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with more extensive or profound deviations from the design and function of the reference method may be subject to other tests, full wind-tunnel tests similar to those described in § 53.62, or to special tests adapted or developed individually to accommodate the specific type of measurement or operation of the candidate method.

(4) All designated FEM for $PM_{2.5}$ or $PM_{10-2.5}$ must be manufactured in an ISO 9001-registered facility, as defined in § 53.1 and as set forth in § 53.51.

[71 FR 61271, Oct. 17, 2006]

§ 53.4 Applications for reference or equivalent method determinations.

(a) Applications for FRM or FEM determinations shall be submitted in duplicate to: Director, National Exposure Research Laboratory, Reference and Equivalent Method Program (MD–D205–03), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711 (Commercial delivery address: 4930 Old Page Road, Durham, North Carolina 27703).

(b) Each application shall be signed by an authorized representative of the applicant, shall be marked in accordance with § 53.15 (if applicable), and shall contain the following:

(1) A clear identification of the candidate method, which will distinguish it from all other methods such that the method may be referred to unambiguously. This identification must consist of a unique series of descriptors such as title, identification number, analyte, measurement principle, manufacturer, brand, model, etc., as necessary to distinguish the method from all other methods or method variations, both within and outside the applicant's organization.

(2) A detailed description of the candidate method, including but not limited to the following: The measurement principle, manufacturer, name, model number and other forms of identification, a list of the significant components, schematic diagrams, design drawings, and a detailed description of the apparatus and measurement procedures. Drawings and descriptions pertaining to candidate methods or samplers for $PM_{2.5}$ or $PM_{10-2.5}$ must meet all applicable requirements in reference 1 of appendix A of this subpart, using appropriate graphical, nomenclature, and mathematical conventions such as those specified in references 3 and 4 of appendix A of this subpart.

(3) A copy of a comprehensive operation or instruction manual providing a complete and detailed description of the operational, maintenance, and calibration procedures prescribed for field use of the candidate method and all instruments utilized as part of that method (under § 53.9(a)).

(i) As a minimum this manual shall include:

(A) Description of the method and associated instruments.

(B) Explanation of all indicators, information displays, and controls.

(C) Complete setup and installation instructions, including any additional materials or supplies required.

(D) Details of all initial or startup checks or acceptance tests and any auxiliary equipment required.

(E) Complete operational instructions.

(F) Calibration procedures and descriptions of required calibration equipment and standards.

(G) Instructions for verification of correct or proper operation.

(H) Trouble-shooting guidance and suggested corrective actions for abnormal operation.

(I) Required or recommended routine, periodic, and preventative maintenance and maintenance schedules.

(J) Any calculations required to derive final concentration measurements.

(K) Appropriate references to any applicable appendix of part 50 of this chapter; reference 6 of appendix A of this subpart; and any other pertinent guidelines.

(ii) The manual shall also include adequate warning of potential safety hazards that may result from normal use and/or malfunction of the method and a description of necessary safety precautions. (See § 53.9(b).) However, the previous requirement shall not be interpreted to constitute or imply any warranty of safety of the method by EPA. For samplers and automated methods, the manual shall include a clear description of all procedures pertaining to installation, operation, preventive maintenance, and trouble-shooting and shall also include parts

identification diagrams. The manual may be used to satisfy the requirements of paragraphs (b)(1) and (2) of this section to the extent that it includes information necessary to meet those requirements.

(4) A statement that the candidate method has been tested in accordance with the procedures described in subparts B, C, D, E, and/or F of this part, as applicable.

(5) Descriptions of test facilities and test configurations, test data, records, calculations, and test results as specified in subparts B, C, D, E, and/or F of this part, as applicable. Data must be sufficiently detailed to meet appropriate principles described in part B, sections 3.3.1 (paragraph 1) and 3.5.1 and part C, section 4.6 of reference 2 of appendix A of this subpart; and in paragraphs 1 through 3 of section 4.8 (Records) of reference 5 of appendix A of this subpart. Salient requirements from these references include the following:

(i) The applicant shall maintain and include records of all relevant measuring equipment, including the make, type, and serial number or other identification, and most recent calibration with identification of the measurement standard or standards used and their National Institute of Standards and Technology (NIST) traceability. These records shall demonstrate the measurement capability of each item of measuring equipment used for the application and include a description and justification (if needed) of the measurement setup or configuration in which it was used for the tests. The calibration results shall be recorded and identified in sufficient detail so that the traceability of all measurements can be determined and any measurement could be reproduced under conditions close to the original conditions, if necessary, to resolve any anomalies.

(ii) Test data shall be collected according to the standards of good practice and by qualified personnel. Test anomalies or irregularities shall be documented and explained or justified. The impact and significance of the deviation on test results and conclusions shall be determined. Data collected shall correspond directly to the specified test requirement and be labeled and identified clearly so that results can be verified and evaluated against the test requirement. Calculations or data manipulations must be explained in detail so that they can be verified.

