of 5°. Perform this test three times each at:

(1) Maximum operating velocity (±15 percent);

(2) 67 percent ±7.5 percent of the maximum operating velocity; and

(3) 33 percent ±7.5 percent of the maximum operating velocity if (2) and (3) are normal operating practices.

6. *Calculations data analysis and reporting.*

6.1 *Procedure for determination of stack gas volumetric flow rate.* Calculate the reference stack gas velocity and corresponding stack gas volumetric flow rate with the calibrated type S pitot tube measurements by the reference method. Calculate the measurement system stack gas volumetric flow rate as specified by the manufacturer's written instructions. Record the volumetric flow rates for each in the appropriate tables.

6.2 *Procedure for determination of mean values and 95 percent confidence intervals.*

6.2.1 *Mean value.* The mean value of a data set is calculated according to Equation E–1.

EQUATION E–1

$$\bar{\chi} = \frac{1}{n}\sum_{i=1} \chi_i$$

where:

x_i=individual values.

Σ=sum of the individual values.

x=mean value.

n=data points.

6.2.2 *95 percent confidence level.* The 95 percent confidence level (two sided) is calculated according to Equation E–2.

EQUATION E–2

$$C.I._{95} = \frac{t_{.975}}{n\sqrt{n-1}}\sqrt{n\left(\sum \chi_i 2\right)-\left(\sum \chi_i\right)^2}$$

where:

Σx_i=sum of all data points.

(Σx_i)=sum of squares of all data points.

$C.I._{95}$=95 percent confidence interval estimate of the average mean value.

VALUES FOR $t_{.975}$

n	$t_{.975}$	n	$t_{.975}$	n	$t_{.975}$
2	12.706	7	2.447	12	2.201
3	4.303	8	2.365	13	2.179
4	3.182	9	2.306	14	2.160
5	2.776	10	2.262	15	2.145
6	2.571	11	2.228	16	2.131

The values in this table are already corrected for n–1 degrees of freedom. Use n

equal to the number of samples as data points.

6.3 *Data analysis and reporting.*

6.3.1 *Accuracy (relative).* First, calculate the mean reference value (Equation E–1) of the 14 average volumetric flow rates calculated by the reference method. Second, from the 14 pairs of average volumetric flow rates calculated by the reference method and measurement system volumetric flow rate readings, calculate the mean value (Equation E–1) of the differences of the 14 paired readings. Calculate the 95 percent confidence interval (Equation E–2) using the differences of fourteen paired readings. To calculate the values in the second part of this section substitute d_i for x_i and d for x in Equations E–1 and E–2 where d_i equals the difference of each paired reading and d equals the mean value of the fourteen paired differences. Third, report the sum of the absolute mean value of the differences of the fourteen paired readings and the 95 percent confidence interval of the differences of value calculated in the first part of the section. Divide this total by the mean reference value and report the result as a percentage. This percentage is the relative accuracy.

6.3.2 *Zero drift (24 hour).* From the zero values measured each 24 hours during the field test, calculate the differences between successive readings expressed in volumetric flow rate units. Calculate the mean value of these differences and the confidence interval of these differences using Equations E–1 and E–2. Report the sum of the absolute value of the mean difference and the confidence interval as a percentage of the measurement system span. This percentage is the zero drift.

6.3.3 *Calibration drift (24 hour).* From the calibration values measured every 24 hours during the field test calculate the differences between: (1) The calibration reading after zero and calibration adjustment, and (2) the calibration reading 24 hours later after zero adjustment but before calibration adjustment. Calculate the mean value of these differences and the confidence interval using Equations E–1 and E–2. Report the sum of the absolute value of the mean difference and confidence interval as a percentage of the measurement system span. This percentage is the calibration drift.

6.3.4 *Operation period.* Other than that clearly specified as required in the operation and maintenance manual, the measurement system shall not require any corrective maintenance, repair, replacement or adjustment during the 168-hour performance and operational test period. If the measurement system operates within the specified performance parameters and does not require corrective maintenance, repair, replacement or adjustment other than as specified above during the 168-hour test period, the operational period will be successfully concluded. Failure of the measurement to meet this requirement shall call for a repetition of the 168-hour test period. Portions of the test, except for the 168-hour field test period, which were satisfactorily completed need not be repeated. Failure to meet any performance specifications shall call for a repetition of the one-week performance test period and that portion of the testing which is related to the failed specification. All maintenance and adjustments required shall be recorded. Output readings shall be recorded before and after all adjustments.

6.3.5 *Orientation sensitivity.* In the event the conditions of paragraph 5.1.4 of this appendix are required, the following calculations shall be performed. Calculate the ratio of each measurement system reading divided by the reference pitot tube readings. Graph the ratio vs. angle of deflection on each side of center. Report the points at which the ratio differs by more than ±4 percent from unity (1.00).

[40 FR 5521, Feb. 6, 1975]

FINDING AIDS

A list of CFR titles, subtitles, chapters, subchapters and parts and an alphabetical list of agencies publishing in the CFR are included in the CFR Index and Finding Aids volume to the Code of Federal Regulations which is published separately and revised annually.

Vermont CEM Requirements Revision 5

Appendix D
Proposed Amendments to
40 CFR Part 60 Appendix F Procedure 3-QualityAssurance Requirements for Continuous Opacity Monitoring Systems at Stationary Sources (*68 Federal Register, page 24696, May 8, 2003)*

Federal departments' or agencies' stocks, Federal departments or agencies may wish to submit requests as far in advance of the 15 calendar days as possible. The written notification of the proposed sale must include:

(1) The name and amount of the chemical to be sold;

(2) The name and address of the prospective bidder;

(3) The name and address of the prospective end-user, in cases where a sale is being brokered;

(4) Point(s) of contact for the prospective bidder and, where appropriate, prospective end-user; and

(5) The end use of the chemical.

