

§ 53.51

CFR part 50, appendix L, as well as additional requirements specified in this subpart E. These latter test procedures shall be used to test the performance of candidate samplers against the performance specifications and requirements specified in each procedure and summarized in table E-1 of this subpart.

(d) Test procedures prescribed in § 53.59 do not apply to candidate reference method samplers. These procedures apply primarily to candidate Class I equivalent method samplers for PM_{2.5} which have a sample air flow path configuration upstream of the sample filter that is modified with respect to that specified for the reference method sampler, as set forth in 40 CFR part 50, appendix L, figures L-1 to L-29, such as might be necessary to provide for sequential sample capability. The additional tests determine the adequacy of aerosol transport through any altered components or supplemental devices that are used in a candidate sampler upstream of the sample filter. In addition to the other test procedures in this subpart, these test procedures shall be used to further test the performance of such an equivalent method sampler against the performance specifications given in the procedure and summarized in table E-1 of this subpart.

(e) A 10-day operational field test of measurement precision is required under § 53.58 for both candidate reference and equivalent method samplers. This test requires collocated operation of three candidate method samplers at a field test site. For candidate equivalent method samplers, this test may be combined and carried out concurrently with the test for comparability to the reference method specified under § 53.34, which requires collocated operation of three reference method samplers and three candidate equivalent method samplers.

(f) All tests and collection of test data shall be performed in accordance with the requirements of reference 1, section 4.10.5 (ISO 9001) and reference 2, part B, section 3.3.1, paragraphs 1 and 2 and part C, section 4.6 (ANSI/ASQC E4) in appendix A of this subpart. All test data and other documentation obtained specifically from or pertinent to these

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tests shall be identified, dated, signed by the analyst performing the test, and submitted to EPA in accordance with subpart A of this part.

§ 53.51 Demonstration of compliance with design specifications and manufacturing and test requirements.

(a) *Overview.* (1) The subsequent paragraphs of this section specify certain documentation that must be submitted and tests that are required to demonstrate that samplers associated with a designated reference or equivalent method for PM_{2.5} are properly manufactured to meet all applicable design and performance specifications and have been properly tested according to all applicable test requirements for such designation. Documentation is required to show that instruments and components of a PM_{2.5} sampler are manufactured in an ISO 9001-registered facility under a quality system that meets ISO-9001 requirements for manufacturing quality control and testing.

(2) In addition, specific tests are required to verify that two critical features of reference method samplers impactor jet diameter and the surface finish of surfaces specified to be anodized meet the specifications of 40 CFR part 50, appendix L. A checklist is required to provide certification by an ISO-certified auditor that all performance and other required tests have been properly and appropriately conducted, based on a reasonable and appropriate sample of the actual operations or their documented records. Following designation of the method, another checklist is required, initially and annually, to provide an ISO-certified auditor's certification that the sampler manufacturing process is being implemented under an adequate and appropriate quality system.

(3) For the purposes of this section, the definitions of ISO 9001-registered facility and ISO-certified auditor are found in § 53.1. An exception to the reliance by EPA on ISO-certified auditors is the requirement for the submission of the operation or instruction manual associated with the candidate method to EPA as part of the application. This manual is required under § 53.4(b)(3). EPA has determined that acceptable technical judgment for review of this

manual may not be assured by ISO-certified auditors, and approval of this manual will therefore be performed by EPA.

(b) *ISO registration of manufacturing facility.* (1) The applicant must submit documentation verifying that the samplers identified and sold as part of a designated PM_{2.5} reference or equivalent method will be manufactured in an ISO 9001-registered facility and that the manufacturing facility is maintained in compliance with all applicable ISO 9001 requirements (reference 1 in appendix A of this subpart). The documentation shall indicate the date of the original ISO 9001 registration for the facility and shall include a copy of the most recent certification of continued ISO 9001 facility registration. If the manufacturer does not wish to initiate or complete ISO 9001 registration for the manufacturing facility, documentation must be included in the application to EPA describing an alternative method to demonstrate that the facility meets the same general requirements as required for registration to ISO-9001. In this case, the applicant must provide documentation in the application to demonstrate, by required ISO-certified auditor's inspections, that a quality system is in place which is adequate to document and monitor that the sampler system components and final assembled samplers all conform to the design, performance and other requirements specified in this part and in 40 CFR part 50, appendix L.

