

40 C.F.R. § 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.

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