



REFERENCE AND EQUIVALENT METHOD APPLICATIONS

GUIDELINES FOR APPLICANTS

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I. INTRODUCTION

Monitoring of atmospheric air quality for purposes of determining compliance with the U.S. National Ambient Air Quality Standards (NAAQSs) – specified in 40 CFR Part 50,* – generally requires the use of either **reference methods (FRMs)** or **equivalent methods (FEMs)**, as specified in Section 2.1 of Appendix C to 40 CFR Part 58. Such “compliance” monitoring is primarily carried out by State and local governmental air pollution control agencies. Requirements and procedures by which ambient air monitoring methods for NAAQS pollutants may be designated by EPA as FRMs and FEMs have been set forth in **40 CFR Part 53**. This regulation prescribes detailed procedures for testing candidate methods as well as the formal technical and non-technical requirements for submitting applications to EPA for reference or equivalent method determinations.

These guidelines are intended to assist applicants in preparing and submitting complete and adequate applications for reference or equivalent method determinations for candidate methods. FRM and FEM applications are accepted for methods for monitoring the NAAQS pollutants: SO₂, O₃, CO, NO₂, Pb, and particulate matter (as PM₁₀, PM_{2.5}, or PM_{10-2.5}). The information in this Guideline is intended to help clarify and, in some cases, interpret and supplement the application requirements given in 40 CFR Part 53. Particular emphasis is directed to areas of the regulation that have been noted to have caused some confusion, based on applicant inquiries and previously received applications. **However, the information herein is provided only for guidance; the formal requirements for reference and equivalent method designations and their associated applications are those set forth in 40 CFR Part 53.** Where appropriate, references to specific sections or paragraphs of 40 CFR Part 53 are given in brackets []. Use of the auxiliary verb "should" rather than "must" generally implies that compliance is highly recommended, but not necessarily mandatory.

* Short for Part 50 of Title 40 of the U. S. Code of Federal Regulations. The EPA regulations are found in the various Parts of Title 40 of the CFR.

II. BASIC GENERAL REQUIREMENTS

Methods for monitoring the various NAAQS pollutants mentioned in Section I (above) that are to be considered for FRM or FEM designation by EPA are defined in Part 53 as **candidate methods**. The various types of candidate methods are described below (see paragraph 53.1 of Part 53 for definitions). The specific provisions and requirements of Part 53 that are applicable to each type of candidate FRM and FEM are described in paragraphs 53.2 and 53.3 of Part 53, respectively. The requirements of Part 53 are occasionally amended, so care should be taken to use the latest version available. In particular, Subpart B has been amended in 2010 and 2011, and Subpart C in 2006. Also, the nature and design of candidate equivalent methods can vary widely, and the various Part 53 requirements may not fully accommodate some types of methods not envisioned when the provisions were promulgated. The Reference and Equivalent Methods Program office should be consulted for further guidance in such cases (see Section VIII).

A. Reference Methods (FRMs)

1. Manual Reference Methods

Only those manual methods that are uniquely specified as reference methods in Appendixes A-2 (SO₂), G (Pb), J (PM₁₀), L (PM_{2.5}), O (PM_{10-2.5}) and Q (Pb) to 40 CFR Part 50 are manual FRMs. In these cases, the FRM specifies all details of a unique analytical procedure, such as the original FRMs for SO₂ and Pb in Appendixes A and G (respectively), and no other manual FRMs for these pollutants will be considered by EPA for designation as FRMs. However, if the FRM Appendix describes the functional aspects of a commercial sampler that may differ somewhat from different manufacturers, such as in Appendixes L (PM_{2.5}) and O (PM_{10-2.5}), then each such sampler, together with other specified aspects of the FRM, may be considered as a candidate manual method for FRM designation. Accordingly, in the latter case, multiple FRMs (representing different samplers) may be designated by EPA for these pollutants. [53.2(a)]

2. Automated Reference Methods

a. Automated reference methods are specified in Part 50, Appendixes A-1 (SO₂), C (CO), D (O₃), and F (NO₂). Each of these reference methods is specified as a measurement principle and calibration procedure (as opposed to specifying a unique manual procedure). The generically described measurement principle allows considerable variation in design and operation of a commercially produced analyzer utilizing the specified measurement principle. Each such analyzer that meets the requirements specified in the measurement principle and utilizes the specified calibration procedure may be considered a candidate method. Accordingly, multiple FRMs may be designated by EPA for these pollutants. [53.2(b)]

b. Candidate automated methods must employ the specific measurement principle and calibration procedure specified in the appropriate appendix to Part 50. [53.2(b)]

c. Candidate automated methods must be shown to meet all applicable requirements of Subparts A and B of 40 CFR Part 53. [53.2(b)]

B. Equivalent Methods (FEMs)

1. Manual Equivalent Methods

a. Candidate manual equivalent methods may use a sampler, sampling technique, or analytical procedure that is different from that specified for the corresponding FRM. However, some of the specifications or requirements of the FRM may apply to a candidate FEM, depending on the type of method. In particular, two types of candidate FEMs are defined for $PM_{2.5}$ and $PM_{10-2.5}$, Class I and Class II, based on the extent to which the candidate method deviates from the FRM specifications.

b. Candidate manual FEMs are tested both for conformance to applicable requirements of the corresponding FRM as well as for “comparability” of the candidate method to the FRM under collocated field monitoring conditions (Part 53, Subpart C).

c. Candidate manual methods must be shown to meet all applicable requirements of Subparts A, D, E, or F of 40 CFR Part 53, as appropriate, as well as Subpart C. [53.3(a)]

2. Automated Equivalent Methods (analyzers)

a. Candidate automated methods may utilize a different measurement principle and/or calibration procedure than that specified for FRMs, and may otherwise differ substantially from FRMs. However, some of the specifications or requirements of the FRM may apply to a candidate FEM, depending on the type or nature of the method. In particular, Class III candidate FEMs for $PM_{2.5}$ and $PM_{10-2.5}$, which are defined as automated methods (analyzers), are likely to be profoundly different from the corresponding FRM.

b. Candidate automated FEMs are tested both for conformance to applicable requirements of the corresponding FRM as well as for “comparability” of the candidate method to a designated FRM analyzer under collocated field monitoring conditions (Part 53, Subpart C). In the case of candidate Class III FEMs, qualification for designation is based substantially on the results of extensive field comparability tests by collocated monitoring with the corresponding FRM.

c. Candidate automated methods must be shown to meet all applicable requirements of Subparts A, B, D, E, or F and Subpart C of 40 CFR Part 53. [53.3(b)]

C. Test Requirements

In general, a candidate method must be tested in accordance with applicable test procedures and requirements specified in various Subparts and Sections of Part 53 to determine its qualification for FRM or FEM designation. Section applicability is determined by the specific pollutant that the method measures, whether it is a manual or automated method, and whether it is considered as a candidate FRM or FEM. Usually, either an analyzer or one or more PM samplers that is (are) representative of the candidate method must be tested. Candidate FEMs that are alternative sample analysis procedures, such as for lead, are also required to be tested.

See more detailed guidance in Sections IV, V, VI, and VII for testing candidate automated methods for gaseous pollutants and PM_{10} , candidate Class II and III methods for $PM_{2.5}$ and $PM_{10-2.5}$, candidate FRMs and Class I FEMs for $PM_{2.5}$ and $PM_{10-2.5}$, and candidate methods for lead, respectively.

D. Test Data

1. Much of the test data for continuous analyzer methods must be recorded contemporaneously by an analog strip chart recorder or similar digital data recorder, and these data recordings become an important part of the documentation for the test data. Please see Section IV for more information on data recording.

2. Calibrations of a test analyzer must be verified by a strip chart record of the calibration point readings and a listing of calibration point concentrations and the corresponding test analyzer readings. Calibration of samplers should be supported by appropriate records of calibration data obtained during calibrations.
[53.4(b)(5), 53.20(f), 53.30(d)]

4. Malfunctions of a test analyzer are covered in section 53.21(d) of Part 53. Malfunctions of chart recorders or other test equipment resulting in significant loss of test data will cause invalidation of the results of the immediate test being conducted at the time. In such cases, only the immediate test(s) for which the results are invalid need to be repeated.

5. Use of the suggested data forms for reporting test data will expedite processing of the application; spreadsheet simulations of such forms are also acceptable.

6. All test data and calculations are verified during processing of the application. Processing will thus be expedited if the origin of all test readings is clearly identified and if calculations are clearly shown.

7. In long or complex procedures (the NO₂ reference method calibration, for example), give intermediate calibration curves. Always give the dates of calibrations.

E. Operation/Instruction Manual

The Operation or Instruction Manual associated with the candidate method is considered to be a very important component of the method. See Section III for information about the application requirements for the Manual.

F. Required Statements

1. Identification - Indicate exactly how the method is to be identified in the Notice of Designation. This identification of the method should (a) distinguish it from all other methods or method variations, (b) indicate the pollutant measured by the method, and (c) use "analyzer" to identify automated methods. For example: "Acme Model 1001-A SO₂ Ambient Air Analyzer." [53.4(b)(1)]

2. Range - Indicate the measurement range(s) tested. [53.20(b), 53.31(d)]

3. Compliance - Submit a statement that the candidate method was tested in accordance with the applicable procedures described in 40 CFR Part 53.
[53.4(b)(4)]

4. Representativeness - Submit a statement that the method, sampler(s), or analyzer tested is representative of the candidate method described in the application. [53.4(b)(6)]

5. Quality Control Program – For automated candidate methods, submit a description of the quality control program that will be used to ensure that all analyzers offered for sale under the designation will have essentially the same performance as the test analyzer. [53.4(c)(1)] For candidate PM_{2.5} and PM_{10-2.5} FRMs and Class I and II FEMs, special, more extensive quality control requirements are described in Section 53.51 (*Demonstration of compliance with design specifications and manufacturing and test requirements*). These requirements include specific manufacturing tests, ISO registration of the manufacturing facility, sampler manufacturing quality control, supporting documentation, final assembly and inspection requirements, and manufacturer's audit checklists. [53.51]

6. Durability – For automated gas methods, submit a description of the durability characteristics of the analyzer [53.4(c)(2)] or provide a statement that any analyzer offered for sale under the designation shall be guaranteed to function within the limits of the performance specifications given in section 53.20(a) for at least 1 year after delivery and acceptance, when maintained and operated in accordance with the associated operation/instruction manual. [53.9(c)]

7. Same Analyzer - For candidate automated gas and PM₁₀ analyzers, submit a statement that all Subpart B and C tests, as applicable, were carried out with the same test analyzer. If possible, provide the serial number of the test analyzer. [53.21(e)]

8. Adjustments (Automated methods) - If not adequately shown by the strip chart records, submit a statement that adjustments to the test analyzer were made only at those times permitted in the test procedures. [53.21(c), 53.23(e)(5), (6), (7)]

G. Options

1. An application for a reference or equivalent method determination may include a request that the method, if designated, include the use of one or more options that are available to the user. [53.4(b)]

2. If such option(s), when installed or implemented on the candidate analyzer, clearly will not affect the performance characteristics of the analyzer, the application should so state, giving adequate reasons or justification for this belief.

3. If such option(s), when installed on the candidate analyzer, will or might affect the performance characteristics of the analyzer, additional test data may be necessary to verify that analyzer performance meets the requirements with the option(s) installed. Depending on the nature of the option and its possible effect(s) on the candidate analyzer, only certain pertinent tests may be required to test the option-installed configuration. The application should state the applicant's belief as to the nature and extent of the effect(s) that each option will or might have on the candidate analyzer. Test data as may be necessary to support such statements or to show that the analyzer meets the performance specifications with the option(s) installed should also be submitted. Such test data may be in the form of:

- a. Test data from all applicable subpart B and C tests performed on a test analyzer that includes the option(s).
- b. Test data from only those subpart B tests pertaining to performance parameters likely to be affected by the option(s) and performed on a test analyzer that includes the option(s).
4. Each option must be completely and clearly described, and its use or installation should be shown both physically and schematically. Drawings such as electrical and flow schematics or component location drawings should be marked to show the installation of each option. [53.4(b)]
5. When approved options are supplied to the analyzer user, the operation/instruction manual must indicate whether the use of each option is approved under the method designation and, if so, describe its function and use, giving suitable operating and/or maintenance procedures where necessary. [53.4(b)(3)]
6. Options related to an internal provision to carry out a zero-and-span check operation should not be named or referred to by the term "calibration" unless such operation meets the requirements of a bona fide calibration with a suitable, certified standard.