(c) Within 15 calendar days of receipt of a request for certification, the Administrator will certify in writing to the head of the Federal department or agency that there is, or is not, reasonable cause to believe that the sale of the specific chemical to the specific bidder and end-user would result in the illegal manufacture of a controlled substance. In making this determination, the following factors must be considered:

(1) Past experience of the prospective bidder or end-user in the maintenance of effective controls against diversion of listed chemicals into other than legitimate medical, scientific, and industrial channels;

(2) Compliance of the prospective bidder or end-user with applicable state and local law;

(3) Prior conviction record of the prospective bidder or end-user relating to listed chemicals or controlled substances under Federal or state laws; and

(4) Such other factors as may be relevant to and consistent with the public health and safety.

(d) If the Administrator certifies to the head of a Federal department or agency that there is no reasonable cause to believe that the sale of a specific chemical to a prospective bidder and end-user will result in the illegal manufacture of a controlled substance, that certification will be effective for one year from the date of issuance with respect to further sales of the same chemical to the same prospective bidder and end-user, unless the Administrator notifies the head of the Federal department or agency in writing that the certification is withdrawn. If the certification is withdrawn, DEA will also provide written notice to the bidder and end-user, which will contain a statement of the legal and factual basis for this determination.

(e) If the Administrator determines there is reasonable cause to believe the sale of the specific chemical to a specific bidder and end-user would result in the illegal manufacture of a controlled substance, DEA will provide written notice to the head of a Federal department or agency refusing to certify the proposed sale under the authority of 21 U.S.C. 890. DEA also will provide, within fifteen calendar days of receiving a request for certification from a Federal department or agency, the same written notice to the prospective bidder and end-user, and this notice also will contain a statement of the legal and factual basis for the refusal of certification. The prospective bidder and end-user may, within thirty calendar days of receipt of notification of the refusal, submit written comments or written objections to the Administrator's refusal. At the same time, the prospective bidder and end-user also may provide supporting documentation to contest the Administrator's refusal. If such written comments or written objections raise issues regarding any finding of fact or conclusion of law upon which the refusal is based, the Administrator will reconsider the refusal of the proposed sale in light of the written comments or written objections filed. Thereafter, within a reasonable time, the Administrator will withdraw or affirm the original refusal of certification as he determines appropriate. The Administrator will provide written reasons for any affirmation of the original refusal. Such affirmation of the original refusal will constitute a final decision for purposes of judicial review under 21 U.S.C. 877.

(f) If the Administrator determines there is reasonable cause to believe that an existing certification should be withdrawn, DEA will provide written notice to the head of a Federal department or agency of such withdrawal under the authority of 21 U.S.C. 890. DEA also will provide, within fifteen calendar days of withdrawal of an existing certification, the same written notice to the bidder and end-user, and this notice also will contain a statement of the legal and factual basis for the withdrawal. The bidder and end-user may, within thirty calendar days of receipt of notification of the withdrawal of the existing certification, submit written comments or written objections to the Administrator's withdrawal. At the same time, the bidder and end-user also may provide supporting documentation to contest the Administrator's withdrawal. If such written comments or written objections raise issues regarding any finding of fact or conclusion of law upon which the withdrawal of the existing certification is based, the Administrator will reconsider the withdrawal of the existing certification in light of the written comments or written objections filed. Thereafter, within a reasonable time, the Administrator will withdraw or affirm the original withdrawal of the existing certification as he determines appropriate. The Administrator will provide written reasons for any affirmation of the original withdrawal of the existing certification. Such affirmation of the original withdrawal of the existing certification will constitute a final decision for purposes of judicial review under 21 U.S.C. 877.

Dated: April 25, 2003.

John B. Brown III,

Acting Administrator.

[FR Doc. 03–11393 Filed 5–7–03; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[AD–FRL–7496–1]

RIN 2060–AH23

Amendments to Standards of Performance for New Stationary Sources; Monitoring Requirements

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule and request for public comments.

SUMMARY: In this proposal we, the Environmental Protection Agency (EPA), propose to add Procedure 3, Quality Assurance Requirements for Continuous Opacity Monitoring Systems at Stationary Sources, to the regulations. This action provides quality assurance/quality control procedures for a continuous opacity monitoring system (COMS) used for compliance purposes. We are seeking public comments on this proposal.

DATES: *Comments.* You must submit comments so that they are received on or before July 7, 2003.

Public Hearing. If a public hearing has been requested, and anyone contacts us requesting to speak at a public hearing by May 22, 2003, a public hearing will be held on August 6, 2003 beginning at 9 a.m. EST. If you are interested in attending the hearing, you must call the contact person listed below (see **FOR FURTHER INFORMATION CONTACT**). If a hearing is held, rebuttal and supplementary information may be submitted to the docket for 30 days following the hearing.

Request to Speak at Hearing. If you wish to present oral testimony at the public hearing, you must call the contact person listed below (see **FOR FURTHER INFORMATION CONTACT**) by July 7, 2003.

ADDRESSES: *Comments.* Comments may be submitted electronically, by mail, by facsimile, or through hand delivery/courier. Follow the detailed instructions as provided in Section I of the **SUPPLEMENTARY INFORMATION** section. The EPA requests a separate copy also be sent to the contact person listed in **FOR FURTHER INFORMATION CONTACT**.

Public Hearing. If a public hearing is held, it will be held at the EPA campus in Research Triangle Park, North Carolina. You should contact Mr. Solomon Ricks, Source Measurement Analysis Group, Emissions, Monitoring, and Analysis Division (D243–02), U. S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541–5242, to request to speak at a public hearing or to find out if a hearing will be held.

FOR FURTHER INFORMATION CONTACT: Mr. Solomon Ricks, Source Measurement Analysis Group, Emissions, Monitoring, and Analysis Division (D243–02), U. S. EPA, Research Triangle Park, North Carolina 27711; telephone number (919) 541–5242; facsimile number (919) 541–1039; electronic mail (e-mail) address: *ricks.solomon@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. How Can I Get Copies of Related Information?

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. A–91–08. The official public docket is the collection of materials that is available for public viewing at the Air and Radiation Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket is (202) 566–1742.

