Summary of Comments and Responses on

Restructuring of the Stationary

Source Audit Program

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1.0 SUMMARY

On June 16, 2009, the U.S. Environmental Protection Agency (EPA) proposed Restructuring of the Stationary Source Audit Program (SSAP). This action proposed amendments to the General Provisions to allow accredited providers to supply stationary sources with audit samples from the accredited providers instead of from EPA as is the current practice. This document outlines the criteria an accredited provider program must meet for the samples to be acceptable.

Requirements pertaining to the audit samples have all been moved to the General Provisions and have been removed from the test methods because the current language in the test methods regarding audit samples is inconsistent from method to method. Therefore deleting all references to audit samples in the test methods eliminates any possible confusion and inconsistencies. Under this proposed amendment, the requirement to use an audit sample during a compliance test will apply to all test methods for which commercially available audits exists.

2.0 LIST OF COMMENTERS

Item Number in OAR-2008-0531	Commenter and Affiliation
0007	Arlene Bell Delta Air Quality Services, Inc.
0008	Filipa Rio Alliance of Automobile Manufactures
0009	Jerry Parr The NELAC Institute
0010	Michael Klein New Jersey DEP
0011	Scoot S. Slocum Weston Solutions, Inc.
0012	Maria Friedman The NELAC Institute and TestAmerica
0013	Eileen C. Moran Regional Air Pollution Control Agency
0014	John Piotrowski Packaging Corporation of America
0015	Melvin E. Keener, Ph.D. Coalition of Responsible Waste Incineration
0016	Robert D. Bessette Council of Industrial Boiler Owners
0017	Alabama Department of Environmental Management
0018	Brian Mader 3M Company

2.0 LIST OF COMMENTERS

Item Number in OAR-2008-0531	Commenter and Affiliation
0019	Jim Griffin American Chemistry Council
0020	Leslie Sue Ritts The National Environmental Development Association's Clean Air Project
0021	Stationary Source Expert Committee The NELAC Institute
0022	Jay Hudson, PE Santee Cooper
0023	Russell A. Woznaik Dow Chemical Company
0024	Lauren Friedman Hunton & Williams, LLP
0026	Ashok K. Jain National Council for Air and Stream Improvement, Inc.
0027	Michael A. Palazzolo Alcoa
0028	Paul R. Jann Dupont Engineering

3.0 PUBLIC COMMENTS AND RESPONSES

Supportive Comments

1. Comment: This is a good change since a lot of testing that should have had audits now will. Audits can save facilities and testers money by identifying problems with their testing program. By identifying the problems this may salvage a poor test that is sufficient enough to show compliance after all the rest of the test information is reviewed. In time this will mean better testing and this should work to lower the cost for all involved. (0021)

Response: No response is necessary.

2. Comment: The commenter strongly supports EPA's decision to privatize the stationary source audit program (SSAP). The commenter currently witnesses 100 percent of the stationary source tests in their jurisdiction and requests numerous audits samples from EPA annually. In their experience, audits are crucial to verify the accuracy of the source test results. (0013)

Response: No response is necessary.

EPA should rely on accreditation program instead of audit program

3. Comment: The audit program is not needed because there are accreditation programs that certify laboratories and assess their analytical proficiency and accuracy. The proposed audit program duplicates the existing accreditation process. (0015, 0016, 0018, 0019, 0023, 0028)

Response: An accreditation program serves a different purpose than an audit program. An accreditation program looks to see if the laboratory has the capabilities to conduct the analysis in question. The audit program is an event driven program that looks to see at a particular time that the combination of equipment and analyzer is able to analyze the sample within an acceptable range. Analyzing the audit samples at the same time as the field samples using the same equipment and analyst give the compliance authority and the regulated community more confidence in the test results.

4. Comment: EPA should exempt NELAC accredited laboratories from the requirement to analyze audit samples under the proposed program. (0027)

Response: See response to Comment 3.

5. Comment: The audit program should be applied to the testing bodies or laboratories as part of an accreditation program instead of a compliance program and therefore have no bearing on the compliance status of the source. (0008, 0014, 0022)

Response: See response to Comment 3

6. Comment: EPA should conduct a proficiency testing program instead of an audit program in which source testing companies and analytical laboratories periodically analyze a

sample. The commenters defined periodic as every year or every 2-3 years. One commenter suggested EPA maintain a list of testing consultants that passed the proficiency testing sample. (0008, 0018)

Response: A proficiency testing program serves a different purpose than an audit program. A proficiency testing program looks to see if the laboratory has the capabilities to conduct the analysis in question on a periodic basis. The audit program is an event driven program that looks to see at a particular time that the combination of equipment and analyzer is able to analyze the sample within an acceptable range. Analyzing the audit samples at the same time as the field samples using the same equipment and analyst gives the regulator and the regulated community more confidence in the test results.