H. Submission Of Applications

1. There is no prescribed format for FRM or FEM applications. However, to expedite processing, such applications should be logically organized, divided into appropriate sections with suitable section titles and a brief Table of Contents, address all regulatory requirements applicable to the candidate method, and contain sufficient detail and supplemental documents to support that all regulatory requirements have been met.
2. Suggested forms for submitting test or other data may be found in Subparts B, C, D, E, and F; however, use of these forms is not mandatory. An alternative format may be used for test or other data as long as it presents the data in an appropriate, clear, and logical format. Test or other data may be submitted in electronic (computer-readable) form provided that it is in a common, compatible word-processing, spreadsheet or graphical format. Printouts of such data are expected, unless the number of data submitted is so large that printing is impractical.
3. Applications for reference or equivalent method determinations should be signed by an authorized agent of the applicant [53.4(b)] and contain contact information for the person to whom applicant-related correspondence should be directed. See the next Subsection I regarding proprietary or confidential information. Applications should be submitted in duplicate to:

Director, National Exposure Research Laboratory
Process Modeling Research Branch (MD D205-03)
United States Environmental Protection Agency
Research Triangle Park, North Carolina 27711

Commercial delivery address: 4930 Old Page Road
Durham, NC 27703 [53.4(a)]

4. EPA is obligated to process an application and formally respond to the applicant within 120 calendar days after receipt of the application. [53.5]

5. Applications that are inadequate or incomplete will result in a request to the applicant for additional information and possible additional testing as may be necessary. There is no time limit for submission of such additional information. Receipt of the new information starts a new 120-day period for processing of the application. [53.5]

I. Proprietary Information (CBI)

Any information in an FRM or FEM application submitted to EPA that the applicant considers proprietary or confidential business information (CBI) should be clearly and prominently identified. EPA will treat such identified information in accordance with 40 CFR Part 2, EPA's rules implementing the Freedom of Information Act. Such information will not be released outside of EPA without further contact with the applicant. Conversely, information *not* identified as CBI may be released outside of EPA without further contact with the applicant. Applications are typically processed by an EPA contractor, so EPA will likely request permission from the applicant to release the application, including any CBI information that it may contain, to its application processing contractor solely for the purpose of application review. This contractor has agreed to protect CBI information from further release to the same extent as is required for EPA. To expedite processing of the application, the applicant may include this limited-release permission in the application containing CBI. An example statement granting such permission would be: "[Applicant contact or organization] hereby grants permission to EPA to release all information contained in this application to EPA's application processing contractor for the sole purpose of processing the application in accordance with EPA's processing contractor agreement." [53.15]

III OPERATION / INSTRUCTION MANUAL REQUIREMENTS

The Operation or Instruction Manual associated with a candidate method is a required [53.4(b)(3)] and very important part of the FRM or FEM application. This manual must be comprehensive, clear, complete, and effectively describe the proper installation, calibration, operation, and maintenance of the method so that method's operators can obtain ambient air quality measurements of high quality. Its minimum content is outlined in 53.4(b)(3), and it will be reviewed thoroughly and carefully as part of the FRM or FEM determination, particularly with regard to the aspects described below. Manuals must be in English, and those from foreign instrument manufacturers or translated from non-English languages should be reviewed completely by an English editor for clarity and proper English terminology, grammar, and syntax. A candidate method will not be designated as an FRM or FEM until its manual is determined to be adequate. Additional information in regard to some of these content items follows.

A. Calibration

1. The instruction manual must clearly indicate the distinction between "calibration" and "zero-and-span check" or include Table 1, below. "Calibration" for automated methods refers to an adequate, multi-point definition of the analyzer's response to an accurate, reliable standard over the entire analyzer measurement range. (A simpler, 2-point zero and span calibration is often acceptable for more frequent calibrations between more complete multipoint calibrations.) For gas analyzers, such calibration must be performed dynamically by allowing the analyzer to measure, in its normal mode of operation, actual air samples containing accurately known concentrations of the pollutant. PM analyzers must be calibrated with an alternative technique suitable to the nature of the method. In contrast, a "zero-and-span check" consists of a zero baseline check with clean air or other zero representation and a one-point check of analyzer response with a possibly less accurate, less reliable, or non-dynamic standard to detect possible analyzer malfunctions between calibrations. Table 1 provides more detail to clarify the distinction between multi-point calibrations, 2-point zero/span calibrations, and zero/span checks.

Table 1 applies primarily to analyzers for gaseous pollutants. For PM analyzers, some adaptation is necessary since actual pollutant standards are not likely to be available, and calibration of sample flow rate may be of much greater importance. Also, there may be much less distinction (if any) between calibration and zero/span checks for PM analyzers. [53.4(b)(3), 53.21(b)]

Table 1. Guidance for Analyzer Calibration and Calibration Checks

	<u>Zero/Span Check</u>	<u>Zero/Span Calibration</u> (2-Point Calibration)	<u>Multipoint Calibration</u>
Application/ Formality	Informal "screening" check only.	Formal analyzer calibration; acceptable for analyzers having a linear (or linearized) response whose linearity has been confirmed by a previous multipoint calibration. May be either manual or automatic. May not be acceptable for significantly non-linear analyzers.	The most formal, rigorous analyzer calibration.
Zero standard	Any reasonable internally or externally generated zero air or alternative zero check. A zero check reading should be obtained immediately following any analyzer calibration to obtain a reference reading for comparison to subsequent checks.	Reliable zero air standard such as compressed zero air or thoroughly cleaned ambient air. Zero air may be "sucked" through a zero scrubber by the analyzer, provided the scrubber pressure drop does not affect the analyzer reading.	Reliable zero air standard such as compressed zero air or thoroughly cleaned ambient air.
Span standard	Any reasonable internally or externally generated upscale span concentration or an alternative response check. A span check reading should be obtained immediately following any analyzer calibration to obtain a reference reading for comparison to subsequent checks.	NIST-traceable, certified pollutant standard in air balance. Calibration standards in nitrogen balance are acceptable if diluted more than 50:1 with zero air. NO ₂ analyzers must be calibrated with either a certified NO ₂ standard or NO ₂ standard derived from a certified NO standard via gas-phase titration. CO calibration standards should contain approximately 350 ppm CO ₂ . For flow-rate-sensitive analyzers, the pollutant standard generally must be presented to the analyzer at atmospheric pressure and at a flow rate in excess of, and controlled independently of, the analyzer flow rate, with the excess flow vented at atmospheric pressure.	NIST-traceable, certified pollutant standard in air balance. Calibration standards in nitrogen balance are acceptable if diluted more than 50:1 with zero air. For NO ₂ analyzers, the calibration must be referenced to either a certified NO ₂ standard or NO ₂ standard derived from a certified NO standard via gas-phase titration and include a determination of the converter efficiency. CO calibration standards should contain approximately 350 ppm CO ₂ . For flow-rate-sensitive analyzers, the pollutant standard generally must be presented to the analyzer at atmospheric pressure and at a flow rate in excess of, and controlled independently of, the analyzer flow rate, with the excess flow vented at

	Zero/Span <u>Check</u>	Zero/Span <u>Calibration</u> (2-Point Calibration)	Multipoint Calibration
			atmospheric pressure.
Analyzer zero adjustment?	No	Yes, if significant deviation from nominal.	Yes. Multiple calibration points (4 or more) are obtained <i>after</i> adjustment.
Analyzer span adjustment?	No	Yes, if significant deviation from nominal.	Yes. Multiple calibration points (4 or more) are obtained <i>after</i> adjustment.
Frequency	Frequent, daily or several times per week as appropriate.	Less frequent than zero/span check. From daily to bi-weekly, as appropriate, based on the results of zero/span checks or a QA control chart.	Infrequent. Upon initial installation, major instrument repairs, evidence of possible non-linearity, for a more authoritative calibration, or as an occasional alternative to zero/span calibration. Perhaps semi-annually to bi-annually on a routine basis.
Action if readings are out of tolerance	Carry out Zero/span or multipoint calibration.	Adjust zero and/or span, if necessary. Compare adjustment or setting with previous ones. Extensive deviation or drift from last zero/span adjustment, or continual unilateral drift should be investigated as indication of possible malfunction.	Adjust zero and span. Indication of non-linearity should be investigated as possible malfunction, if linearity is expected.

2. The manual must prescribe one or more calibration procedures to be used to calibrate the method or analyzer and provide sufficiently detailed instructions to allow the analyzer operator to carry it out correctly and competently. References to EPA or *Federal Register* publications are acceptable, although it is preferable to have the complete procedure described in the instruction manual for the convenience of the user. When references are used, they must be revised or supplemented as necessary to insure that the procedure is complete in regard to all important details and that it is readily and fully applicable or tailored to the specific analyzer to be calibrated. Alternate (non-FRM) means of calibration may be included in an equivalent method designation if suitable tests are conducted to show that the alternate procedure(s) provide(s) the same performance or response.

3. Proper and credible calibration of the analyzer is one of the most critical aspects of analyzer operation. The analyzer operator needs to have a calibration procedure that is usefully organized, clear, complete, sufficiently detailed yet concise, effective, and easy to follow by an operator with minimal training or experience. The Calibration section of the analyzer instruction manual should be written to meet these objectives. This applies for both 2-point zero and span calibrations and multi-point calibrations and for the special calibrations of PM methods. These instructions should cover, as a minimum, the following topics (with adaptation or substitution of alternative techniques, to the extent necessary or appropriate, for PM analyzers):

a. Concentration standards required for calibration. These can include permeation devices or compressed gas cylinders (bottles) containing certified concentrations of calibration gases. A discussion of the standards required for the technique or techniques described in item b below should cover sources for obtaining concentration standards, traceability to an authoritative primary standard such as a U.S. National Institute of Standards and Technology (NIST) standard reference material (SRM), precautions for storing and using concentration standards, recommended range of concentration values, the possibility of contamination of NO or NO₂ standards with other oxides of nitrogen, and—in the case of NO₂ standards—that a companion NO standard may also be required for full calibration of the monitor.

b. Calibration technique. A discussion should describe one or more techniques for preparing calibration concentrations, such as dilution of compressed gas concentration standards, gas phase titration (GPT) using a compressed gas NO standard (if applicable), or use of a permeation device.

c. Calibration apparatus. A diagram and description of one or more suggested systems or apparatus suitable for preparing calibration concentrations, including identification and specifications, if appropriate, for the various components and how they are to be connected, or identifying a suitable commercially available system. Details should also be provided for how to connect the calibration system to the analyzer using a vent or other means to provide the calibration concentrations at atmospheric pressure. In general, a calibration system must provide its own source of zero air and not rely on air drawn through a zero scrubber by the analyzer under calibration. However, air drawn through a scrubber or filter may be allowed for the zero concentration point if the scrubber is a quality-controlled, commercially manufactured component and it can be shown that the analyzer's zero response is not sensitive to the variable pressure drop caused by the scrubber.

d. Procedure. A detailed, step-by-step procedure should be provided to carry out the entire calibration procedure, including the actions required to generate each calibration concentration (using the system described under item c above), how to correct for or accommodate NO standards that contain some NO₂ or NO₂ standards that contain some NO or other oxides of nitrogen, and the sequence of analyzer keys or controls to be used at each point in the procedure to effect analyzer adjustment. A "full" calibration procedure for NO₂ (often identified as a "multi-point" calibration) should include determination of the NO₂ ⇒ NO converter efficiency and recommendation of the frequency for carrying out a full calibration.