2. *Electronic Access.* An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as confidential business information (''CBI'') and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Section I.B.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

For additional information about EPA's electronic public docket visit EPA Dockets online or see 67 FR 38102, May 31, 2002.

B. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, by facsimile, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket,* and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in Docket ID No. A–91–08. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by electronic mail (e-mail) to *A-and-R-Docket@epa.gov,* Attention Docket ID No. A–91–08. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that

you mail to the mailing address identified in Section I.B.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By Mail.* Send your comments to: Air and Radiation Docket, U.S. Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC, 20460, Attention Docket ID No. A–91–08.

3. *By Hand Delivery or Courier.* Deliver your comments to: Air and Radiation Docket, U.S. Environmental Protection Agency (West), 1301 Constitution Ave., NW., Room B–102, Washington, DC, 20004, Attention Docket ID No. A–91–08. Such deliveries are only accepted during the Docket's normal hours of operation as identified in Section I.A.1.

II. Outline

We provided the following outline to aid in reading the preamble to this proposal.

I. Introduction

A. Regulatory History of the Proposed Rule

Procedure 3, Quality Assurance (QA) Requirements for Continuous Opacity Monitoring Systems at Stationary Sources, was originally published in the **Federal Register** on October 7, 1992 (57 FR 46114) as Method 203. At that time, it was proposed as an addition to appendix M, Example Test Methods for State implementation plans (SIP's), in 40 CFR part 51. Concurrently, work was underway to update and revise Performance Specification 1 (PS–1), Performance Specifications for a Continuous Opacity Monitoring System (COMS). It was decided to postpone further work on Method 203 until the revisions to PS–1 were promulgated. Revisions to PS–1 were published in the **Federal Register** on November 25, 1994 (59 FR 60585). Comments on the November 1994 proposal revealed some concern and confusion with the design specifications and with the test procedures to verify compliance with the design specifications. To ensure adequate understanding of the technical issues uncovered in the comments, a public stakeholders' meeting was held on June 12, 1996. As a result of that meeting, representatives from the American Society for Testing and Materials (ASTM) D22.03, a Subcommittee on Ambient Atmospheres and Source Emissions, volunteered to undertake development of a standard practice for opacity monitor manufacturers.

On September 23, 1998, we published a supplemental proposal in the **Federal Register** (63 FR 50824) to incorporate ASTM D 6216–98 by reference into the proposed revisions to PS–1. After addressing the comments from the supplemental proposal, we published PS–1 as a final rule in the **Federal Register** on August 10, 2000 (65 FR 48914).

Following the promulgation of PS–1, we formed a stakeholders' group to address technical concerns, similar to the concerns revealed in PS–1, with Method 203 as it was originally proposed. The stakeholders' group was open to the public and consisted of opacity monitor manufacturers, representatives from the ASTM D22.03 subcommittee, State/local, and regional office personnel. After holding a series of phone conferences, we decided to re-write and re-propose Method 203. The re-write takes into account technological advances in the design and manufacture of opacity monitors, as well as the revisions to PS–1. We decided to re-propose the method as an additional procedure, Procedure 3, to be added to 40 CFR part 60, appendix F, Quality Assurance Procedures for Continuous Emission Monitoring Systems. Today's proposal provides you the opportunity to comment on the changes made to Method 203 (Procedure 3) since its original proposal in October 1992, including the codification of Procedure 3 in the aforementioned appendix. Comments are not limited to the changes contained in this proposal; you may comment on Procedure 3 in its entirety. It is for this reason we are allowing a 60-day comment period.

II. Differences Between Proposed Method 203 and the Proposed Rule (Procedure 3)

A. Quarterly Performance Audit

In re-writing Method 203 we determined that, because of technological advancements in opacity monitors, requirements proposed in October 1992 were no longer necessary. Specifically, regarding the quarterly performance audits, we decided to delete the optical surface dust accumulation check, the stack exit correlation error (pathlength correction factor) check, as well as the zero and upscale response checks.

The design specifications outlined in ASTM D 6216–98, incorporated by reference into PS–1, requires manufacturers to build opacity monitors capable of adjusting the reading due to the accumulation of dust on exposed optical surfaces. Opacity monitors are also required to display the level of dust accumulation. We also determined it to be in the source's best interest to be aware of dust accumulation on a regular basis, since the result of dust accumulation would lead to higher opacity readings.

The stack exit correlation error (pathlength correction factor [PLCF]) was deleted because opacity monitor manufacturers are required to certify the system has been built so that the PLCF either cannot be changed, is recorded during each calibration cycle, or an alarm sounds when the value is changed from the certified value.

The quarterly zero and upscale response checks were deleted because the calibration drift checks (zero and upscale) are required on a daily basis. We determined that requiring zero and upscale response checks in addition to the calibration drift checks offered no additional benefits in verifying the performance of the COMS.

B. Corrective Action Section

Procedure 3 includes a new section describing the corrective action required to return an opacity monitor to normal operation after a specified maintenance or repair procedure has been executed in response to a monitor failure or pending failure. After successful completion of the applicable corrective action, the monitor can be returned to an on-line status which provides valid emission monitoring data as long as the on-going QA requirements are met.

The corrective action section establishes four classes of maintenance and repair procedures: (1) Routine/preventative maintenance, (2) Measurement non-critical repairs, (3) Measurement critical repairs, and (4)

Rebuilt or refurbished analyzers. A table is included detailing the diagnostic tests required to maintain PS–1 certification following the appropriate corrective action.

C. Replacement Opacity Monitors

Procedure 3 also allows the use of a temporary replacement monitor in the event a certified opacity monitor is removed for extended service and the repair of the monitor requires more downtime than the user wishes to incur. The use of a replacement monitor will be allowed provided the monitor meets requirements specified in Procedure 3.

III. Statutory and Executive Order Reviews

A. Executive Order 12866, Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), we are required to judge whether a regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of this Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligation of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, we have determined that this rule is not ''significant'' because none of the listed criteria apply to this action. That is, this proposed rule, if promulgated, would not establish independent requirements for regulated entities. It would only apply where PS–1 is specified as the applicable method to demonstrate compliance with national emission standards or other control requirements. Consequently, this action was not submitted to OMB for review under Executive Order 12866.