Alternatives to Restructuring the Audit Program

7. Comment: EPA should maintain its current oversight responsibility for reference method development, sample audit and proficiency programs rather than relinquish it to third parties to ensure consistency and quality control. (0008)

Response: This rule does not in anyway change EPA's responsibilities with respect to reference method development. This rule only concerns the SSAP. EPA believes that the criteria outlined in the rule concerning what is required for an audit sample, an accredited audit sample provider (AASP), and an accredited audit sample provider accreditor (AASPA) ensures consistency and quality control.

8. Comment: EPA should keep handling the audit program. Many test consultants are unhappy about the proposed rule because it adds another step for the test consultants and their customers. The current program already contains sufficient Quality Assurance/Quality Control (QA/QC) parameters relative to what is proposed in the rule. (0018, 0021)

Response: It was not EPA's intent when we proposed this rule to imply that the current audit program did not have sufficient QA/QC parameters but to allow the private sector to supply the audit samples. Since the audit samples are used to help validate the compliance results, EPA believes it should be the facilities' responsibility to obtain the audit samples.

9. Comment: EPA needs to have oversight/authority over the audit sample providers instead of turning it over to a voluntary consensus organization. One commenter stated that "EPA should retain responsibility for selecting audit sample providers, approving audit samples and establishing sample "true values" if the results of audit sample analyses are to remain a legally enforceable component of compliance testing and source compliance with Federal and State regulations." (0022, 0027)

Response: EPA retains oversight authority over all parties who have information that may be required by EPA to fully assess the proper implementation of the Clean Air Act (CAA). Section 114 of the Act gives EPA the authority to require the production of information, test results and answers to questions EPA may ask. EPA does not believe that it is necessary to directly approve or provide audit samples in order to ensure integrity in this program.

We do not believe it is necessary to develop a program to certify audit providers when there are already Voluntary Consensus Standard Bodies (VCSBs) in existence that have the capabilities to develop such a program with the input from a wide variety of stakeholders.

10. Comments: We recommend that if EPA is going to rely on private suppliers of audit samples, it should continue its current program and consider developing a procedure for charging user fees. (0026)

Response: The reason for the restructuring is not money. As we stated in the preamble, previously there were no private entities who supplied stationary source audit samples so EPA provided them but now there are private sources for these types of samples. Also EPA is not legally allowed to charge for the samples. If EPA were to charge a fee, it would be a violation of the Miscellaneous Receipts statue, 331 U.S.C. §3302(b) in addition to being an unlawful augmentation of EPA's Congressional appropriation.

11. Comment: EPA should certify audit providers who provide the audit samples at cost to stationary source testing companies. (0020)

Response: EPA does not believe it makes sense to develop a program to certify audit providers when there are already VCSBs in existence who have the capabilities to develop such a program with the input from a wide variety of stakeholders. Also, EPA is not legally allowed to charge for the samples. It would be a violation of the Miscellaneous Receipts statue, 331 U.S.C. §3302(b) in addition to being an unlawful augmentation of EPA's Congressional appropriation.

12. Comment: If EPA is unable to provide the audit samples on a gratis basis then EPA should provide the audit samples at a reasonable fee as part of existing protocol approval procedures. (0020)

Response: See response to Comment 10.

13. Comment: EPA should identify by rule the kind of samples it believes are necessary. If those samples could be produced cost-effectively by private providers then a simple requirement that sources purchase them should be sufficient to stimulate the market instead of restructuring the audit program. (0024)

Response: EPA is basically doing that in the rule except adding some criteria that the private providers must meet as a means to ensure consistency and quality in the audit samples and clarifying some inconsistencies. The use of the term "restructuring" seems to be confusing some people and giving them the idea that we are making major conceptual changes to the audit program which we are not doing. The fundamental audit requirements are the same as they have been for many years, the only real change is that EPA will not be providing the samples.

14. Comment: If EPA's reason for the rule is to address inconsistencies in the current general provisions concerning the use or availability of audit samples then EPA could address these aspects in the general provisions without a complete restructuring of the program. (0024)

Response: See response to Comment 13.

15. Comment: EPA should revise its proposal to remove references to specifications and organizations that do not currently exist and simply allow sources to obtain audit samples from private providers identified by EPA as providing acceptable samples. EPA can propose requirements to obtain samples from accredited providers in the future if and when the details of such an accreditation program are available to include in a rulemaking proposal. (0024)

Response: In accordance with 5 CFR 2635.702(c)(1) and (2), EPA cannot endorse any products, services or enterprises except: in furtherance of statutory authority to promote products, services or enterprises, or as a result of documentation of compliance with Agency requirements or standards or the result of recognition for achievement given under an agency program of recognition for accomplishment in support of the Agency's mission. This is not one of those cases.