4. Statements in the manual that indicate that the analyzer is ready for sampling before a dynamic calibration has been performed are unacceptable. [53.4(b)(3), 53.21(b)]

5. The manual must indicate that the analyzer requires initial and periodic calibration according to the specified calibration procedure. In addition, the manual should suggest initial frequencies for both calibration and (if applicable) zero and span checks, and point out that the user should have a quality control plan whereby these frequencies and the number of points required for calibration can be modified on the basis of calibration and zero and span check data collected over a period of time. It is suggested that the manual further point out to the user that such a quality assessment/control program is essential to ascertain the accuracy and reliability of the air quality data collected and to alert the user if the accuracy or reliability of the data should become unacceptable. [53.4(b)(3), 53.21(b), 53.31(c)]

6. For reference methods, the manual must prescribe the calibration procedure specified in the appropriate appendix to 40 CFR Part 50 for calibration of the analyzer and include any adaptations necessary to accommodate the particular candidate method. A complete description or suitable reproduction of that calibration procedure should be provided. Analyzers which utilize the measurement principle specified in the appropriate appendix to 40 CFR Part 50, but prescribe some other calibration procedure, will be considered as candidates for an equivalent method determination. [53.2, 53.3]

7. During calibration, the analyzer must sample the standard atmosphere in the same way as it would normally sample the ambient atmosphere. The calibration standard must pass through the same path and the same components as the ambient air samples. This is perhaps best accomplished by using a vented manifold and passing the calibration gas through it at a higher flow rate than that demanded by the analyzer under calibration. The analyzer is then allowed to draw a sample from the manifold in its normal mode of operation. An exception is permissible for analyzers that have special, approved zero and span inlets and automatic valves to specifically allow introduction of calibration standards at near atmospheric pressure; such inlets may be used for calibration in lieu of the sample inlet.

8. Since several various pollutant concentrations are necessary for multipoint calibration, it may be expedient and economical to use a single standard gas cylinder containing a high pollutant concentration, diluting this standard with zero air to obtain the required calibration concentrations rather than attempting to use a number of gas cylinders of different concentrations directly. One departure from the normal sampling mode is permissible: If the analyzer normally operates with a purge or vent flow such that a portion of the sampled air is exhausted without passing through the detector, this vent flow may be reduced or stopped during the calibration (or zero-and-span) to avoid waste of calibration standard gas as long as the calibration sensitivity of the analyzer is not affected by this action.

9. Calibration standards used for CO analyzers should consist of CO in air, to most closely simulate the ambient air to be measured. Moreover, the air should be real air rather than synthetic air, and it should contain approximately 350 ppm of CO. Use of CO standards prepared in nitrogen or helium may be acceptable if they are substantially diluted with zero air or for a zero-and-span operation.

B. Hazard Warnings

The manual must provide warnings to the user concerning any hazards or potential hazards which might be present during installation, calibration, operation, maintenance, or trouble-shooting of the analyzer. Such warnings should be appropriately located in the manual preceding the section where the hazard is likely to be encountered. The warnings should stand out prominently in the textual format of the manual. The following are examples of hazards which would require warnings: [53.4(b)(3)]

1. Use of compressed flammable gases. The manual must warn of the hazards involved and recommend suitable safety precautions, such as locating cylinders outdoors, safety pressure relief valves vented to the outside, use of a flow-limiting orifice, exclusive use of metal delivery lines and fittings, and effective leak-detection procedures.

2. Use of toxic calibration gases. Calibration gases vented from the analyzer or from the calibration manifold may present a toxic hazard to the operator. The manual should caution the operator to vent such gases to the outside and to check for leaks in the calibration system.

3. Electrical terminals and high voltages. In general, electrical terminals carrying dangerous voltages should be covered. Warnings should be provided preceding any operations where such covers must be removed or where hazardous electrical terminals might be exposed.

4. Electrical grounding. Where appropriate, analyzers should be fitted with 3-wire, grounding type line cords and plugs. The manual should warn about the hazards of defeating this grounding system.

5. Analyzer damage. If inadvertent actions by the analyzer operator during installation, operation, or repair of the analyzer could cause damage to the analyzer or its components, suitable caution warnings should be provided in the manual.

C. Other Requirements

1. Non-designated measurement ranges or information pertaining to items that are not a specific part of the method to be designated must be clearly identified as such in the manual. [53.4(b)(3)]

2. The manual must contain a complete listing and identification of all user-replaceable components. [53.4(b)(3)]

3. When an analyzer has one or more user-adjustable controls, the manual must specify the proper setting for each such control. If the setting of such a control is elective, at the discretion of the user (for example, a "response time" control), the manual must provide guidance to the user on how to make the setting, giving the tradeoffs involved. If any settings of the control will not be covered by the requested designation, the manual must clearly identify such settings. [53.4(b)(3)]

4. The manual must describe all maintenance operations required and provide either specific frequencies at which they must be carried out, or guidance for determining how often they must be carried out. [53.4(b)(3)]

5. The manual's installation section should describe all aspects of proper installation (particularly for PM methods) and (for gas analyzers) include recommendations for the sample line material and any restrictions on length, size, pressure drop or other parameters of the sample line. [53.4(b)(3)]

6. The manual should inform the user if the calibration is subject to change with changes in temperature, barometric pressure, or altitude. [53.4(b)(3)]

7. The required test procedures of Subpart B are structured to test the performance of the analyzer over an operating temperature range of 20° C to 30° C. Thus, use of an analyzer under a normal designation would be limited to that 20° C to 30° C temperature range, and any statements in the manual concerning operating temperature range must make that limitation clear. (A wider temperature range may be approved based on tests conducted over a wider temperature range.)

8. The manual should provide a statement summarizing the restrictions in the operation of the analyzer that apply when the analyzer is used under its designation as a reference or equivalent method. This statement should preferably appear either on one of the introductory pages of the manual or in conjunction with a listing of the analyzer's operational or performance specifications. The statement should include all applicable restrictions, such as measurement range, voltage, operating temperature, response setting, other control settings, operational parameters (e.g. wavelength), etc. Such a statement might be similar to the following. "Use of this analyzer under EPA designation as a [reference] [equivalent] method as defined in 40 CFR Part 53 requires operation under the following conditions:

Measurement range: []
Response time: []
Ambient temperature: 20 - 30° C
Line Voltage: 105 - 125 vac.

In addition, the analyzer must be operated and maintained according to the instruction manual."

**IV. CANDIDATE AUTOMATED METHODS FOR GASES AND PM₁₀
(FRMs and FEMs for SO₂, CO, O₃, and NO₂, and FEMs for PM₁₀)**

A. Test Requirements (**Note:** Items preceded with ** are not applicable to PM₁₀ analyzers.)

1. **Candidate FRM and FEM analyzers for gaseous pollutants (SO₂, CO, O₃, and NO₂) must be tested according to the general provisions of Part 53, Subpart B and also those provisions that are specifically applicable to methods for the pollutant that the candidate method measures. Candidate FEM analyzers must also be field-tested for comparability to a FRM analyzer according to the applicable test requirements of Subpart C. [53.2(b), 53.3(b)]

2. Candidate FEM analyzers for PM₁₀ must be tested in accordance with the applicable requirements of Part 53, Subparts C and D. [53.3(b)]

3. A proper multipoint dynamic calibration [53.21(b)] must be performed on the test analyzer prior to conducting any of the required test procedures. The calibration procedure used must be one prescribed in the operation/instruction manual for regular use by the analyzer operator.

4. Calibration curves must be submitted showing the relationship between input concentration and both test analyzer recorder reading and test analyzer output (volts, millivolts, ppb, etc.). [53.21(b), 53.31(c)]

5. **In the event that there are substances likely to cause a significant interference but which have not been specified in Table B-3, analyzers must be tested for interference from these substances at a concentration substantially higher than that normally found in the ambient air. [53.23(d)(2)]

6. **Applicants whose method is of a type not listed in Table B-3 should contact the EPA for direction as to which substances must be tested for interference with the candidate method. [Table B-3]

7. A proper multipoint dynamic calibration (flow rate calibration for PM FRM samplers) must be performed on the reference method prior to conducting the required test procedures for determining comparability between a candidate method and a reference method (Subpart C). The calibration procedure used must be the one prescribed in the reference method. [53.31(c)]

8. When an analyzer has one or more user-adjustable controls, the operation/instruction manual must specify the proper setting for each such control, and the tests must be carried out at that proper setting. If the setting of such controls is elective, at the discretion of the user (for example, a "response time" control), then either all possible positions or settings of the control must be adequately covered by test data to show compliance to the performance specifications, or the manual must clearly indicate which position(s) or setting(s) is (are) acceptable for use under the designation. The former alternative is preferable. All possible positions of the control might be covered by conducting all tests at one extreme position of the control and repeating certain tests at the other extreme of the control. Tests for only those performance parameters that might be affected by the control setting would normally be required to be repeated. For example, where a "response time" control is used, all tests might be conducted at the lowest time constant setting (fastest response) and then the tests for lag time, rise time, and fall time could be repeated at the highest time constant setting (slowest response). A statement must be

provided to give the rationale and justification for the test scheme selected and any tests logically omitted. [Table B-1, Footnote 3]

9. The application should provide details (descriptions, diagrams, sketches, pictures, etc.) of the apparatus and procedures used to calibrate the test analyzer and to carry out the required tests. Describe the ultimate source and traceability for standards used. [53.4(b)(5), 53.20(f), 53.22(g), 53.30(g)]

10. Correct or specify all gas flow measurements in terms of standard volume units at 25° C and 760 mm Hg. [53.22(f)]

11. Test readings recorded on the strip chart record must show properly stabilized readings. A stable reading is not obtained until the strip chart trace clearly shows a sustained reading that, except for possible signal noise, is no longer changing with time.

12. **In Subpart C tests where pollutant concentrations were augmented, provide documentation that the sample air used was at least 80% ambient air, or submit flow rate data to verify this requirement. [53.32(f)(4)]

13. All tests must be conducted with the test analyzer in its normal mode of operation. Alterations in the analyzer or analyzer configuration or operation are generally not permitted unless absolutely necessary to the conduct of the test. [53.31(a), 53.30(e)]

14. **Describe the methods, apparatus, and standards used to generate or verify interferent concentrations. [53.22]

15. **Describe the method used to obtain zero air. [53.22(a), (d), (g)]

16. Describe the calibration or traceability of flow measuring instruments used. [53.22(f)]

17. **Methods for measuring and controlling line voltage and temperature during the drift, response, and precision test sequence should be described. If possible, such measurements should be documented. [53.20(f), 53.23(e)]

18. **Be sure to provide strip chart records for the Z₀', M₀', and S₀' readings in the drift test procedure. [53.4(b)(5), 53.23(e)]

19. All data pertinent to the tests should be submitted with the application. Information that may seem trivial to the applicant may often be important in the evaluation of individual test data. [53.20(f)]

20. **Exercise care in calculating the results of the tests for noise, span drift, and precision. Rounding-off should be done only after the final result is obtained. The final result should be expressed to one significant figure beyond the specification listed in Table B-1. For example, where the noise specification is 0.005, a noise calculation result of 0.00347 ppm should be rounded off to 0.0035 ppm. [53.23]

21. The test site used for Subpart C tests must be adequately identified and justified by supporting evidence as specified in paragraph 53.30(b). Include details concerning the sample inlet, the sample manifold, its location, installation, test set-up, artificial pollutant generator (if

used), etc. For PM₁₀ analyzers, show the configuration of the test samplers and instruments at the site and other details of the test setup. [53.30(b), (c), (d), (e); 53.34(b), (d), (e)]

22. **In calibrating the test analyzer, as well as during conduct of the required performance tests, it is very important that the test analyzer operate exactly as it would in its normal ambient air sampling mode of operation. Unless specifically approved, no modifications or alterations may be made to the test analyzer's components, to its flow system, in its prescribed flow rate, or in any other operational parameter or configuration of the test analyzer to facilitate conduct of the tests. The test concentrations must be generated by means entirely independent of the test analyzer (except for NO₂ test concentrations generated by gas phase titration). Further, the volume of the test atmospheres generated must generally exceed the volume sampled by the test analyzer during each test. The test analyzer itself must not be used to "draw" the test atmosphere through a zero or pollutant generation system, or as any part of a zero or pollutant generation apparatus. The most common test configuration used is to force the test atmosphere through a vented manifold at a flow rate at least 10 to 30 percent higher than the flow rate demand of the test analyzer. The test analyzer is then connected to the manifold upstream of the vent and allowed to draw its sample from the manifold. The vent exhausts the excess test atmosphere and must be designed to insure atmospheric pressure inside the manifold. The vent should also be designed to prevent any possibility of ambient air getting back into the manifold.