B. Paperwork Reduction Act

This proposed rule does not contain any information collection requirements subject to the Office of Management and Budget review under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

C. Regulatory Flexibility Act

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act (APA) or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business whose parent company has fewer than 750 employees; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities because no significant additional cost will be incurred by such entities because of the proposed rule. The requirements of the proposal details quality assurance (QA)/quality control (QC) procedures for COMS to demonstrate continued conformance with PS–1. Facilities required by other rules to use COMS for compliance purposes have some form of QA/QC in place already; this proposal adds only minor additional requirements.

Although this proposed rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this rule on small entities. We formed a stakeholders' group to address technical concerns, similar to the concerns revealed in PS–1, with the proposed rule. The stakeholders' group was open to the public and consisted of opacity monitor manufacturers, representatives from the ASTM D22.03 subcommittee, representatives from electric utilities, State/local, and regional office personnel. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under Section 202 of the UMRA, we must prepare a budgetary impact statement to accompany any proposed rule, or any final rule for which a notice of proposed rulemaking was published, that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate, or to the private sector, of $100 million or more in any one year. Under Section 205, if a budgetary impact statement is required under Section 202, we must select the least costly, most cost-effective, or least burdensome alternative that achieves the objective of the rule, unless we explain why this alternative is not selected or the selection of this alternative is inconsistent with law. Section 203 requires us to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule. Section 204 requires us to develop a process to allow elected State, local, and tribal government officials to provide input in the development of any proposal containing a significant Federal intergovernmental mandate.

We have determined that this proposed rule does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector in any one year. Rules establishing test methods and/or quality assurance requirements impose no costs independent from national emission standards which require their use, and such costs are fully reflected in the regulatory impact assessment for those emission standards. We have also determined that this proposed rule does not significantly or uniquely impact small governments. Therefore, today's rule is not subject to the requirements of Section 203 of the UMRA.

E. Executive Order 13132, Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires that we develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.''

''Policies that have federalism implications'' is defined in the

Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Section 6 of Executive Order 13132, we may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the State and local governments, or we consult with State and local officials early in the process of developing the proposed regulation. We also may not issue a regulation that has federalism implications and that preempts State law unless we consult with State and local officials early in the process of developing the proposed regulation.

This proposed rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Thus, the requirements of Section 6 of the Executive Order do not apply to this proposed rule.

F. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

This proposed rule does not have tribal implications, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, EPA must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives that EPA considered. This proposed rule is not subject to Executive Order 13045 because it is not economically significant under Executive Order 12866 and because it does not concern environmental health and safety risks.

H. Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not expected to have a significant adverse affect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act of 1995

The National Technology Transfer and Advancement Act of 1995 (NTTAA), Section 12(d), Public Law 104–113, requires Federal agencies and departments to use voluntary consensus standards instead of government-unique standards in their regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, material specifications, test method, sampling and analytical procedures, business practices, etc.) that are developed or adopted by one or more voluntary consensus standards bodies. Examples of organizations generally regarded as voluntary consensus standards bodies include the American Society for Testing and Materials (ASTM), the National Fire Protection Association (NFPA), and the Society of Automotive Engineers (SAE). The NTTAA requires federal agencies like us to provide Congress, through OMB, with explanations when an agency decides not to use available and applicable voluntary consensus standards.

During this rulemaking, we identified no voluntary consensus standards that might be applicable. Specifically, there were none which specified quality assurance/quality control procedures for continuous opacity monitoring systems.

List of Subjects in 40 CFR Part 60

Environmental protection, Air pollution control, Continuous opacity monitoring.

Dated: May 2, 2003.

Christine Todd Whitman,

Administrator.

We propose that 40 CFR part 60 be amended as follows:

1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

2. Appendix F of part 60 is amended by adding Procedure 3 to read as follows:

Appendix F to Part 60—Quality Assurance Procedures

* * * * *

Procedure 3—Quality Assurance Requirements for Continuous Opacity Monitoring Systems at Stationary Sources

1. What Are the Purpose and Applicability of Procedure 3? The purpose of Procedure 3 is to help implement procedures established by Performance Specification 1 (PS–1) for testing and verification of continuous opacity monitoring systems (COMS) applicable to new stationary sources by establishing the minimum quality control (QC) and quality assurance (QA) requirements to assess and assure the quality of a continuous opacity monitoring system (COMS). Procedure 3 applies to a COMS used for continuously determining compliance with emission standards as specified in an applicable federally enforceable regulation.

1.1 Who must comply with Procedure 3? You must comply with Procedure 3 if you are required by a federally enforceable regulation to install and operate a COMS on a continuous basis.

1.2 What are the data quality objectives of Procedure 3? The overall data quality objective (DQO) of Procedure 3 is the generation of valid, representative opacity data. Procedure 3 specifies the minimum requirements for controlling and assessing the quality of COMS data submitted to us or the delegated regulatory agency. Procedure 3 requires you to perform periodic evaluations of a COMS performance and to develop and implement QA/QC programs to ensure that a COMS data quality is maintained. You must meet these minimum requirements if you are responsible for one or more COMS used for compliance monitoring.

1.3 What is the intent of the QA/QC procedures found in Procedure 3? Procedure 3 is intended to establish the minimum requirements to verify and maintain an acceptable level of quality of the data produced by COMS. Its general terms are intended to allow you to develop a program that is most effective for your circumstances. You may adopt QA/QC procedures which go beyond these minimum requirements to ensure compliance with applicable regulations.

1.4 When must I comply with Procedure 3? You must comply with Procedure 3

following successful completion of the field audit performance tests outlined in PS–1.

2. What are the basic functions of Procedure 3? The basic functions of Procedure 3 are assessment of the quality of your COMS data, and control and improvement of the quality of the data by implementing QC requirements and corrective actions. Procedure 3 provides requirements for:

(1) Daily instrument zero and upscale drift checks, as well as daily status indicators check,

(2) Quarterly performance audits, which includes the following assessments:

(i) Optical alignment,

(ii) Calibration error,

(iii) Zero compensation, and

(3) Zero alignment.