(2) Phase-in period. For a period of 1 year following the effective date of this subpart, a candidate reference or equivalent method for PM_{2.5} that utilizes a sampler manufactured in a facility that is not ISO 9001-registered or otherwise approved by EPA under paragraph (b)(1) of this section may be conditionally designated as a reference or equivalent method under this part. Such conditional designation will be considered on the basis of evidence submitted in association with the candidate method application showing that appropriate efforts are currently underway to seek ISO 9001 registration or alternative approval of the facility's quality system under paragraph (b)(1) of this section within the next 12 months. Such conditional designation

shall expire 1 year after the date of the FEDERAL REGISTER notice of the conditional designation unless documentation verifying successful ISO 9001 registration for the facility or other EPA-acceptable quality system review and approval process of the production facility that will manufacture the samplers is submitted at least 30 days prior to the expiration date.

(c) *Sampler manufacturing quality control.* The manufacturer must ensure that all components used in the manufacture of PM_{2.5} samplers to be sold as part of a reference or equivalent method and that are specified by design in 40 CFR part 50, appendix L, are fabricated or manufactured exactly as specified. If the manufacturer's quality records show that its quality control (QC) and quality assurance (QA) system of standard process control inspections (of a set number and frequency of testing that is less than 100 percent) complies with the applicable QA provisions of section 4 of reference 4 in appendix A of this subpart and prevents nonconformances, 100 percent testing shall not be required until that conclusion is disproved by customer return or other independent manufacturer or customer test records. If problems are uncovered, inspection to verify conformance to the drawings, specifications, and tolerances shall be performed. Refer also to paragraph (e) of this section—final assembly and inspection requirements.

(d) *Specific tests and supporting documentation required to verify conformance to critical component specifications—(1) Verification of PM_{2.5} impactor jet diameter.* The diameter of the jet of each impactor manufactured for a PM_{2.5} sampler under the impactor design specifications set forth in 40 CFR part 50, appendix L, shall be verified against the tolerance specified on the drawing, using standard, NIST-traceable ZZ go/no go plug gages. This test shall be a final check of the jet diameter following all fabrication operations, and a record shall be kept of this final check.

The manufacturer shall submit evidence that this procedure is incorporated into the manufacturing procedure, that the test is or will be routinely implemented, and that an appropriate procedure is in place for the disposition of units that fail this tolerance test.

(2) *Verification of surface finish.* The anodization process used to treat surfaces specified to be anodized shall be verified by testing treated specimen surfaces for weight and corrosion resistance to ensure that the coating obtained conforms to the coating specification. The specimen surfaces shall be finished in accordance with military standard specification 8625F, Type II, Class I (reference 4 in appendix A of this subpart) in the same way the sampler surfaces are finished, and tested, prior to sealing, as specified in section 4.5.2 of reference 4 in appendix A of this subpart.

(e) *Final assembly and inspection requirements.* 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.

(f) *Manufacturer's audit checklists.* Manufacturers shall require an ISO-certified auditor to sign and date a statement indicating that the auditor is aware of the appropriate manufacturing specifications contained in 40 CFR part 50, appendix L, and the test or verification requirements in this subpart. Manufacturers shall also require an ISO-certified auditor to complete the checklists, shown in figures E-1 and E-2 of this subpart, which describe the manufacturer's ability to meet the requirements of the standard for both designation testing and product manufacture.

(1) *Designation testing checklist.* The completed statement and checklist as shown in figure E-1 of this subpart shall be submitted with the application for reference or equivalent method determination.

(2) *Product manufacturing checklist.* Manufacturers shall require an ISO-certified auditor to complete a Product Manufacturing Checklist (figure E-2 of this subpart), which evaluates the manufacturer on its ability to meet the requirements of the standard in maintaining quality control in the production of reference or equivalent devices. The initial completed checklist shall be submitted with the application for reference or equivalent method determination. Also, this checklist (figure E-2 of this subpart) must be completed and submitted annually to retain a reference or equivalent method designation for a PM_{2.5} method.

(3) *Phase-in period.* If the conditions of paragraph (b)(2) of this section apply, a candidate reference or equivalent method for PM_{2.5} may be conditionally designated as a reference or equivalent method under this part 53 without the submission of the checklists described in paragraphs (f)(1) and (f)(2) of this section. Such conditional designation shall expire 1 year after the date of the FEDERAL REGISTER notice of the conditional designation unless the checklists are submitted at least 30 days prior to the expiration date.

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§ 53.52 Leak check test.

(a) *Overview.* In section 7.4.6 of 40 CFR part 50, appendix L, the sampler is required to include the facility, including components, instruments, operator controls, a written procedure, and other capabilities as necessary, to allow the operator to carry out a leak test of the sampler at a field monitoring site without additional equipment. This test procedure is intended to test the adequacy and effectiveness of the sampler's leak check facility. Because of the variety of potential sampler configurations and leak check procedures possible, some adaptation of this procedure may be necessary to accommodate the specific sampler