B. Strip Chart Records

1. For most of the required tests of candidate FRM and FEM analyzers, some sort of data recorder is required to log or record the readings of the test analyzer(s), and of the FRM analyzer(s), if applicable, during the tests. These data recordings form a critical part of the documentation of the tests and test results. The test requirements of Subparts B and C generally assume the use of a conventional strip chart (analog) data recorder. However, an alternative type of data recorder, such as a digital data logger, is permitted, provided that the alternative data recorder "...is reasonably suited to the nature and purposes of the tests, and an analog representation of the analyzer measurements for each test can be plotted or otherwise generated that is reasonably similar to the analog measurement recordings that would be produced by a conventional analog chart recorder connected to a conventional analog signal output." [53.21(a), as amended 8/31/11]

2. All strip chart or other data records for any of the tests must be identified, dated, signed by the analyst performing the test, and submitted. The identification should include:

- a. Type of test
- b. Test number
- c. Test conditions (line voltage, temperature, etc., if applicable)
- d. Chart speed
- e. Test start and stop points
- f. Test atmosphere concentrations and concentration changes (if applicable)
- g. Range of test analyzer, if applicable
- h. Date and time of each test
- i. Clear marking of any changes in the test conditions, chart speed, operating conditions, control settings, etc.
- j. Any other pertinent information [53.4(b)(5), 53.20(f), 53.30(g)]

3. The strip chart records are extremely important to the evaluation of the application. They must be complete, legible, and properly identified. Strip chart records must be submitted for all required tests (except the noise test), as well as for calibrations of the test analyzer (if appropriate). Chart records for the noise test are not mandatory but are desirable and should be submitted if available. [53.4(b)(5), 53.20(f), 53.30(g)]

4. Strip chart records should be continuous whenever possible. All test and non-test periods should be identified. Mark all adjustments, maintenance, or service performed on the test analyzer. Clearly mark any changes in chart speed. [53.21(c)]

5. Justify or explain any erratic recorder traces, spikes, or other abnormalities. If such anomalies would or might cause failure of the test specification, briefly state on the chart why such anomaly should be ignored when evaluating the test result.

6. The application should provide details on the type of chart recorder used, its response time, deadband, etc. [53.20(f), 53.21(a)]

7. In view of the difficulty of copying strip charts, and the often poor legibility that results, it is not necessary to submit the strip chart records in duplicate, as is required for the application in general. Accordingly, it is highly desirable that the original strip chart records be submitted with the application. If requested, these original strip charts will be returned to the applicant after processing of the application is complete.

C. Frequently Asked Questions (FAQs)

The following is a list of some of the questions pertinent to the requirements of 40 CFR Part 53, Ambient Air Monitoring Reference and Equivalent Methods, that have been posed by users of the regulation. The associated answers may represent official interpretation of the regulation provisions or established policy and are provided to assist other users of the regulations having similar questions. The list may be increased whenever new questions are submitted. Additional questions or requests for updated lists should be sent to the Reference and Equivalent Methods Program at the address given in Section VIII.

Question: There appears to be no requirements for the calibration gases. Also Table B-2 appears to refer only to interference test atmospheres. Was this the intent?

Answer: No. Table B-2, titled "Test Atmospheres," applies to all test atmospheres including those required for interference tests and for calibration.

In reference to Table B-2:

Question: May cylinder blends of 50 to 100 ppm (or fractional ppm) NH₃, H₂S, and SO₂ be used instead of permeation tubes?

Answer: Yes, however in such cases the concentrations must be verified by some independent method, such as the method shown in the "Verification" column of Table B-2. (See the last sentence of Section 53.22(a).)

Question: Could they be verified by obtaining 2 cylinder standards that agree within 2%?

Answer: Yes, provided that the cylinder standards are obtained from *independent* sources.

Question: According to paragraph (a) of Section 53.22, the NO cylinder blend does not require verification, since it “can produce reproducible concentrations.” Was this the intent?

Answer: Yes, however that paragraph also requires that the concentration must be established by some method. Thus the concentration of NO in the cylinder must be established by some reasonably reliable method, such as a certifiable accuracy traceable to a NIST standard, for example, or by the gas phase titration verification method listed in Table B-2.

Question: If the NO cylinder blend does have to be verified, may it be done by obtaining 2 cylinders that agree within 2%?

Answer: Yes, obtaining 2 cylinders from *independent* sources that agree within 2% would normally be an acceptable method for establishing NO concentrations.

Question: May the ozone generator be calibrated by means of the NO cylinder and gas phase titration?

Answer: Yes, provided the NO cylinder concentration has been adequately established.

Question: Is it likely or possible that further changes or modifications of these Rules and Regulations may be made in the near, or not so near, future? If so, will they be retroactive?

Answer: EPA rules are subject to amendment or change at any time; however, changes or modifications to Part 53 are generally made infrequently. Some changes have been made recently, and others may be will be made in the near future in EPA's effort to update Subpart B of the Part 53 regulations. Whenever substantive changes become necessary or prudent, they would be formally proposed (by publication in the *Federal Register*) for comment before final promulgation. If changes or modifications are made, whether or not they would be retroactive would depend on the nature, circumstances, and possible effects of such changes, and such issues would be discussed in the preamble associated with proposal of any rule amendments.

Question: Ambient air generally contains at least 350 ppm CO₂. Should the zero air used for the interference test contain CO₂ and if so must the interferent concentration of CO₂ be 750 ppm higher than the zero air?

Answer: Since the concentration of CO₂ in ambient air is now at least 390 ppm, zero air used for any test should contain approximately 390 ppm CO₂. For the CO₂ interferent test, the interferent concentration should be 750 ppm absolute, or at least 360 ppm higher than the zero air. [3/75]

Question: Does the regulation require that all “analyzers” must include sample pumps and filters?

Answer: Yes. The regulation is not specific about sample pumps, but it is our interpretation and policy that for an analyzer to be considered for a reference or equivalent method designation as an automated method, it must be complete, self-contained, and able to operate with only the addition of consumables (reagents, gases, filters, scrubbers, etc.) and “umbilicals” (e.g. electric power). (The only exception to this is the lack of a requirement for a visual measurement readout because of the wide variation in user readout requirements.) While a requirement for connection to a source of vacuum could be considered as an “umbilical connection,” we believe that the vast majority of such analyzers are used with a dedicated vacuum pump. Thus this vacuum pump becomes a component that is not only vital to the operation of the analyzer, but also one that could easily affect the performance of the analyzer.

Requiring analyzers to include vacuum pumps will insure that the analyzer purchaser will obtain an adequate pump and will also assist the purchaser in analyzer price comparisons and in conveniently obtaining warranty and repair service through the analyzer manufacturer. This policy, of course, also applies to pumps other than vacuum pumps. Situations where user requirements depart from normal usage of a vacuum pump would be covered under the provision allowing modifications by users (see 40 CFR 58, Appendix C, Section 2.8, Modifications of Methods by Users). **Note:** In recent years, vacuum pumps not supplied by the analyzer manufacturer have been allowable if they meet the analyzer manufacturer's stated performance specifications for the pump.

The use of particulate filters is left to the manufacturer's discretion and depends on the analyzer's susceptibility to interference, malfunction, or damage due to particulate matter.

Question: When generating test atmospheres, small variations in dilution airflow rate may cause failure of a test. Is better flow regulation or a record of flow variations needed?

Answer: The specifications allow for some inevitable variations in a generated concentration. If such variations cause or may cause failure of a test, then better flow regulation may be required. In such cases, a continuous record of flow and flow variations may be necessary to show that such variations were or were not a possible cause of a test failure.

Question: How should measurements be rounded off?

Answer: Measurements should normally be made to 1 decimal place beyond that of the applicable specification, where possible. For example, measurements for precision (CO) should be carried out to 2 decimal places – one more than the 1.0 percent specification. In calculations, intermediate results should not be rounded until the final result is obtained.

Question: How much stabilization time should be allowed to obtain a stable reading on an analyzer?

Answer: Ample time should be allowed to be certain the analyzer has reached a final, stable reading that is no longer changing with time. The time period required for such stabilization will vary from analyzer to analyzer. There is no fixed time limit for such stabilization. Where times to reach a stable reading appear to be excessive, individual judgment may be required to limit such times or to determine the magnitude of the stabilized reading.

Question: What length of sample inlet line should be used with the test analyzer?

Answer: Sample inlet lines should always be as short as practical. Changes in the lag time, rise time, and fall time of the test analyzer caused by a modest sample inlet line are normally small with respect to the specifications for those parameters. However, where there is a possibility that tests for these parameters may be failed, the sampled inlet line will not be considered as a part of the test analyzer unless the manufacturer supplies a particular sample inlet line to be used with the analyzer. Thus the test concentrations would be introduced directly to the analyzer's sample inlet. If a sample inlet line is supplied as part of the analyzer, the test concentrations would be introduced through it.

Question: By nature of their design, some analyzers may not be able to accommodate a particular test procedure. For example, the NO interferent test calls for 0.1 ppm NO₂ plus 0.5 ppm NO; the resultant 0.6 ppm NO_x may be off scale on the test analyzer. Must the analyzer be changed?

Answer: In such a case, a modification of the test procedure would be considered on a special case basis.

Question: Can the 12-hour zero drift test run longer than 12 hours? If so, how should it be evaluated?

Answer: Yes, the 12-hour zero drift test may run longer than 12 hours. In such cases, any consecutive 12-hour period may be used to evaluate the test.

Question: Is a line voltage regulator necessary for the drift and precision tests?

Answer: Specifications call for the line voltage to be controlled to ± 1 volt during these tests. If normal line voltage variations exceed this value, some type of line voltage regulator is recommended. Alternatively, a continuous record of line voltage may be used to show that the line voltage remained within the specification.

Question: A designated equivalent method will necessarily have a certain calibration procedure as part of the operation/instruction manual. Can an alternate method of calibration be used to calibrate an equivalent analyzer?

Answer: An equivalent method may be calibrated only by (1) a procedure specified as part of the method or (2) a procedure specified for calibration of a reference method as specified in an appropriate appendix to 40 CFR Part 50.

Question: In the interference test, must a scrubber be conditioned for each interferent even though it is intended to remove only certain interferents?

Answer: The scrubber must be conditioned for each interferent. Repetitive tests for the same interferent require only a single initial conditioning period.

Question: In the interference test, may a scrubber be conditioned for all interferents before starting the interferent tests?

Answer: Yes. Once the prefilter or scrubber has been conditioned for an interferent, the required 7 (or more) interference equivalent test results for that interferent may be obtained any time thereafter, as long as the prefilter or scrubber is not changed or serviced. This is true even if other tests or conditioning for other interferents is carried out between the interferent conditioning and the corresponding interference equivalent tests for that interferent. Since no more than 3 test results for each interferent are permitted per 24 hours [see paragraph 53.20(d)], it may be advantageous to condition the prefilter or scrubber for all required interferents before starting any of the interference equivalent tests. Once the conditioning has been completed for all required interferents, then up to 3 test results for each interferent may be obtained per day.

Question: What variation is allowed in the upper measurement range limit with respect to the range specification? In analyzers that do not have a span adjustment control, manufacturing tolerances may cause the upper range limit of individual analyzers to be above or below the required value.

Answer: Reasonable range variation would be $\pm 10\%$ of the required range. We feel that this variation represents an equitable compromise among the intended purposes and objectives of the equivalency program, the needs and expectations of the analyzer users, and a reasonable allowance for production tolerances by the manufacturer.

In general, we advocate the provision and use of span adjustment controls on air monitoring analyzers because (1) it emphasizes the need for initial and periodic calibration of the analyzer, (2) it allows the operator to obtain convenient scale units on his chart recorder or other data recording device, and (3) it avoids the inconvenience and possible errors in having to use

individual calibration curves or scale factors for each of several analyzers in a network. However, Federal regulations do not specifically require that air monitoring analyzers have span adjustments, and we respect the right of manufacturers not to provide a span adjustment control if they so wish. Of course, the prescribed calibration procedure for the analyzer must adequately instruct the user in how to calibrate and record accurate measurements from an analyzer that has no span adjustment. Similarly, if no zero adjustment control is provided, the required instruction manual must accordingly reflect the necessary procedures for calibration of the analyzer and for recording measurements under that condition.

Question: Gas chromatographic analyzers have certain characteristic differences from continuous analyzers. What interpretations or changes are necessary in the test procedures to accommodate such analyzers? In particular, how should the tests for noise, zero drift, lag time, rise and fall time be conducted?

Answer: Analyzers employing gas chromatographic principles of operation analyze a sample stream periodically, with a cycle time generally on the order of 4 to 10 minutes. Normally, at least two separate outputs are provided. One output provides a real time chromatogram (when recorded on a chart recorder) showing a series of peaks whose height is related to input concentration. The other output (memory) provides a continuous signal equivalent to the height of the most recent pollutant peak, and is updated after each analysis cycle.