3. What Special Definitions Apply to Procedure 3? The definitions of Procedure 3 include those provided in PS–1 and ASTM D 6216–98 (incorporated by reference into PS–1), with the following additions:

3.1 *Out-of-Control Periods.* ''Out of control'' means that one or more COMS parameters falls outside of the acceptable limits established by this rule.

(1) *Daily Assessments.* Whenever the calibration drift (CD) exceeds twice the specification of PS–1, the COMS is out-of-control. The beginning of the out-of-control period is the time corresponding to the completion of the daily calibration drift check. The end of the out-of-control period is the time corresponding to the completion of appropriate adjustment and subsequent successful CD assessment.

(2) *Quarterly and Annual Assessment.* Whenever a quarterly performance audit or annual zero alignment indicates unacceptable results, the COMS is out-of-control. The beginning of the out-of-control period is the time corresponding to the completion of the performance audit indicating an unacceptable performance. The end of the out-of-control is the time corresponding to the completion of appropriate corrective actions and subsequent successful audit (or, if applicable, partial audit).

4. What interferences must I avoid? Opacity cannot be measured accurately in the presence of water droplets. Thus, COMS opacity compliance determinations cannot be made when water droplets are present such as downstream of a wet scrubber without reheat or other saturated flue gas locations. Therefore, COMS must be located to avoid interferences with moisture or water droplets.

5. What Do I Need to Know to Ensure the Safety of Persons Using Procedure 3? People using Procedure 3 may be exposed to hazardous materials, operations, and equipment. Procedure 3 does not purport to address all of the safety issues associated with its use. It is your responsibility to establish appropriate safety and health practices, and determine the applicable regulatory limitations before performing this procedure. You should consult the COMS user's manual for specific precautions to take.

6. What Equipment and Supplies Do I Need? The equipment and supplies you need are those specified in PS–1.

7. What Reagents and Standards Do I Need? The reagents and standards you need are those specified in PS–1.

8. What Sample Collection, Preservation, Storage, and Transport Are Relevant to This Procedure? [Reserved]

9. What Quality Control Measures Are Required by This Procedure for My COMS? You must develop and implement a QC program for your COMS. Your QC program must, at a minimum, include written procedures which describe in detail complete step-by-step procedures and operations for the activities in paragraphs (1) through (4):

(1) Procedures for performing drift checks, including both zero and upscale drift, and the status indicators check,

(2) Procedures for performing the quarterly performance audits,

(3) A means of checking the zero alignment of the COMS, and

(4) A program of corrective action for a malfunctioning COMS. The corrective action must include, at a minimum, the requirements specified in Section 10.5.

9.1 What QA/QC documentation must I have? You are required to keep the QA/QC written procedures on record and available for inspection by us, the State and/or local enforcement agency for the life of your COMS or until you are no longer subject to the requirements of this procedure.

9.2 What are the consequences of failing QC audits? Your QC procedures are deemed to be inadequate or your COMS incapable of providing quality data if you fail two consecutive QC audits (*i.e.,* out-of-control conditions revealed by the annual audits or quarterly audits). Therefore, if you fail the same two consecutive quarterly audits or five consecutive daily checks, you must either revise your QC procedures or repair (or replace) your COMS to correct the deficiencies causing the excessive inaccuracies. If you determine your COMS requires extensive repair, you may use a substitute COMS provided the substitute meets the requirements specified in Section 10.6.

10. What Calibration and Standardization Procedures Must I Perform for My COMS? You must perform routine system checks to assure proper operation of system electronics and optics, light and radiation sources and detectors, electric or electro-mechanical systems, and general stability of the system calibration. You must subject your COMS to a performance audit, to include checks of the individual COMS components and factor affecting the accuracy of the monitoring data, at least once per calendar quarter. At least annually, you must compare the COMS simulated zero to the actual clear path zero.

10.1 What routine system checks must I perform on my COMS? Necessary components of the routine system checks will depend upon design details of your COMS. At a minimum, you must verify the system operating parameters listed in paragraphs (1) through (3) on a daily basis. Some COMSs may perform one or more of these functions automatically, or as an integral portion of unit operations; other COMS may perform one or more of these functions manually.

(1) You must check the zero drift to assure stability of your COMS response to the zero check value. The simulated zero device, an automated mechanism within the transmissometer that produces a simulated clear path condition or low-level opacity condition, is used to check zero drift. You must, at a minimum, take corrective action on your COMS whenever the daily zero drift exceeds twice the applicable drift specification given in appendix B.

(2) You must check the upscale drift to assure stability of your COMS response to the upscale drift value. The upscale calibration device, an automated mechanism (employing a filter or reduced reflectance device) within the transmissometer that produces an upscale opacity value, is used to check the upscale drift. You must, at a minimum, take corrective action on your COMS whenever the daily upscale drift check exceeds twice the applicable drift specification given in appendix B.

(3) You must, at a minimum, check the status indicators, data acquisition system error messages, and other system self-diagnostic indicators. You must take appropriate corrective actions based on manufacturer's recommendations when the COMS is operating outside preset limits. All COMS data recorded during periods in which the fault status indicators are illuminated are to be considered invalid.

10.2 What are quarterly auditing requirements for my COMS? At a minimum, the parameters listed in paragraphs (1) through (3) are to be included in the quarterly performance audit.

(1) For units with automatic zero compensation, you must determine the zero compensation for the COMS. The value of the zero compensation applied at the time of the audit must be calculated as equivalent opacity, corrected to stack exit conditions, according to the procedures specified by the manufacturer. The compensation applied to the effluent recorded by the monitor system must be recorded.

