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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.

(5) Teflon sample filter, as specified in section 6 of 40 CFR part 50, appendix L.

(d) *Calibration of test measurement instruments.* Submit documentation showing evidence of appropriately recent calibration, certification of calibration accuracy, and NIST-traceability (if required) of all measurement instruments used in the tests. The accuracy of flow rate meters shall be verified at the highest and lowest pressures and temperatures used in the tests and shall be checked at zero and one or more non-zero flow rates within 7 days of use for this test.

(e) *Test setup.* (1) The test sampler shall be set up for testing as described in the sampler's operation or instruction manual referred to in §53.4(b)(3). The sampler shall be installed upright and set up in its normal configuration for collecting PM samples, except that the sample air inlet shall be removed and the flow rate measurement adaptor shall be installed on the sampler's downtube.

(2) The flow rate control device shall be set up to provide a constant, controlled flow rate of 80 mL/min into the sampler downtube under the conditions specified for the leak check in the sampler's leak check procedure.

(3) The flow rate measurement device shall be set up to measure the controlled flow rate of 80 mL/min into the sampler downtube under the conditions specified for the leak check in the sampler's leak check procedure.

(f) *Procedure.* (1) Install the impermeable membrane in a filter cassette and install the cassette into the sampler. Carry out the internal leak check procedure as described in the sampler's operation/instruction manual and verify that the leak check acceptance criterion specified in table E–1 of this subpart is met.

(2) Replace the impermeable membrane with a Teflon filter and install the cassette in the sampler. Remove the inlet from the sampler and install the flow measurement adaptor on the sampler's downtube. Close the valve of the adaptor to seal the flow system. Conduct the external leak check procedure as described in the sampler's operation/instruction manual and verify that the leak check acceptance criteria specified in table E–1 of this subpart are met.

(3) Arrange the flow control device, flow rate measurement device, and other apparatus as necessary to provide a simulated leak flow rate of 80 mL/min into the test sampler through the downtube during the specified external leak check procedure. Carry out the external leak check procedure as described in the sampler's operation/instruction manual but with the simulated leak of 80 mL/min.

(g) *Test results.* The requirements for successful passage of this test are:

(1) That the leak check procedure indicates no significant external or internal leaks in the test sampler when no simulated leaks are introduced.

(2) That the leak check procedure properly identifies the occurrence of the simulated external leak of 80 mL/min.

[62 FR 38799, July 18, 1997, as amended at 71 FR 61291, Oct. 17, 2006]

§ 53.53 Test for flow rate accuracy, regulation, measurement accuracy, and cut-off.

(a) *Overview.* This test procedure is designed to evaluate a candidate sampler's flow rate accuracy with respect to the design flow rate, flow rate regulation, flow rate measurement accuracy, coefficient of variability measurement accuracy, and the flow rate