The performance test procedures in 40 CFR Part 53 are designed primarily for analyzers that provide a more or less continuous output representing the approximate instantaneous pollutant concentration at the input. In the case of a gas chromatograph, the chromatogram output departs substantially from this conventional output and would require substantial modifications in the test procedures. It is our opinion that a chromatogram output is used primarily as a set-up and diagnostic aid, or for special purpose measurements, as opposed to routine use for collecting hourly and daily averages as needed by State and local control agencies for their surveillance programs. This may be particularly true when the analyzer also provides the more conventional memory output, which is far more convenient for the latter purpose. For these reasons, we discourage applying for designation of the chromatogram output.

For purposes of testing a memory output, the following interpretations are provided:

1. Noise: Conduct the test procedure exactly as specified. The test will interpret as noise such effects as conventional signal noise in the memory output, stability of the memory from one update to the next, and uniformity of output over several cycles when the input concentration is constant. The fact that the memory output should be inherently noise-free is not sufficient reason to omit or restructure the noise test.

2. Zero drift: Conduct the test procedure exactly as specified. The zero drift test is necessary to determine that any automatic zeroing system incorporated into the analyzer is functioning adequately.

Note: In obtaining any stabilized readings from the memory output, extra stabilization time may be necessary to allow for several cycle updates.

3. Lag time: The measured lag time will depend on the point in the analysis cycle at which the concentration change is made. To meet the lag time specification, we must consider the worst case situation, which is 1 cycle. Thus, for a "batch-type" analyzer such as a chromatograph, the lag time will be equivalent to the cycle time and no actual test is necessary. Alternatively, you could also determine the minimum lag time (by tests) and report the lag time as a range from minimum to maximum. However, the worst case lag time (equivalent to 1 cycle) would still have to meet the lag time specification in Table B-1.

4. Rise and fall time: Conduct the test as specified. The measured rise or fall time may be dependent on the point in the cycle at which the concentration was changed, but this should be ignored when conducting the tests so that random start times are obtained over the 7 (or more) trials. Rise and fall time results will normally be equivalent to 0, 1, or 2 cycles, for purposes of the equivalency tests.

V. CANDIDATE CLASS II AND III FEMs FOR PM_{2.5} and PM_{10-2.5}**A. Testing and Test Plan**

Candidate Class II FEMs for PM_{2.5} and PM_{10-2.5} are defined as manual methods, but candidate Class III FEMs for PM_{2.5} and PM_{10-2.5} are defined as automated methods (analyzers). Both must be tested in accordance with the applicable portions of Subpart C, as well as applicable provisions of Subpart E, and possibly Subpart F as may be determined by the Administrator. [53.3(b)]

New EPA regulations applicable to candidate Class II and Class III equivalent methods for PM_{2.5} and PM_{10-2.5} (amendments to 40 CFR Part 53) were promulgated in 2006 (*Federal Register*, Vol. 71, page 61236, October 17, 2006). These rules set forth the specific field-testing and other requirements that candidate methods for measuring concentrations of PM_{2.5} and PM_{10-2.5} in the ambient air must meet to be designated by EPA as Class II or Class III equivalent methods under Part 53. Organizations or entities wishing to have a particular PM_{2.5} or PM_{10-2.5} monitoring method considered by EPA for such designation are required to carry out the prescribed testing of the candidate method and submit an application containing the test results and other information to EPA in accordance with the provisions of Part 53.

In view of the complexity of the prescribed test requirements and the variety of possible candidate methods and testing venues, questions may arise in regard to specific method or testing situations. The EPA encourages potential applicants to seek timely answers from EPA for such questions so that candidate method testing is carried out properly and in accordance with the regulatory requirements. In response to such questions, the EPA provides clarification of the requirements, decisions in regard to specific technical issues, and recommendations or guidance as may be appropriate.

In particular, applicants considering FEM testing for these types of candidate methods may wish to submit a proposed test plan to EPA in advance for review and comment by EPA in regard to its apparent conformance to the applicable test requirements. Such a test plan should include a description of the candidate method (make, model, PM size range, nature of the PM measurement, etc. so that its Class can be positively determined and any operational or aspiration characteristics can be considered), proposed test sites with rationale or justification for their selection, proposed sampling dates, identification of the FRM samplers to be used, the number of FRM and candidate methods to be included, and any other information that may have a bearing on the acceptability of the tests with regard to the Part 53 requirements. The more information that is included, the less chance there may be of overlooking some relevant aspect of the testing that could affect acceptability of the test results.

Also, it should be noted that the candidate method instruments tested must be representative of the final product to be manufactured and offered for sale as a designated equivalent method under Part 53 [§53.4(b)(6)]. That means that all method design and configuration details must remain unchanged throughout testing and commercial production. Significant changes to the method during or after the testing process (such as might be suggested from test data or test results) may render the test results inapplicable to the equivalent method determination. Minor changes to the method after testing must be described in detail and accompanied by adequate justification that the change or changes would result in no significant deterioration in the performance of the candidate method.

For purposes of documentation, all questions or information submitted to EPA in regard to Part 53 requirements should be in writing and sent to the address given in Section VIII. EPA will provide a timely written response, which should be re-submitted to EPA as part of the content of an associated application under Part 53. Note that any information you submit to EPA that is claimed to be confidential or privileged information must be marked or identified as such

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(see Section VIII), so that it will be treated in accordance with 40 CFR Part 2 concerning confidential business information (CBI). Non-CBI questions or information may also be submitted to EPA via e-mail. Responses to questions or issues of a generic nature that are not deemed CBI and may be helpful to other potential applicants may be posted on EPA's AMTIC web site (www.epa.gov/ttn/amtic), added to this Guidelines document, or otherwise made available to other potential applicants or to the public. This AMTIC site may also carry additional technical corrections, clarifications, general guidance, FYI announcements, spreadsheet templates for the required test data calculations, application templates, or other information concerning PM_{2.5} and PM_{10-2.5} FEM applications that may be of particular interest to potential Part 53 applicants. Applicants are advised to check this web site frequently for new information prior to and during the testing and application process.

B. FRMs for PM_{2.5}

On October 17, 2006, the EPA promulgated an amendment to 40 CFR 50, Appendix L (Reference Method for the Determination of Fine Particulate Matter as PM_{2.5} in the Atmosphere) which changed in the specification of the particle size separator used in the sampler (Section 7.3.4) to allow an alternative separator other than the originally specified WINS impactor. The alternative separator is a cyclone-type separator specifically identified as "BGI VSCC™ Very Sharp Cut Cyclone" particle size separator specified as part of EPA-designated equivalent method EQPM-0202-142 (67 FR 15567, April 2, 2002) and as manufactured by BGI Incorporated, 58 Guinan Street, Waltham, Massachusetts 20451. This change thus permits a PM_{2.5} reference method (FRM) sampler to now be configured with either the original WINS impactor separator or the alternative cyclone separator.

A consequence of this change is that seven PM_{2.5} samplers configured with the BGI VSCC™ separator that were originally designated as FEMs have been re-designated as FRMs, and may therefore be used in the comparability tests for candidate Class II and III PM_{2.5} FEMs. The 7 methods have retained their previous equivalent method designations as well, and thus the methods carry dual designations as both reference and equivalent methods. These seven methods are as follows:

Method	Reference method	Equivalent method
BGI Models PQ200-VSCC, PQ200A-VSCC	RFPS-0498-116	EQPM-0202-142
R & P Partisol®-FRM 2000 PM-2.5 FEM	RFPS-0498-117	EQPM-0202-143
R & P Partisol® 2000 PM-2.5 FEM Audit	RFPS-0499-129	EQPM-0202-144
R & P Partisol®-Plus 2025 PM-2.5 FEM Seq.	RFPS-0498-118	EQPM-0202-145
Thermo Electron RAAS2.5-100 FEM	RFPS-0598-119	EQPM-0804-153
Thermo Electron RAAS2.5-200 FEM	RFPS-0299-128	EQPM-0804-154
Thermo Electron RAAS2.5-300 FEM Seq.	RFPS-0598-120	EQPM-0804-155

The reference method identification numbers for these samplers are those originally assigned to the corresponding PM_{2.5} sampler models configured with the WINS separator.

C. Test Data Spreadsheet Template

Test requirements for candidate Class II and III FEMs for PM_{2.5} and PM_{10-2.5} specify collection of a substantial number of collocated measurements of multiple candidate test monitors and FRM samplers over many days at several sites. Test results are calculated from these test data according to specified procedures. A spreadsheet template in Microsoft Excel format has been developed by EPA to facilitate compiling these test data and performing the required calculations to produce the required test results. EPA strongly recommends that

applicants use this spreadsheet template for compiling and calculating test data and submitting the test results in the FEM application. The template may be obtained from the Reference and Equivalent Methods Program at the address given in Section VIII.

D. Frequently Asked Questions (FAQs)

1. Test Sites

Question: Is a test site located in Canada or Mexico acceptable?

Answer: No, §53.35(b)(1) clearly requires testing "...at each of the applicable U.S. test sites....," so all test sites must be in the United States.

Question: How is a "midwestern city" defined? [§53.35(b)(i)(C), §53.35(b)(ii)(C)]

Answer: A city located in the northern region of the central United States east of the Rocky Mountains, in the area comprising the states of Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin.

Question: What is a "western" city? [§53.35(b)(i)(B), §53.35(b)(ii)(B)]

Answer: A city located in the western U. S. (but not the Pacific Coast states) in the area comprising the states of Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, and Wyoming.

Question: A "northeastern" city? [§53.35(b)(i)(D)]

Answer: A city located in the northeastern U.S., in the area comprising the states of Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.

Question: A "mid-Atlantic" city? [§53.35(b)(i)(D)]

Answer: A city in the mid-Atlantic section of the U.S., in the area comprising the states of Delaware, Maryland, North Carolina, Virginia, West Virginia and the District of Columbia.

Question: How should "...characteristic wintertime temperatures of 0° C or lower" be determined regarding a proposed test site? [§53.35(b)(ii)]

Answer: The site should be in an area where climatologic records for the area show an average temperature (average of the daily high and low temperature or similar average) of 0° C (32 °F) or lower for the month in which testing occurred or is planned to occur. (Many web sites provide average temperature data; one site that is particularly easy to use is www.weatherbase.com.)

2. Test Seasons

Question: To complete testing this winter [in Bakersfield, CA], I need to know the calendar sampling window. That is, what is the latest date we can sample and fall within the approved test period window? (This question applies to all test locations and not just Bakersfield.)

Answer: The winter season is defined in §53.35(b)(2) as the "...coolest three or four months of the year at the site." For example, according to our research, the coolest 4 months for Bakersfield (30 year average, 1961-1990) are December (average temperature 47.5° F), January (47.8° F), February (53.3° F) and November (55.8° F). Therefore, the latest test sampling day (of that particular season) would be February 28 (for 2007). (If the testing were started in February, a few days of sampling that carried over into early March (57.4° F) would not necessarily be disallowed if there were "extenuating circumstances.") Note that those four months may not necessarily be the coolest 4 months of the year at another test site. However, if a test site has been selected as one that must have a "characteristic wintertime temperature of 0° C (32°F) or lower ([53.35(b)(ii)]; see the previous question), then the latest test sampling day (for that particular season) would be the last day of the month for which the average temperature is 0° C (32°F) or lower.

Question: Do we need to sample at the two winter sites during the same year and season? Or, if the logistics do not work out, can the samples be collected at the different sites during different years/seasons?

Answer: There is no requirement that test samples have to be collected in the same year. Thus, for example, Bakersfield samples could be collected in December of one year and January of the next year in the same winter season. Further, there is no requirement that seasonal test measurements must be obtained contiguously. Thus, winter test sampling could be started in, for example, February and completed in November. Tests at different sites are not required to be carried out in the same year or in the same specific calendar-year season.

3. Test Procedures

Question: May sequential, multi-filter type reference method (FRM) samplers be used for the Comparability tests?

Answer: No, §53.35(c) clearly requires that the FRM samplers must be "...of single-filter design (not multi-filter, sequential sample design)." Further, operation of a multi-filter, sequential sampler in a manual, "single-filter" mode, where collected filter samples are retrieved after each test day, does not meet the "single-filter design" requirement. Note, however, that there is no requirement that the daily measurements start at any particular time of day, as long as they meet the 22 to 25 hour duration requirement of §53.35(c)(4).