(2) You must conduct a three-point calibration error test of the COMS. For either calibration error test methods identified below, three neutral density filters, meeting the requirements of PS–1, must be placed in the COMS light beam path for three nonconsecutive readings. The monitor responses must then be independently recorded from the COMS permanent data recorder. Additional guidance for conducting this test is included in section 8.1(3)(ii) of PS–1. The low-, mid-, and high-range calibration error results must be computed as the mean difference and 95 percent confidence interval for the difference between the expected and actual responses of the monitor as corrected to stack exit conditions. The equations necessary to perform the calculations are found in section 12.0 of PS–1. For the calibration error method, you must use the external audit device. You must confirm that the external audit device produces the proper zero value on the COMS data recorder.

(3) You must check the optical alignment of the COMS. The optical alignment must be checked when the stack temperature is ± 20 percent of the typical operating temperature as measured in degrees Farenheit.

10.3 What are the annual auditing requirements for my COMS?

(1) You must perform the primary zero alignment method under clear path conditions. The COMS may be removed from its installation and setup under clear path conditions or, if the process is not operating and the monitor path is free of particulate matter, the zero alignment may be conducted at the installed site. Determining if the monitor path is free of particulate matter can be accomplished by, but is not limited to, the following procedure: (1) Observe the instantaneous or one minute average opacity for at least two hours prior to the clear path adjustment; (2) open the reflector or detector housing and observe the projected light beam and look for the presence of forward scattered light (halo-effect); (3) if the beam observation reveals no perceptible particulate and the 2-hour readings do not vary more than ± 3 percent opacity, adjust the clear path zero based on the lowest opacity reading recorded during the 2-hour period. There must be no adjustments to the monitor other than the establishment of the proper monitor path length and correct optical alignment of the COMS components. You must record the COMS response to a clear condition and to the COMS's simulated zero condition as percent opacity corrected to stack exit conditions. For a COMS with automatic zero compensation, you must disconnect or disable the zero compensation mechanism or record the amount of correction applied to the COMS's simulated zero condition. The response difference in percent opacity to the clear path and simulated zero conditions must be recorded as the zero alignment error. You must adjust the COMS's simulated zero device to provide the same response as the clear path condition. You must perform the zero alignment audits with the COMS off the stack at least every three (3) years.

(2) As an alternative, monitors capable of allowing the installation of an external zero device (commonly referred to as a zero-jig) may use the device for the zero alignment, provided: (1) the zero-jig setting has been established for the monitor path length and recorded for the specific COMS by comparison of the COMS responses to the installed zero-jig and to the clear path condition; and (2) the zero-jig is demonstrated to be capable of producing a consistent zero response when it is repeatedly (*i.e.*, three consecutive installations and removals prior to conducting the final zero alignment check) installed on the COMS. The zero-jig setting must be permanently set at the time of initial zeroing to the clear path zero value and protected when not in use to ensure that the setting equivalent to zero opacity does not change. The zero-jig setting must be checked and recorded prior to initiating the zero alignment. If the zero-jig setting has changed, you must remove the COMS from the stack in order to reset the zero-jig. If you employ a zero-jig, you must perform the zero alignment audits with the COMS off the stack every three (3) years. If the zero-jig is adjusted within the three-year period, you must perform the zero alignment with the COMS off the stack three years from the date of adjustment.

10.4 What are my limits for excessive audit inaccuracy? Unless specified otherwise in the applicable subpart, the criteria for excessive inaccuracy are listed in paragraphs (1) through (4).

(1) What is the criterion for excessive zero or upscale drift? Your COMS is out-of-control if either the zero drift check or upscale drift check exceeds twice the applicable drift specification in appendix B for any one day.

(2) What is the criterion for excessive zero alignment? Your COMS is out-of-control if the zero alignment exceeds 2 percent opacity.

(3) What is the criterion to pass the quarterly performance audit? Your COMS is out-of-control if the results of a quarterly performance audit indicate noncompliance with the following criteria:

(i) The optical alignment misalignment error exceeds 3 percent opacity,

(ii) The zero compensation exceeds 4 percent opacity, or

(iii)The calibration error exceeds 3 percent opacity.

(4) What is the criterion for data capture? The data capture will be considered insufficient if your COMS fails to obtain valid opacity data for at least 95 percent of your operating hours per calendar quarter, considering COMS downtime for all causes (*e.g.*, monitor malfunctions, data system failures, preventative maintenance, unknown causes, etc.) except for downtime associated with routine zero and upscale checks and QA/QC activities required by this procedure. Whenever less than 95 percent of the valid data averages are obtained, you must either:

(i) Perform additional QA/QC activities as deemed necessary to assure acceptable data capture, or

(ii) Determine if the COMS is functioning properly. If your COMS is malfunctioning, you may use a substitute COMS until repairs are made, provided the substitute meets the requirements specified in Section 10.6.

10.5 What corrective action must I take if my COMS is malfunctioning? You must have a corrective action program in place to address the repair and/or maintenance of your COMS. There are four classes of maintenance and repair procedures to be considered; the classes are described in paragraphs (1) through (4). They may be performed either at the manufacturer's facility, a service provider's facility, the user's instrument laboratory, or at the stack/duct at the discretion of the owner/operator and within the recommendations of the manufacturer. They must be performed by persons either skilled and/or trained in the operation and maintenance of the analyzer. After the repair/maintenance of your COMS, you must ensure the COMS is still in compliance with PS–1. Table 17–1 outlines the tests required to maintain PS–1 certification.

(1) *Routine/preventative maintenance.* Includes the routine replacement of consumables, cleaning of optical surfaces, and adjustment of monitor operating parameters as needed to maintain normal operation. Replacement of consumables which have the possibility of adversely affecting the performance of an analyzer may cause the nature of the maintenance procedure to fall within one of the classifications described below.

(2) *Measurement Non-Critical Repairs.* Includes repair and/or replacement of standard non-critical components, the unique characteristics of which do not materially affect the performance of the monitor. These components include, but are not limited to, resistors, capacitors, inductors, transformers, semiconductors such as discrete components and integrated circuits, brackets and machined parts (not associated with internal optical components), cabling and connectors, electro mechanical components such as relays, solenoids, motors, switches, blowers, air filters, pressure/flow indicators, tubing, indicator lights, fuses, software with the same version and/or revision level, glass windows (uncoated or anti-reflection coated, but with no curvature), lenses with mounts where such mounts are not adjustable as installed, circuit boards where such boards are interchangeable and without unique adjustments (except offset and gain adjustments) for the specific analyzer of the same model, with such repairs to include the maintenance procedures required to ensure that the analyzer is appropriately setup.

