

range of 400–500 ppm sulfur for 500 ppm sulfur diesel fuel. Therefore, a minimum of 20 total tests would be required for sufficient demonstration of accuracy for a given sulfur test method at a given laboratory facility. Finally, any known interferences for a given test method would have to be mitigated.

These requirements are not intended to be overly burdensome. Indeed, we believe these requirements are equivalent to what a laboratory would do during the normal start up procedure for a given test method. In addition, we believe this approach would allow regulated entities to know that they are measuring diesel fuel sulfur levels accurately and within reasonable site reproducibility limits. Nevertheless, we request comment on this performance criteria approach and the specific precision and accuracy criteria we are proposing.

ii. What Information Would Have To Be Reported to the Agency?

For test methods that have already been approved by a voluntary consensus standards body³³¹ (VCSB), such as ASTM or the International Standards Organization (ISO), each laboratory facility would be required to report to the Agency the precision and accuracy results as described above for each method for which it is seeking approval. Such submissions to EPA, as described elsewhere, would be subject to the Agency's review for 90 days, and the method would be considered approved in the absence of EPA comment. Laboratory facilities would be required to retain the fuel samples used for precision and accuracy demonstration for 30 days. We seek comment on an alternative number of days for which such fuel samples should be retained.

For test methods that have not been approved by a VCSB, full test method documentation, including a description of the technology/instrumentation that makes the method functional, as well as subsequent EPA approval of the method would also be required. These submissions would also be subject to the Agency's review for 90 days, and the method would be considered approved in the absence of EPA comment. Submission of VCSB methods would not be required since they are available in the public domain. In addition, industry and the Agency have likely had substantial experience with such methods. The approval of non-VCSB methods would be valid for five years.

After this time period, the approval would be rescinded unless the method had been adopted by a consensus body. If, a consensus body does not ultimately approve the method then the method could no longer be used as an approved method.

As described above, federal government and EPA policy is to use standards developed by voluntary consensus bodies when available. The purpose of the NTTAA, at least in part, is to foster consistency in regulatory requirements, to take advantage of the collective industry wisdom and widespread technical evaluation required before a test method is approved by a consensus body, and to take advantage of the ongoing oversight and evaluation of a test method by the consensus body that results from wide-spread use of an approved method *e.g.*, the ongoing round-robin type analysis and typical annual updating of the method by the consensus body. These goals are not met where the Agency allows use of a non-consensus body test method in perpetuity. Moreover, it is not possible to realize many of the advantages that result from consensus status where a test method is used by only one or a few companies. It will not have the practical scrutiny that comes from ongoing wide-spread use, or the independent scrutiny of the consensus body and periodic updating. In addition, EPA does not have the resources to conduct the degree of initial scrutiny or ongoing scrutiny that are practiced by consensus bodies. Nevertheless, EPA believes it is appropriate to allow limited use of a proprietary test method for a limited time, even though the significant advantages of consensus test methods are absent, because EPA can evaluate the initial quality of a method and a company may have invested significant resources in developing a method. However, if after a reasonable time a test method fails to gain consensus body approval, EPA believes approval of the method should be withdrawn because of the absence of ongoing consensus oversight. Accordingly, we propose that a non-VCSB method will cease to be qualified five years from the date of its original approval by EPA in the absence of VCSB approval.

To assist the Agency in determining the performance of a given sulfur test method, non-VCSB methods, in particular, we propose to reserve the right to send samples of commercially available fuel to laboratories for evaluation. Such samples would be intended for situations in which the Agency had concerns regarding a test method and, in particular, its ability to measure the sulfur content of a random

commercially available diesel fuel. Laboratory facilities would be required to report their results from three tests of this material to the Agency.

iii. What Quality Control Provisions Would Be Required?

We are proposing to require ongoing Quality Control (QC) procedures for sulfur measurement instrumentation. These are procedures used by laboratory facilities to ensure that the test methods they have qualified and the instruments on which the methods are run are yielding results with appropriate accuracy and precision, *e.g.*, that the results from a particular instrument do not "drift" over time to yield unacceptable values. It is our understanding that most laboratories already employ QC procedures, and that these are commonly viewed as important good laboratory practices. Under the performance-based approach, laboratories would be required, at a minimum, to abide by the following QC procedures for each instrument used to certify batches of diesel fuel under these regulations:

(1) Follow the mandatory provisions of ASTM D 6299–02, Standard Practice for Applying Statistical Quality Assurance Techniques to Evaluate Analytical Measurement System Performance. Laboratories would be required to construct control charts from the mandatory QC sample testing prescribed in paragraph 7.1, following the guidelines under A 1.5.1 for individual observation charts and A 1.5.2 for moving range charts.

(2) Follow ASTM D6299–02 paragraph 7.3.1 (check standards) using a standard reference material. Check standard testing would be required to occur at least monthly and should take place following any major change to the laboratory equipment or test procedure. Any deviation from the accepted reference value of the check standard greater than 1.44 ppm for diesel fuel subject to the 15 ppm sulfur standard and 19.36 ppm for diesel fuel subject to the 500 ppm sulfur standard³³² would have to be investigated.

(3) Upon discovery of any QC testing violation of A 1.5.2.1 or A 1.5.3.2 or check standard deviation greater than 1.44 ppm and 19.36 ppm for 15 ppm sulfur diesel and 500 ppm sulfur diesel, respectively, as provided in item 2 above, any measurement made while the system was out of control would be required to be tagged as suspect and an

³³¹ These are standard-setting organizations, like ASTM, and ISO that have broad representation of all interested stakeholders and make decisions by consensus.

³³² 1.44 ppm is equal to two times the proposed precision of 0.72 ppm for 15 ppm diesel and 19.36 is equal to two times the proposed precision of 9.68 ppm for 500 ppm diesel.