VI. CANDIDATE FRMs AND CLASS I FEMs FOR PM_{2.5} and PM_{10-2.5}
(How to complete Checklists E-1 and E-2 – For Auditors of PM_{2.5} Sampler Manufacturers as specified in 40 CFR 53.51)

A. Introduction

Why ISO 9001: To ensure that PM_{2.5} samplers that are designated as reference or equivalent samplers are manufactured according to acceptable quality standards, the U.S. Environmental Protection Agency (EPA) requires an auditor to verify, on an annual basis, the manufacturer's testing and manufacturing processes or documented evidence of these processes. This auditor must be certified by the Regulatory Accreditation Board (RAB) or must meet the same general requirements. (The definition of ISO-certified auditor in Part 53 allows alternative auditors, provided they meet the same general requirements as auditors certified by RAB. The EPA has some flexibility to accept auditors, but alternatively certified auditors would be asked to provide some documentation of their qualifications.)

The Checklists: Figures E-1 and E-2 are audit checklists that the manufacturer must submit to EPA to certify that their FRM or FEM PM_{2.5} samplers are manufactured and tested in accordance with EPA's design and performance specifications. These checklists must be signed and dated by the auditor. The Designation Testing Checklist (see Figure E-1) is submitted only once, with the manufacturer's application for a candidate PM_{2.5} sampler to be designated as a reference or equivalent method. The Product Manufacturing Checklist (see Figure E-2) is to be submitted with the application and annually thereafter.

The Auditor: The auditor does not need to be completely familiar with the PM_{2.5} instrument, the sampling process, or the performance tests. The auditor's primary goals are (1) to determine whether the documentation required by EPA regarding the testing and production of the PM_{2.5} sampler complies with EPA's specifications, and (2) to complete the checklists that indicate whether there is compliance. (Although the auditor may complete the checklists after direct observation of the testing and manufacturing processes, they may also be completed after review of documented evidence of the testing and manufacturing processes.) The auditor is not being asked to make a technical judgment as to the adequacy of the test procedure, only that an apparently appropriate (*i.e.*, not trivial) test procedure is in place, is properly documented, and is being implemented.

The Audit: The testing and manufacturing documentation can consist of raw data and calculations derived from such data. It may be recorded on various media such as hand-written entries in laboratory notebooks, physical records such as strip chart traces, and computer files generated by data acquisition systems that are connected to test instruments. An exhaustive review of the documentation is not necessary; a general review of a manufacturer's documentation system coupled with detailed review of a representative subset of the documentation can permit the auditor to make a valid assessment of the credibility of the recording and transfer of data, data calculations, documentation of procedures, and selection and attainment of appropriate data quality indicator goals.

Filling in the Checklists: During the review, the following questions should be addressed to the auditor's satisfaction:

- Is there sufficient documentation of the procedures used to collect data to determine whether the data were collected in accordance with EPA specifications?

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- Were the procedures specified for collecting data properly followed? Is there sufficient documentation to determine this?
- Do the data indicate that the PM_{2.5} sampler meets EPA's performance, application, and design specifications?

Regarding Checklist E-1, since the manufacturer has prepared a designation application (either internally or through a consultant), auditors who must sign this checklist can respond easily to E-1 by:

- Asking the company for a copy of the application,
- Reading the application,
- Asking the manufacturer to show its records, test procedures, test reports, and other data used to complete the application.

The auditor can then follow at least a sample of the data trail to original information, or copies.

Once this process is accomplished, the auditor will have a better idea of where to find the equivalent record starting points for the production specification tests and associated company records for verification of the test items in Checklist E-2. The auditor then can follow at least a sample of the data trail maintained in the manufacturer's records to enable them to document the existence of records for the performance tests listed in Checklist E-2.

The Checklist E-2 items are based on the Part 53 tests as a starting point. However, the manufacturer determines what actual final tests are needed or are adequate to assure shipment of a quality product. The E-2 form is to verify that such procedures have been established and implemented. If no procedure is in place for an E-2 item, the auditor can check "No" on the E-2 form, in which case the EPA will likely require some justification from the manufacturer as to why the test procedure is determined to be unnecessary.

The following paragraphs present a summary of the performance, application, and design specifications and the documentation that should be associated with each item in the checklists.

B. Designation Testing Checklist (Figure E-1)

Sample flow rate coefficient of variation

(See Part 53, Section 53.53 and Part 50, Appendix L, Section 7.4.3)

Performance Test	Performance Specification	Test conditions
Comparison between flow rate coefficients of variation measured by the sampler flow meter (%CV _{ind}) and a reference flowmeter (%CV _{ref})	$ \%CV_{ind} - \%CV_{ref} \leq 0.3$	6-hour operational laboratory test, data recorded at least every 5 minutes

What to look for: The manufacturer must describe the test measurement instruments that were used in this test and must have documentation showing that the instruments have been recently calibrated, with certification of calibration accuracy and traceability to NIST (if required). The test procedure must be described. Test results for reference and sampler flow rates and statistical calculations comparing the %CVs of these two flow rates must be documented.

Filter temperature control (sampling)*

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(See Part 53, Section 53.57 and Part 50, Appendix L, Section 7.4.10)

Performance Test	Performance Specification	Test conditions
Comparison between air temperature measurements taken downstream of the filter by a reference probe ($T_{ref,filter}$) and the sampler's filter temperature probe ($T_{ind,filter}$)	$ T_{ind,filter} - T_{ref,filter} \leq 5$ degrees Celsius for any consecutive intervals covering more than a 30-minute period	4-hour operational laboratory test with solar insolation (see Military Standard Specification 810-E), with readings at least every 5 minutes

* Note: This is the first half of the filter temperature control test specified in Section 53.57.

What to look for: The manufacturer must describe the reference temperature instrument and solar radiometer that were used in this test and must have documentation showing that these instruments have been recently calibrated, with certification of calibration accuracy and traceability to NIST (if required). The test setup and procedure must be described. Test results for the reference and candidate test sampler temperature measurements and the solar insolation measurements must be documented.

Elapsed sample time accuracy

(See Part 53, Section 53.54 and Part 50, Appendix L, Section 7.4.13)

Performance Test	Performance Specification	Test conditions
Evaluation of sampler's time measurement accuracy, excluding periods of power interruption	± 20 seconds	6-hour operational laboratory test

What to look for: The manufacturer must have documentation showing that the sampler's time measurement system is accurate to within 10 seconds per day. The test procedure must be described. Test results for elapsed time measurements must be documented.

Filter temperature control (Post-sampling)*

(See Part 53, Section 53.57 and Part 50, Appendix L, Section 7.4.10)

Performance Test	Performance Specification	Test conditions
Comparison between air temperature measurements taken downstream of the filter by a reference probe ($T_{ref,filter}$) and the sampler's filter temperature probe ($T_{ind,filter}$)	$ T_{ind,filter} - T_{ref,filter} \leq 5$ degrees Celsius for any consecutive intervals covering more than a 30-minute period	4-hour laboratory test with solar insolation after sampling (see Military Standard Specification 810-E), with solar flux of 1000 watts per square meter and readings at least every 5 minutes

* Note: This is the second half of the filter temperature control test specified in Section 53.57.

What to look for: The manufacturer must describe the reference temperature instrument and solar radiometer that were used in this test and must have documentation showing that these instruments have been recently calibrated, with certification of calibration accuracy and traceability to NIST (if required). The test setup and procedure must be described. Test results for the reference and candidate test sampler temperature measurements and the solar insolation measurements must be documented.

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Field precision

(See Section 53.58 and Part 50, Appendix L, Section 5.1)

Application Test	Application Specification	Test conditions
Evaluation of precision (P_j or RP_j) of the 3 PM _{2.5} concentrations ([PM _{2.5}]) measured during the same test period	$P_j < 2 \text{ } (\mu\text{g}/\text{m}^3)$ for [PM _{2.5}] $< 40 \text{ } \mu\text{g}/\text{m}^3$ (for 24-hr) or $< 30 \text{ } \mu\text{g}/\text{m}^3$ (for 48-hr); or, $RP_j < 5$ percent for [PM _{2.5}] $> 40 \text{ } \mu\text{g}/\text{m}^3$ (for 24-hr) or $> 30 \text{ } \mu\text{g}/\text{m}^3$ (for 48-hr)	Ten 24- or 48-hour periods of field operation with 3 collocated candidate test samplers, with mean measured [PM _{2.5}] $> 10 \text{ } \mu\text{g}/\text{m}^3$ for each day

What to look for: The manufacturer must identify the 3 candidate test samplers and have documentation showing that they were installed, leak checked, calibrated, and operated in accordance with their instruction manual and EPA's quality assurance guidance for the method (see Reference 3). Test results for pre- and post-sampling filter weights, volumetric flow rates, elapsed times, and subsequent calculations of the PM_{2.5} concentrations and the precision values must be documented.

Meets all Appendix L requirements

(See Part 53, Sections 53.2(a)(3) and 53.51(a) and (d))

What to look for: The manufacturer must have documentation that the candidate test sampler meets all the requirements of Part 50, Appendix L, including all dimensions shown in the figures. The manufacturer must have documentation showing that the impactor jet diameter and the surface finish have been verified by testing.

Filter weighing

(See Part 50, Appendix L, Section 8)

Application Test	Application Specification	Test conditions
Analytical balance readability	± 1 microgram	
Mean temperature		20 to 23 degrees Celsius
Temperature control		± 2 degrees Celsius over 24 hours
Mean relative humidity		30 to 40 percent
Relative humidity control		± 5 percent over 24 hours
Conditioning time	≥ 24 hours	

What to look for: The manufacturer must describe the temperature and relative humidity control systems, the analytical balance, and the temperature and relative humidity instruments that were used during filter weighing and must have documentation showing that these instruments have been recently calibrated, with certification of calibration accuracy and traceability to NIST (if required). The filter weighing procedure must be documented.

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Field sampling procedure*

(See Part 53, Sections 53.30, 53.31, and 53.34)

Application Test	Application Specification	Test conditions
Linear regression slope, intercept, and correlation coefficient (r) and precision (P _j or RP _j) of the two sets of three PM _{2.5} concentrations ([PM _{2.5}]) measured during the same test period	Slope = 1 ± 0.1 Intercept = 0 ± 5 micrograms per cubic meter (µg/m ³) r ≥ 0.97 P _j < 5 µg/m ³ for [PM _{2.5}] < 40 µg/m ³ (for 24-hr) or < 30 µg/m ³ (for 48-hr); or, RP _j < 7 percent for [PM _{2.5}] > 40 µg/m ³ (for 24-hr) or > 30 µg/m ³ (for 48-hr)	At a minimum of two test sites, ten 24- or 48-hour periods of field operation with 3 collocated candidate test samplers and 3 collocated reference method samplers

*(This requirement applies only to Class I candidate equivalent methods)

What to look for: The manufacturer must identify the 3 candidate test samplers and the 3 reference method samplers and have documentation showing that they and the analytical balance were installed, leak checked, calibrated, and operated in accordance with their instruction manual and EPA's quality assurance guidance for the method (see Reference 3). Test results for pre- and post-sampling filter weights, volumetric flow rates, elapsed times, and subsequent calculations of the PM_{2.5} concentrations, linear regression parameters, and precision values must be documented.

Filter

(See Part 50, Appendix L, Section 6)

Design Parameter	Design Specification	Test conditions
Size	Circular, 46.2-mm diameter ±0.25 mm (with support ring)	
Medium	Polytetrafluoroethylene (PTFE) Teflon with integral support ring	
Support ring	Polymethylpentene (PMP) or equivalent inert material, 0.38 ± 0.04 mm thickness, outer diameter 46.2 ± 0.25 mm, and width of 3.68 mm.	
Pore size	2 µm	Measured by ASTM Method F316-94
Thickness	30–50 µm	
Maximum pressure drop (clean filter)	30 cm H ₂ O column at 16.67 L/min clean air flow	
Maximum moisture pickup	No more than 10 µg weight increase after 24-hour exposure to air at 40 percent RH, relative to the weight after 24-hour exposure to air at 35 percent RH	
		Measured by the dioctylphthalate

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Design Parameter	Design Specification	Test conditions
Collection efficiency	> 99.7 percent	(DOP) test (ASTM Method D2986-91) with 0.3 µm particles at the sampler's operating face velocity
Filter weight stability	Filter weight loss ≤20 µg	Measured as specified in 40 CFR Part 50, Appendix L
Loose surface particle contamination	<20 µg	Determined by the procedure in 40 CFR Part 50, Appendix L
Temperature stability	Weight change < 20 µg	Determined by the procedure in 40 CFR Part 50, Appendix L, after heating to 40 ±2 °C
Alkalinity	< 25 microequivalents/g of filter	Measured by the procedure given in Appendix A of Reference 3

What to look for: Only EPA-approved filters should be purchased. The manufacturer must certify that these media meet the specifications given in Appendix L, Section 6, or have such certification from the filter manufacturer.