(3) Replace or repair the primary measurement light source.

(4) *Measurement Critical Repairs.* Includes repair and/or replacement of measurement sensitive components, the unique characteristics of which may materially affect the performance of the monitor. These components include, but are not limited to, optical detectors associated with the opacity measurement/reference beam(s), spectrally selective optical filters, beam splitters, internal zero and/or upscale reference reflective or transmissive materials, electro-optical light switches, retro reflectors, adjustable apertures used on external zero devices or reflectors, lenses which have an adjustable mount, circuit boards which are not completely interchangeable and/or require unique adjustments for the specific analyzer, with such repairs to include the maintenance procedures required to ensure that the analyzer is appropriately setup.

(5) *Rebuilt or Refurbished analyzers.* Includes analyzers for which a major sub-assembly(ies) has/have been replaced or multiple lesser sub-assemblies with different revision levels from the original have been replaced and/or modified. Also, to be defined as a major change in the analyzer measurement detection and processing hardware or software.

(6) For other repairs or replacements not specifically described above, you must consult the manufacturer for the appropriate classification of that procedure. Manufacturers must use the above guidelines in determining the appropriate classification and provide a written recommendation. The final determination as to which category a given repair falls within will be made by the Administrator.

10.6 What requirements must I meet if I use a substitute opacity monitor? In the event your certified opacity monitor has to be removed for extended service, you may install a temporary replacement monitor to obtain required opacity emissions data, provided that:

(1) The temporary monitor is a like-kind replacement, where like-kind is defined as made by the same manufacturer; carries the same model number; uses the same reflector

configuration as the original (and may use the actual original reflector unit) for double pass monitors, or uses the same source or detector configuration as the original for single pass monitors (and may use the actual original source or detector unit—whichever one that did not fail); uses the same of later revision of software/firmware; setup with the same selection of configuration parameters; provides the same input/output signals; and uses the same peripheral equipment. Same in this context means the same as the original certified monitor which is being temporarily replaced,

(2) The temporary monitor has been certified according to ASTM D 6216–98 for which a manufacturer's certificate of conformance (MCOC) has been provided,

(3) The temporary monitor has not been used for more than 720 hours (30 days) of operation per year as a replacement for a fully certified opacity monitor on one location. After that time, the analyzer must complete a full certification according to PS–1 prior to further use as a temporary replacement monitor. Once a temporary replacement monitor has been installed and required testing and adjustments have been successfully completed, it can not be replaced by another temporary replacement monitor to avoid the full PS–1 certification testing required after 720 hours (30 days) of use,

(4) The temporary monitor has been installed and successfully completed an optical alignment assessment and status indicator assessment,

(5) The temporary monitor has successfully completed an off-stack clear path zero assessment and zero calibration value adjustment procedure,

(6) The temporary monitor has successfully completed an abbreviated zero and upscale drift check consisting of seven zero and upscale calibration value drift checks which may be conducted within a 24-hour period with not more than one calibration drift check every three hours, and not less than one calibration drift check every 25 hours. Calculated zero and upscale drift requirements are the same as specified for the normal PS–1 certification,

(7) The temporary monitor has successfully completed a three point calibration error test,

(8) The upscale reference calibration check value of the new monitor has been updated in the associated data recording equipment,

(9) The overall calibration of the monitor and data recording equipment has been verified, and

(10) The user has documented all of the above in the maintenance log, or in other appropriate permanent maintained records.

10.7 When do the out-of-control periods begin and end? The out-of-control periods are as specified in Section 3.1.

10.8 What are the limitations on use of my COMS data collected during out-of-control periods? During the period your COMS is out-of-control, you may not use your COMS data to calculate emission compliance or to meet minimum data availability requirements in this procedure or the applicable regulation.

10.9 What are the QA/QC reporting requirements for my COMS? You must report the accuracy results from Section 10 for your COMS at the interval specified in this procedure or the applicable regulation. Report the drift and accuracy information as a Data Assessment Report (DAR), and include one copy of this DAR for each quarterly audit with the report of emissions required under the applicable regulation. An example DAR is provided in Procedure 1, appendix F of this part.

10.10 What minimum information must I include in my DAR? As a minimum, you must include the information listed in paragraphs (1) through (5) in the DAR.

(1) Your name and address,

(2) Identification and location of your COMS(s),

(3) Manufacturer, model and serial number of your COMS(s),

(4) Assessment of COMS data accuracy/acceptability, and date of assessment, as determined by a performance audit described in section 10. If the accuracy audit results show your COMS to be out-of-control, you must report both the audit results showing your COMS to be out-of-control and the results of the audit following corrective action showing your COMS to be operating within specifications, and

(5) Summary of all corrective actions you took when you determined your COMS to be out-of-control.

10.11 Where and how long must I retain the QA data that this procedure requires me to record for my COMS? You must keep the records required by this procedure for your COMS onsite and available for inspection by us, the State and/or local enforcement agency for a period of 5 years.

11. What Analytical Procedures Apply to This Procedure? [Reserved]

12. What Calculations and Data Analysis Must I Perform for My COMS? The calcalations required for the performance audit are contained in Section 12 of PS–1.

13. Method Performance. [Reserved]

14. Pollution Prevention. [Reserved]

15. Waste Management. [Reserved]

16. Which References Are Relevant to This Procedure?

16.1 Performance Specification 1—Specifications and Test Procedures for Continuous Opacity Monitor Systems in Stationary Sources, 40 CFR part 60, appendix B, August 10, 2000.

16.2 ASTM D 6216–98: Standard Practice for Opacity Monitor Manufacturers to Certify Conformance with Design and Performance Specifications. American Society for Testing and Materials (ASTM), April 1998.