(6) A statement that the method, analyzer, or sampler tested in accordance with this part is representative of the candidate method described in the application.

(c) For candidate automated methods and candidate manual methods for PM_{10}, $PM_{2.5}$, and $PM_{10-2.5}$ the application shall also contain the following:

(1) A detailed description of the quality system that will be utilized, if the candidate method is designated as a reference or equivalent method, to ensure that all analyzers or samplers offered for sale under that designation will have essentially the same performance characteristics as the analyzer(s) or samplers tested in accordance with this part. In addition, the quality system requirements for candidate methods for $PM_{2.5}$ and $PM_{10-2.5}$ must be described in sufficient detail, based on the elements described in section 4 of reference 1 (Quality System Requirements) of appendix A of this subpart. Further clarification is provided in the following sections of reference 2 of appendix A of this subpart: part A (Management Systems), sections 2.2 (Quality System and Description), 2.3 (Personnel Qualification and Training), 2.4 (Procurement of Items and Services), 2.5 (Documents and Records), and 2.7 (Planning); part B (Collection and Evaluation of Environmental Data), sections 3.1 (Planning and Scoping), 3.2 (Design of Data Collection Operations), and 3.5 (Assessment and Verification of Data Usability); and part C (Operation of Environmental Technology), sections 4.1 (Planning), 4.2 (Design of Systems), and 4.4 (Operation of Systems).

(2) A description of the durability characteristics of such analyzers or samplers (see § 53.9(c)). For methods for $PM_{2.5}$ and $PM_{10-2.5}$ the warranty program must ensure that the required specifications (see Table A–1 to this subpart) will be met throughout the warranty period and that the applicant accepts responsibility and liability for ensuring this conformance or for resolving any nonconformities, including

all necessary components of the system, regardless of the original manufacturer. The warranty program must be described in sufficient detail to meet appropriate provisions of the ANSI/ASQC and ISO 9001 standards (references 1 and 2 in appendix A of this subpart) for controlling conformance and resolving nonconformance, particularly sections 4.12, 4.13, and 4.14 of reference 1 in appendix A of this subpart.

(i) Section 4.12 in reference 1 of appendix A of this subpart requires the manufacturer to establish and maintain a system of procedures for identifying and maintaining the identification of inspection and test status throughout all phases of manufacturing to ensure that only instruments that have passed the required inspections and tests are released for sale.

(ii) Section 4.13 in reference 1 of appendix A of this subpart requires documented procedures for control of nonconforming product, including review and acceptable alternatives for disposition; section 4.14 in reference 1 of appendix A of this subpart requires documented procedures for implementing corrective (4.14.2) and preventive (4.14.3) action to eliminate the causes of actual or potential nonconformities. In particular, section 4.14.3 requires that potential causes of nonconformities be eliminated by using information such as service reports and customer complaints to eliminate potential causes of nonconformities.

(d) For candidate reference or equivalent methods for $PM_{2.5}$ and Class II or Class III equivalent methods for $PM_{10-2.5}$, the applicant, if requested by EPA, shall provide to EPA for test purposes one sampler or analyzer that is representative of the sampler or analyzer associated with the candidate method. The sampler or analyzer shall be shipped FOB destination to Director, National Exposure Research Laboratory, Reference and Equivalent Method Program (MD-D205–03), U.S. Environmental Protection Agency, 4930 Old Page Road, Durham, North Carolina 27703, scheduled to arrive concurrent with or within 30 days of the arrival of the other application materials. This analyzer or sampler may be subjected to various tests that EPA determines to be necessary or appropriate under § 53.5(f), and such tests may include special tests not described in this part. If the instrument submitted under this paragraph malfunctions, becomes inoperative, or fails to perform as represented in the application before the necessary EPA testing is completed, the applicant shall be afforded an opportunity to repair or replace the device at no cost to EPA. Upon completion of EPA testing, the analyzer or sampler submitted under this paragraph shall be repacked by EPA for return shipment to the applicant, using the same packing materials used for shipping the instrument to EPA unless alternative packing is provided by the applicant. Arrangements for, and the cost of, return shipment shall be the responsibility of the applicant. The EPA does not warrant or assume any liability for the condition of the analyzer or sampler upon return to the applicant.

[71 FR 61271, Oct. 17, 2006]

§ 53.5 Processing of applications.

After receiving an application for a FRM or FEM determination, the Administrator will, within 120 calendar days after receipt of the application, take one or more of the following actions:

(a) Send notice to the applicant, in accordance with § 53.8, that the candidate method has been determined to be a reference or equivalent method.

(b) Send notice to the applicant that the application has been rejected, including a statement of reasons for rejection.

(c) Send notice to the applicant that additional information must be submitted before a determination can be made and specify the additional information that is needed (in such cases, the 120-day period shall commence upon receipt of the additional information).

(d) Send notice to the applicant that additional test data must be submitted and specify what tests are necessary and how the tests shall be interpreted (in such cases, the 120-day period shall commence upon receipt of the additional test data).