Range of operational conditions

(See Part 50, Appendix L. Section 7.4.7)

Design Parameter	Design Specification	Test conditions
Ambient temperature	-30 to +40 degrees Celsius	See Part 53, Section 53.55
Ambient relative humidity	0 to 100 percent	
Barometric pressure	600 to 800 millimeters of mercury	See Part 53, Section 53.56

What to look for: The manufacturer must have documentation showing that the candidate test sampler has been designed to operate over the ranges specified above. The manufacturer must have documentation showing test results of the effect of variations of ambient temperature and ambient pressure on sampler performance as specified under Part 53, Sections 53.55 and 55.56.

Aerosol transport*

(See Part 53, Section 53.59)

Design Parameter	Design Specification	Test conditions
Aerosol transport	≥ 97 percent for all channels	

*(This requirement applies only to Class I candidate equivalent methods)

What to look for: The manufacturer must describe all test measurement instruments that were used in this test and must have documentation showing that these instruments have been recently calibrated, with certification of calibration accuracy and traceability to NIST (if required). The test procedure must be

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described. Test results for the mass of fluorometric material deposited on all active filters, washed surfaces, and no-flow filters, and subsequent calculations of aerosol transport must be documented.

C. Product Manufacturing Checklist (Figure E-2)

Assembled operational performance (Burn-in test)

(See Part 53, Section 53.51(e))

What to look for: Each sampler shall be tested after manufacture and before delivery to the final user. Each manufacturer shall document its post-manufacturing test procedures. As a minimum, each test shall consist of the following: Tests of the overall integrity of the sampler, including leak tests; calibration or verification of the calibration of the flow measurement device, barometric pressure sensor, and temperature sensors; and operation of the sampler with a filter in place over a period of at least 48 hours. The results of each test shall be suitably documented and shall be subject to review by an ISO-certified auditor.

Sample flow rate

(See Part 53, Section 53.53 and Part 50, Appendix L, Sections 7.4.1 and 7.4.2)

Performance Test	Performance Specification	Test conditions
Mean sample flow rate (Q_{ref}) as measured by the reference flowmeter	16.67 L/min \pm 5 percent	6-hour operational laboratory test, with readings at least every 5 minutes

What to look for: The manufacturer must describe the test measurement instruments that were used in this test and must have documentation showing that the instruments have been recently calibrated, with certification of calibration accuracy and traceability to NIST (if required). The test procedure must be described. Test results for reference flow rates and statistical calculations of the mean reference flow rate must be documented.

Sample flow rate regulation

(See Part 53, Section 53.53 and Part 50, Appendix L, Section 7.4.3)

Performance Test	Performance Specification	Test conditions
Sample flow rate coefficient of variation ($\%CV_{ref}$) as measured by a reference flowmeter	\leq 2 percent	6-hour operational laboratory test, with readings at least every 5 minutes

What to look for: The manufacturer must describe the test measurement instruments that were used in this test and must have documentation showing that the instruments have been recently calibrated, with certification of calibration accuracy and traceability to NIST (if required). The test procedure must be described. Test results for reference flow rates and statistical calculations of the coefficient of variation for the reference flow rate must be documented.

Flow rate and average flow rate measurement accuracy

(See Part 53, Section 53.53 and Part 50, Appendix L, Section 7.4.5)

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Performance Test	Performance Specification	Test conditions
Comparison of the flow rates measured by the reference (Q _{ref}) and candidate test sampler (Q _{ind}) flowmeters.	$ Q_{ind} - Q_{ref} \leq 2$ percent	6-hour operational laboratory test, with readings at least every 5 minutes
Comparison of the mean flow rates measured by the reference (Q _{ref}) and candidate test sampler (Q _{ind}) flowmeters.	$ \text{mean } Q_{ind} - \text{mean } Q_{ref} \leq 2$ percent	6-hour operational laboratory test, with readings at least every 5 minutes

What to look for: The manufacturer must describe the test measurement instruments that were used in this test and must have documentation showing that the instruments have been recently calibrated, with certification of calibration accuracy and traceability to NIST (if required). The test procedure must be described. The test results for the reference and sampler flow rates and the statistical calculations comparing these two flow rates and their means must be documented.

Ambient air temperature measurement accuracy

(See Part 53, Section 53.55 and Part 50, Appendix L, Section 7.4.8)

Performance Test	Performance Specification	Test conditions
Evaluation of the sampler's ambient air temperature measurement accuracy as indicated by the difference between a reference temperature instrument (T _{ref}) and the candidate test sampler (T _{ind}) measurements	$ T_{ind} - T_{ref} \leq 2$ degrees Celsius	Four 6-hour operational laboratory tests at two chamber temperatures and two line voltages, with readings at least every 5 minutes

What to look for: The manufacturer must describe the reference temperature instrument that was used in this test and must have documentation showing that it has been recently calibrated, with certification of calibration accuracy and traceability to NIST (if required). The test procedure must be described. Test results for the reference and candidate test sampler temperature measurements must be documented.

Ambient barometric pressure measurement accuracy

(See Part 53, Section 53.56 and Part 50, Appendix L, Section 7.4.9)

Performance Test	Performance Specification	Test conditions
Evaluation of the accuracy of the mean ambient air barometric pressure measurement as indicated by a reference barometer (mean P _{ref}) and the candidate test sampler (mean P _{ind})	$ \text{mean } P_{ind} - \text{mean } P_{ref} \leq 10$ millimeters of mercury	Two 6-hour operational tests at two pressures, with readings at least every 5 minutes

What to look for: The manufacturer must describe the reference barometer that was used in this test and must have documentation showing that it has been recently calibrated, with certification of calibration

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accuracy and traceability to NIST (if required). The test procedure must be described. Test results for reference barometer and candidate test sampler barometric pressure measurements must be documented.

Sample flow rate cut-off

(See Part 53, Section 53.53 and Part 50, Appendix L, Section 7.4.4)

Performance Test	Performance Specification	Test conditions
Time for candidate test sampler to automatically cut-off after the sample flow rate slowly decreases to less than 15.0 L/min	30 seconds < cut-off time < 90 seconds. Sampler sets a warning flag to indicate that the cut-off occurred.	Flow rate reduction device installed between flow rate measurement adapter and downtube, with readings at least every 30 seconds.

What to look for: The manufacturer must document sampler flow rate data and corresponding time data showing that the candidate test sampler cut off automatically within the specified time period.

Sampler leak check facility

(See Part 53, Section 53.52 and Part 50, Appendix L, Section 7.4.6)

Performance Test	Performance Specification	Test conditions
Sampler external leak rate (or the equivalent pressure increase in the partially evacuated sampler). An alternative leak test may be approved by EPA	Leakage < 80 mL/min	Install and close flow rate measurement adapter, partially evacuate and seal candidate test sampler, measure vacuum in sampler for at least 10 minutes.
Sampler internal leak rate (or the equivalent pressure increase in the partially evacuated sampler). An alternative leak test may be approved by EPA	Leakage < 80 mL/min	Install flow-impervious membrane material in filter cassette, partially evacuate and seal candidate test sampler, measure vacuum in sampler for at least 10 minutes

What to look for: The manufacturer must describe the test measurement instruments that were used in this test and must have documentation showing that the instruments have been recently calibrated, with certification of calibration accuracy and traceability to NIST (if required). The test procedure must be described. If necessary for the calculations, the manufacturer must present evidence of the relationship between leak rate and pressure increase based on the actual internal volume of the portion of the sampler under vacuum. Test results for external and internal leak rates (or for the equivalent pressure increases) and any subsequent calculations must be documented.

Flow rate calibration transfer standard

(See Part 50, Appendix L, Section 9.2)

Application Test	Application Specification	Test conditions
Accuracy of calibration	± 2 percent over the expected	

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relationship	range of ambient temperatures and pressures at which the flow rate standard may be used	
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What to look for: The manufacturer must describe the flow rate transfer standard and the reference flowmeter that were used in this test and must have documentation showing that the two flowmeters have been recently calibrated, with certification of calibration accuracy and traceability to NIST (if required). The test procedure must be described. Test results for the calibration of the flow rate transfer standard and the subsequent calculation of the calibration relationship and accuracy must be documented.

Operational/instruction manual
(See Part 50, Appendix L, Section 7.4.18)

What to look for: As described in Part 53, Section 53.51 (a) (3), EPA has determined that acceptable technical judgment for review of this manual may not be assured by ISO affiliates, and approval of this manual will therefore be performed by EPA.

Impactor (jet width)
(See Part 53, Section 53.51(d)(2) and Part 50, Appendix L, Section 7.3.4.1)

Design Parameter	Design Specification	Test conditions
Internal diameter of impactor jet	A 0.152 inch diameter pin to go completely through the jet, but a 0.156-inch pin not to go from either end	Class ZZ go/no-go plug gages traceable to NIST

What to look for: The manufacturer must describe the plug gages that were used in this test and must have documentation showing that they have been calibrated, with traceability to NIST (if required). Test results from measurements of the internal diameter must be documented.

Surface finish
(See Part 53, Section 53.51 and Part 50, Appendix L. Section 7.3.7)

Design Parameter	Design Specification	Test conditions
Weight of internal surface finish of sulfuric anodized parts	≥ 1000 milligrams/foot ² (1.08 milligrams/centimeter ²)	See Military Standard Specification 8625F, Type II, Class I
Corrosion resistance of internal surface finish of sulfuric anodized parts	336 hours	See ASTM Method B117-95 with 5 percent salt solution

What to look for: The manufacturer must describe the procedures used to measure the weight and corrosion resistance of the surface finish and must document the test results from these measurements. The manufacturer may submit a certificate from a metal finisher documenting these test results in lieu of performing these tests in the manufacturer's facility.

References (from Appendix A of Subpart E of Part 53)

- (1) Quality systems--Model for quality assurance in design, development, production, installation and servicing, ISO 9001. July 1994. Available from American Society for Quality Control, 611 East Wisconsin Avenue, Milwaukee, WI 53202.
- (2) American National Standard – Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs. ANSI/ASQC E4-1994. January 1995. Available from American Society for Quality Control, 611 East Wisconsin Avenue, Milwaukee, WI 53202.
- (3) Copies of Quality Assurance Guidance Document 2.12 – Monitoring PM_{2.5} in Ambient Air Using Designated Reference or Class I Equivalent Methods. Available at www.epa.gov/ttnamti1/files/ambient/pm25/qa/m212covd.pdf.
- (4) Military Standard Specification (mil. spec.) 8625F, Type II, Class 1 as listed in Department of Defense Index of Specifications and Standards (DODISS), available from DODSSP – Customer Service, Standardization Documents Order Desk, 700 Robbins Avenue, Building 4D, Philadelphia, PA 1911-5094.
- (5) QA Handbook for Air Pollution Measurement Systems: Volume IV: Meteorological Measurements Version 2.0. EPA-454/B08-002 (March 2008). Available at www.epa.gov/ttn/amtic/qalist.html.
- (6) Military Standard Specification (mil. spec.) 810-E as listed in Department of Defense Index of Specifications and Standards (DODISS), available from DODSSP – Customer Service, Standardization Documents Order Desk, 700 Robbins Avenue, Building 4D, Philadelphia, PA 1911-5094.

