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summarized in table E–1 of this subpart.

(e) Test procedures prescribed in § 53.59 do not apply to candidate reference method samplers. These procedures apply primarily to candidate Class I or Class II equivalent method samplers for $PM_{2.5}$ or $PM_{10-2.5}$ that have a sample air flow path configuration upstream of the sample filter that is modified from that specified for the FRM sampler, as set forth in 40 CFR part 50, appendix L, Figures L–1 to L–29 or 40 CFR part 50 appendix O, Figure O–1, if applicable, 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 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.

(f) A 10-day operational field test of measurement precision is required under § 53.58 for both FRM and Class I FEM samplers for $PM_{2.5}$. This test requires collocated operation of three candidate method samplers at a field test site. For candidate FEM samplers, this test may be combined and carried out concurrently with the test for comparability to the FRM specified under § 53.34, which requires collocated operation of three FRM samplers and three candidate FEM samplers.

(g) 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 6) and Part C, (section 7) in appendix A of this subpart. All test data and other documentation obtained specifically from or pertinent to these tests shall be identified, dated, signed by the analyst performing the test, and submitted to EPA in accordance with subpart A of this part.

[71 FR 61289, Oct. 17, 2006]

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

(a) *Overview.* (1) Paragraphs (a) through (f) of this section specify certain documentation that must be submitted and tests that are required to demonstrate that samplers associated with a designated FRM or FEM for $PM_{2.5}$ or $PM_{10-2.5}$ 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 $PM_{2.5}$ or $PM_{10-2.5}$ 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 by paragraph (d) of this section to verify that critical features of FRM samplers—the particle size separator and the surface finish of surfaces specified to be anodized—meet the specifications of 40 CFR part 50, appendix L or appendix O, as applicable. 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 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). The 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*. The applicant must submit documentation verifying that the samplers identified and sold as part of a designated $PM_{2.5}$ or $PM_{10-2.5}$ FRM or FEM 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.

(c) *Sampler manufacturing quality control*. The manufacturer must ensure that all components used in the manufacture of $PM_{2.5}$ or $PM_{10-2.5}$ samplers to be sold as part of a FRM or FEM and that are specified by design in 40 CFR part 50, appendix L or O (as applicable), 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 $PM_{2.5}$ (WINS) impactor jet diameter*. For samplers utilizing the WINS impactor particle size separator specified in paragraphs 7.3.4.1, 7.3.4.2, and 7.3.4.3 of appendix L to part 50 of this chapter, the diameter of the jet of each impactor manufactured for a $PM_{2.5}$ or $PM_{10-2.5}$ 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) *VSCC separator*. For samplers utilizing the BGI VSCC™ Very Sharp Cut Cyclone particle size separator specified in paragraph 7.3.4.4 of appendix L to part 50 of this chapter, the VSCC manufacturer shall identify the critical dimensions and manufacturing tolerances for the device, develop appropriate test procedures to verify that the critical dimensions and tolerances are maintained during the manufacturing process, and carry out those procedures on each VSCC manufactured to verify conformance of the manufactured products. The manufacturer shall also maintain records of these tests and their results and 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.

(3) *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 or O (as applicable), 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 FRM or FEM 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 FRM or FEM devices. The completed checklist shall be submitted with the application for FRM or FEM determination.

[71 FR 61290, Oct. 17, 2006]

§ 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 under test. The test conditions and performance specifications associated with this test are summarized in table E–1 of this subpart. The candidate test sampler must meet all test parameters and test specifications to successfully pass this test.

(b) *Technical definitions.* (1) External leakage includes the total flow rate of external ambient air which enters the sampler other than through the sampler inlet and which passes through any one or more of the impactor, filter, or flow rate measurement components.

(2) Internal leakage is the total sample air flow rate that passes through the filter holder assembly without passing through the sample filter.

(c) *Required test equipment.* (1) Flow rate measurement device, range 70 mL/min to 130 mL/min, 2 percent certified accuracy, NIST-traceable.

(2) Flow rate measurement adaptor (40 CFR part 50, appendix L, figure L-30) or equivalent adaptor to facilitate measurement of sampler flow rate at the top of the downtube.

(3) Impermeable membrane or disk, 47 mm nominal diameter.

(4) Means, such as a micro-valve, of providing a simulated leak flow rate through the sampler of approximately 80 mL/min under the conditions specified for the leak check in the sampler's leak check procedure.