17. What Tables, Diagrams, Flowcharts, and Validation Data Are Relevant to This Procedure?

17.1 Table 17.1—Diagnostic Tests Required to Maintain PS–1 Certification Status for COMS.

Description of event	Optical alignment	Optical alignment indicator assessment (Note 1)	Zero calibration check	Clear path (off-stack) zero assessment (Note 3)	Upscale calibration check	Calibration error check	Fault status indicator check	Averaging peirod calculation and recording	7-day zero and upscale drift check (Note 2)	Recertify per PS–1	New MCOC per ASTM D 6216–98	Comments
(1) Replace or repair components described as routine and/or preventative maintenance.	X	.....	X	.....	X	.....	X	.....	.....	.....	.....	Includes replacement of blowers, cleaning optical surfaces, resetting adjustable parameters to maintain normal performance, etc.
(2) Replace or repair primary measurement light.	X	X	X	X	X	.....	X	.....	.....	.....	.....	Light source uniformity and position are key source to many performance parameters
(3) Replace or repair components which are Measurement Non-Critical.	X	.....	X	.....	X	X	X	.....	.....	.....	.....	See text description, sec. 10.5(2)
(4) Replace or repair components which are Measurement Critical.	X	X	X	X	X	X	X	.....	X	.....	.....	See text description, sec. 10.5(3)

Description of event	Optical alignment	Optical alignment indicator assessment (Note 1)	Zero calibration check	Clear path (off-stack) zero assessment (Note 3)	Upscale calibration check	Calibration error check	Fault status indicator check	Averaging peirod calculation and recording	7-day zero and upscale drift check (Note 2)	Recertify per PS–1	New MCOC per ASTM D 6216–98	Comments
(5) Replace or repair components which are Measurement Critical, but not involving optical or electro-optical components.	.....	.....	X	.....	X	X	X	X	.....	.....	.....	Includes change of components involving data acquisition and recording
(6) Rebuild or Substantially Refurbish the analyzer.	.....	.....	.....	.....	.....	.....	.....	.....	.....	XX	.....	See text description, sec. 10.5(4)
(7) Change to, or addition of, analyzer components which may affect MCOC-specified performance parameters.	.....	.....	.....	.....	.....	.....	.....	.....	.....	X	X	Significant changes which are not part of the MCOC-designated configuration

Notes: (1) Optical alignment indicator assessment requires the operator to verify during an off the stack clear path zero assessment that the beam is centered on the reflector/retro reflector when the alignment indicator indicates on-axis centered alignment. If not, the analyzer optical train must be adjusted until this condition is met.

(2) 7-day zero and upscale drift assessment. Opacity measurement data recorded prior to completion of the 7-day drift test will be considered as valid provided that the first 7-day drift test is successful, that it is completed within 14 days of completion of the repair, and that other QA requirements are met during this time period.

(3) Requires verification of the external zero jig response, or re-calibration of the same, after the off-stack clear path zero has been re-established.

[FR Doc. 03–11472 Filed 5–7–03; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 18

RIN 1018–AH86

Marine Mammals; Incidental Take During Specified Activities

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; withdrawal. Availability of Record of Decision.

SUMMARY: We, the Fish and Wildlife Service (Service) have determined that we are unable to authorize the incidental, unintentional take of small numbers of Florida manatees (*Trichechus manatus latirostris*) resulting from governmental activities related to the authorization, regulation, or funding of watercraft and watercraft access facilities within certain regions of the species' range in Florida. Comments and new information received during the public comment period for our proposed rule to authorize such incidental take raised significant questions about the standards, information, and analytic methodologies appropriate for making the necessary findings. These significant questions preclude us from finding that incidental takings of Florida manatee resulting from these governmental activities will have a negligible impact on any of the four stocks in Florida. The Marine Mammal Protection Act (MMPA) does not allow us to authorize incidental take unless we are able to find that the total authorized incidental take will have no more than a negligible impact on the species or stock. Therefore, pursuant to 50 CFR 18.27(d)(4), we are making negative findings for all four stocks. Consistent with this determination we are withdrawing our November 2002 MMPA proposed rule to authorize the incidental take of Florida manatees.

We published a proposed regulation and announced the availability of a Draft Environmental Impact Statement (DEIS) in the **Federal Register** on November 14, 2002. We announced the availability of a Final Environmental Impact Statement (FEIS) for this decision on April 4, 2003. Responses to comments received during the public comment period for the proposed rule and DEIS are available in Appendix N of the FEIS. Through this notice, we are also announcing the availability of the Record of Decision related to the FEIS.

ADDRESSES: If you wish to review the FEIS and Record of Decision, obtain copies by any one of the following methods:

1. You may visit our Web site at *http://northflorida.fws.gov*.
2. You may request a copy by electronic mail (e-mail) to *manatee@fws.gov*.
3. You may write the Field Supervisor, Jacksonville Field Office, U.S. Fish and Wildlife Service, 6620 Southpoint Drive, South, Suite 310, Jacksonville, Florida 32216.
4. You may call the Jacksonville Field Office, 904/232–2580, during normal business hours from 8 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Pete Benjamin, at the above address (telephone 904/232–2580; or visit our Web site at *http://northflorida.fws.gov*).

SUPPLEMENTARY INFORMATION:

Background

On November 14, 2002, the Service published a proposed rule to authorize the incidental, unintentional take of small numbers of Florida manatees (*Trichechus manatus latirostris*) resulting from government activities that authorize and regulate watercraft and watercraft access facilities in Florida. Under the provisions of the MMPA of 1972 (16 U.S.C. 1361–1407), all take, including incidental take, is prohibited unless otherwise authorized. To date, there is no authorization for the incidental, unintentional death, injury, or harassment of Florida manatees caused by these otherwise legal activities. In the proposed rule, we examined the issue of take of Florida manatees to determine whether the incidental, unintentional take of manatees could be authorized.

The Secretary of the Interior may authorize the incidental taking of small numbers of marine mammals resulting from specified activities in a specified geographic area pursuant to 16 U.S.C.