Figure E-1. DESIGNATION TESTING CHECKLIST

Auditee			Auditor signature	Date
Compliance Status: Y = Yes N = No NA = Not applicable/Not available				
Verification			Verification by Direct Observation of Process or of Documented Evidence: Performance, Design, or Application Specification Corresponding to Sections of 40 CFR Part 53 or 40 CFR Part 50, Appendix L	Verification Comments (Includes documentation of who, what, where, when, why) (Document No., Revision No., Revision Date)
Y	N	NA		
			Performance Specification Tests	
			Sample flow rate coefficient of variation (Section 53.53 and Appendix L, Section 7.4.3)	
			Filter temperature control (sampling) (Section 53.57 and Appendix L, Section 7.4.10)	
			Elapsed sample time accuracy (Section 53.54 and Appendix L, Section 7.4.13)	
			Filter temperature control (Post-sampling) (Section 53.57 and Appendix L, Section 7.4.10)	
			Application Specification Tests	
			Field precision (Section 53.58 and Appendix L, Section 5.1)	
			Meets all Appendix L requirements (Sections 53.2(a)(3) and 53.51(a),(d))	
			Filter weighing (Appendix L, Section 8)	
			Field sampling procedure (Sections 53.30, 53.31, and 53.34)	
			Design Specification Tests	
			Filter (Appendix L, Section 6)	
			Range of operation conditions (Appendix L, Section 7.4.7)	
The following requirements apply only to Class I candidate equivalent methods				
			Aerosol transport (Section 53.59)	

Figure E-2. PRODUCT MANUFACTURING CHECKLIST

Auditee			Auditor signature	Date
Compliance Status: Y = Yes N = No NA = Not applicable/Not available				
Verification			Verification by Direct Observation of Process or of Documented Evidence: Performance, Design or Application Specification Corresponding to Sections of 40 CFR Part 53 or 40 CFR Part 50, Appendix L	Verification Comments (Includes documentation of who, what, where, when, why) (Document No., Revision No., Revision Date)
Y	N	NA		
			Performance Specification Tests	
			Assembled operational performance (Burn-in test) (Section 53.51)	
			Sample flow rate (Section 53.53 and Appendix L, Sections 7.4.1 and 7.4.2)	
			Sample flow rate regulation (Section 53.53 and Appendix L, Section 7.4.3)	
			Flow rate and average flow rate measurement accuracy (Section 53.53 and Appendix L, Section 7.4.5)	
			Ambient air temperature measurement accuracy (Section 53.55 and Appendix L, Section 7.4.8)	
			Ambient barometric pressure measurement accuracy (Section 53.56 and Appendix L, Section 7.4.9)	
			Sample flow rate cut-off (Section 53.53 and Appendix L, Section 7.4.4)	
			Sampler leak check facility (Section 53.52 and Appendix L, Section 7.4.6)	
			Application Specification Tests	
			Flow rate calibration transfer standard (Appendix L, Section 9.2)	
			Operational/instruction manual (Appendix L, Section 7.4.18)	
			Design Specification Tests	
			Impactor (jet width) (Section 53.51(d)(2) and Appendix L, Section 7.3.4.1)	
			Surface finish (Section 53.51 and Appendix L, Section 7.3.7)	

VII. CANDIDATE FEMs FOR LEAD

A. Test and Other Requirements

1. Candidate FEM methods for lead (Pb) tend to be somewhat different than most other candidate methods. The two FRMs for lead are both manual methods: Appendixes G to Part 50 for lead in total suspended particular matter (TSP), and Appendix Q to Part 50 for lead in PM₁₀. Each method specifies particular types of samplers and prescribed analytical procedures.

Accordingly, candidate methods typically consist of the FRM-specified sampler along with an alternative analytical procedure. The applicant is usually a commercial or State analytical laboratory that wishes to use an alternative analytical procedure that differs to some extent from the procedure specified in the FRM. The alternative procedure is often one of the laboratory's own design, and it is likely to be one that is tailored to their particular in-house analytical instruments and expertise. It may also be one that provides multiple, simultaneous analyses of several species, including lead. Thus, the method is usually not based on a commercially offered monitoring sampler or analyzer, as for most other types of candidate FEMs. However, FEMs that are automated analyzers for lead are not precluded by the Part 53 regulations.

2. A candidate FEM for lead must still be tested as required by Part 53, Subpart C, to determine its comparability to the corresponding FRM. If the candidate method uses the same sampler as the corresponding FRM, then only the analytical portion of the candidate method may need to be tested. Further, if the candidate (analytical) method is compatible with the same type of filter samples – or even the sample filter extract – as obtained with the corresponding FRM, then there may be a possibility of using common filters or common sample extracts for both methods in the comparability tests. This may even obviate the need for a special field-test if suitable filter samples are available from another source.

3. Candidate methods for lead must be complete and self-contained methods for monitoring the air for lead. This means that, in addition to a full description of the candidate analytical procedure (and extraction procedure), the candidate method must also include an identification and description of the sampler and sampling procedure that is specified as part of the candidate method. If the sampler and sampling procedure is the same as that for the corresponding FRM, then a simple reference to the FRM is sufficient. The method description should be separate from, although contained in, the application content.

4. Candidate methods must describe the analytical procedure (aka the SOP), including all instruments, apparatus, reagents, processes, standards required, calibrations, calculations, and quality control steps. It must provide sufficient detail such that an experienced chemist can carry out the method without having been otherwise familiar with it and obtain results representative of the FEM qualification tests. Analytical instruments should be described by model and give the required technical specifications and instrument settings so that a suitable, alternative, equivalent instrument may be used to yield comparable analytical results. All terms and acronyms should be defined and used consistently throughout the procedure. Although generic or functional descriptions of components, supplies, and materials are preferable, specific commercial products may be identified by brand, model, vendor, part number, etc. where necessary or expedient. If desired, a disclaimer may be included to indicate that mention of such specific commercial products does not constitute endorsement of such products.

5. The candidate method should address quality control of the entire measurement process, including the use of both laboratory and field filter blanks. For example, the method might include a statement such as follows: "Blank filters can have positive values for lead (Pb). Each manufacturer lot of filters may need to be investigated to ensure that filters will meet the

data quality objectives of a given project.” Also included should be information on sample filter or digestate storage duration limits and storage condition recommendations.

6. Assessment of the MDL (minimum detection limit) for the candidate method should follow the guidance described in 40 CFR Part 136, Appendix B.

7. As required in 40 CFR 53.33(f) and (g) for Pb FEM applications, audit samples must be obtained from the Reference and Equivalent Methods Program and must be analyzed by the FRM method in Part 50 Appendix G or Q to verify the accuracy of the FRM measurements during the comparability tests. Contact the Reference and Equivalent Methods Program at the address given in Section VIII to obtain these audit samples.

8. Documentation for the comparability tests should include complete details for both the FRM and FEM measurements so that analytical results for both methods can be verified, including all calculations.

9. An example general outline and content suggestions for a lead FEM application are provided below. Deviations should be made to the suggested outline as may be appropriate to the specific nature of the candidate method and its testing.

B. Example Format And Content Suggestions For A Typical Lead FEM Application.

1. Title. The title of the application should serve to briefly identify the candidate method and to differentiate the method – and the associated FEM application – from all other, perhaps similar, lead methods. For example: “Application for an FEM Determination of an ICP-AES Method for Determining Ambient Lead Concentrations Using Samples Collected on Glass Fiber Filters (XYZ Laboratory).”

2. Overview. Identify the entity making the application and a contact person or persons for the application, that the application is being submitted to the EPA under 40 CFR Part 53, and that an FEM determination for the method is requested. Give some additional information to categorize the candidate method, such as whether it is a manual or automated method, whether it measures lead in TSP or PM₁₀, its general nature, identification of the associated sampling procedure (for a manual method) if it is one that is commonly recognized (e.g., high-volume sampler), and any other such similar information. Also, indicate where, when, and by whom the method was tested, particularly if a third party was involved in the testing in any way. Any information contained in the application that is claimed to be proprietary or confidential should be clearly marked and identified as such so that EPA will treat it as confidential business information (CBI) as provided in 40 CFR Part 2 (see Section II-I of this Guideline).

3. Method Identification. This section should provide a full, formal name for the candidate method that completely and uniquely identifies it, identifying its laboratory affiliation (or manufacturer for an automated method), and with any acronyms spelled out.

4. Method Synopsis. Describe the candidate method in more detail than in the title, giving its full analytical nature, identify or describe its associated sampling procedure (for manual methods) and sample extraction procedure (if applicable), cite any applicable references for these procedures, describe how the method is calibrated, and include any other information that helps to frame the type or nature of the method.

5. Statement of Method Testing. Provide a statement that the candidate method, as described in the application, was tested as required by the applicable sections of 40 CFR Part 53, Subparts A and C. The statement should indicate that the method was tested to:

- (a) determine its performance parameters, such as the method detection limit, sensitivity, precision, and accuracy - with standards; and,
- (b) determine its performance relative to the performance of the FRM for lead in total suspended particulate matter (TSP), which is described in Appendix G to Part 50 – Reference Method for the Determination of Lead in Suspended Particulate Matter Collected From Ambient Air. Methods for lead in PM₁₀ are tested relative to the performance of the FRM for lead in PM₁₀ set forth in Appendix O to Part 50.

6. Full Method Description. This section should contain a full description of the candidate method. For manual methods, it should include the detailed SOP or other description of all extraction and analytical procedures, as well as the sampling and calibration procedures and any other procedures required by the method. See items 1, 3, 4, and 5 in Subsection A of this section of the Guideline (above). If appropriate, the method description or SOP may be included as an appendix or attachment to the application. Automated methods or other types of candidate methods should be described in detail to fully identify their analytical method or measurement principle, operation, installation, calibration, maintenance, and all other aspects of the method, including an operation/instruction manual, if applicable.

7. Testing of the Candidate Method. Full descriptions of all tests carried out on the candidate method, as required by the applicable requirements of Subparts A and C of Part 53, should be provided, including what tests were conducted, how they were set up and carried out, the site where they were carried out, how samples were collected, calibration and operational details of both the candidate and reference methods, quality assurance procedures, and other pertinent information. See items 2, 6, 7, and 8 in Subsection A of this section of the Guideline (above). Describe any deviations or modifications that may have been necessary to facilitate the testing and the impact (or lack of impact) these deviations had on the validity of the tests and test results.

8. Test Results. Describe how all test results were obtained, and their quantitative values were calculated, including the audit samples (if appropriate). Review the quality control information and show that both candidate method and FRM measurements were in acceptable control. Compile the test results in a form appropriate to the tests required, and show the required comparisons between the FRM and candidate method test results. For each FEM performance requirement, indicate whether the candidate method met the specific requirement. Discuss any anomalies encountered in the tests and their impact (if any) on the test results.

9. Other information. Include, in appendixes or attachments if appropriate, any other pertinent or supporting information not included elsewhere in the application, such as calibration certificates, quality control information, standards certifications, the formal method SOP, sampling procedures, or any other information necessary or helpful to the completeness of the application.

VIII. INFORMATION AND ASSISTANCE AVAILABLE

The following information and types of assistance for applicants are available from EPA's Reference and Equivalent Methods Program. Requests for information not available on the Internet, as well as any suggestions to augment the information in this Guidelines document, may be submitted to:

Director, National Exposure Research Laboratory
Reference and Equivalent Methods Program
Process Modeling Research Branch (MD D205-03)
United States Environmental Protection Agency
Research Triangle Park, North Carolina 27711
E-mail: Vanderpool.Robert@epa.gov

A. Documents Available:

1. 40 CFR Part 53, 2011 revision (availability pending)*[‡]
Ambient Air Monitoring Reference and Equivalent Methods
(<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>)
2. 40 CFR Part 50, including appendixes*
National Primary and Secondary Ambient Air Quality Standards
(<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>)
3. 40 CFR Part 58, Appendix A*
Quality Assurance Requirements for State and Local Air Monitoring Stations (SLAMS)
(<http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>)
4. Spreadsheet template for entering test data for Class II and III field-test data and calculating test results
5. List of Designated Reference and Equivalent Methods*
(<http://www.epa.gov/ttn/amtic/criteria.html>)
6. Guidelines for Applicants (this document)

*This document is available on the Internet at the site given.

[‡]Pending availability of the 2011 version, use the 2010 version and the amendments to 40 CFR Part 53, Subpart B published in the *Federal Register* on August 31, 2011, page 54326
(<http://frwebgate2.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=0m5xqT/0/2/0&WAIAction=retrieve>)

B. Mail Consultation

1. Clarification or interpretation of technical and procedural requirements of 40 CFR Part 53 and possible adaptations for particular method-specific or other special situations.
2. Answers to technical questions pertaining to test procedures or test apparatus.
3. Pre-approval for test sites, test plans, or other proposed test conditions or methods.
4. Audit samples for comparability tests for lead.

C. Personal Consultation

Reference and Equivalent Method Program personnel may be available at Research Triangle Park, NC for personal consultation with potential applicants on an appointment basis.