16. Comment: EPA should expand and strengthen the current program in ways that would result in properly trained stack testing consultants and laboratory personnel instead of restructuring the audit program. (0008, 0026)

Response: The purpose of the audit program is to check the ability of a tester/analyst in combinations with the equipment to measure/analyze the emissions from a compliance test, not to train testers and analyst. It is the responsibility of the testing firm and laboratory to make sure their employees are properly trained.

Test data bias with respect to the audit program

17. Comment: The commenter noted that by definition a performance audit is intended to provide a measure of test data bias. The commenter stated that this program is presumably intended as an audit of emissions sampling and analysis that would include the sampling technique, sample handling, sample preparation, and sample analysis accounting for the measurement biases relative to all steps of the process, however this is not clear in the proposed rule. Please clarify the intent of the performance audit. (0015)

Response: Most of the current audit samples only evaluate the analysis portion of the method. We believe that in the future restructured program more audits will assess the effect of sampling and handling because we defined blind audit sample as follows: "A blind audit sample is a sample whose value is known only to the sample provider and is not revealed to the tested facility until after they report the measured value of the audit sample. For pollutants that exist in the gas phase at ambient temperature, the audit sample shall consist of an appropriate concentration of the pollutant in air or nitrogen that will be introduced into the sampling system of the test method at or near the same entry point as a sample from the emission source."

Terms need defining or clarifying

18. Comment: Rule needs to define "commercially available". (0027)

Response: EPA agrees that "commercially available" needs to be defined. The final rule was revised to state that an audit is commercially available when there are two or more sources for obtaining the audit. EPA is requiring two or more sources for audit samples to better ensure a competitive environment for setting audit sample prices and to minimize the potential for having a single audit sample provider from controlling the cost of audit samples.

19. Comment: Rule needs to define "true value". The commenter assumes the term "true value" includes an expected value and some acceptable range of variability around the expected value but is concerned that multiple entities may have different interpretations of the term. (0027)

Response: "True value" is the spiked/expected value of the audit. The AASP must provide a separate value for the acceptance range.

20. Comment: Rule needs to clarify what types of "compliance test" are required to use audits. It is not clear if EPA intends to limit it to EPA tests for EPA purposes or if a local regulator could expand the audit requirements to similar test methods and programs. (0007)

Response: The audits are required for compliance tests that use the EPA test methods found in 40 CFR Parts 51, 60, 61, and 63 unless otherwise noted in the rule. An audit sample is required if a State or local compliance authority cites an EPA test method from Parts 51, 60, 61, or 63 to determine compliance with a rule approved into the State Implementation Plan or for enforcement purposes. An audit sample would be optional if the test is primarily for informational purposes and not required by a compliance authority.

21. Comment: The term "performance audit" (PA) should be revised to include the field collection of audit samples. It should read "The PAs consist of blind audit samples supplied by an AASP and collected and analyzed when intended for collection or simply analyzed when not intended for collection, during the performance test in order to provide a measure of test data bias." (0021)

Response: EPA's intent was to include sampling and analysis in the definition of performance audit. The definition in the final rule was revised to state that if gaseous audits are available then they must be collected by the field sampling system during the compliance test just as the compliance samples are collected.

Audit sample failure and non-compliance

22. Comment: The audit samples should not be use as evidence of non-compliance. The audit sample results should be used as a tool to assess the usability of the results for compliance purposes not the sole reason for finding a facility in non-compliance when the emission test may demonstrate compliance. (0014, 0015, 0020, 0022, 0023, 0026, 0027)

Response: The audit sample results can and should be used to assess the usability of the stack test results for compliance purposes, but those audit sample results can and should, as appropriate, also be used to establish non-compliance. Sources may present whatever credible

evidence they have to compliance officials indicating whether or not the audit sample results have a significant bearing on the compliance test results.

23. Comment: It is inappropriate to place compliance responsibility of a failed audit on the owner or operator of a source when a failure could be caused by a variety of factors, such as improper preparation or handling of the audit sample. (0008, 0018, 0019)

Response: While in some circumstances, the evidence would suggest that the owner or operator of a source is not the proper party to identify as the defendant in an enforcement action (such as cases of improper sample dilution), there are other circumstances where this would be entirely appropriate (such as cases where both the audit sample and stack sample results indicate non-compliance with regulatory standards). Therefore, EPA must allow for that possibility among the options. All parties who may have contributed to violations should be held responsible.

24. Comment: EPA should provide clear guidance in the final rule about the interpretation and resolution of audit sample results. The commenter gave the example of a test program for which the audit sample is slightly outside the acceptance criteria and the emission test results are twenty-five percent of the compliance limit. Clearly, outlying audit sample results require case-by-case determination reflecting the input of the source, the source testing firm, the laboratory, and the regulatory agency. (0011)

Response: EPA will make case-by-case determinations in every case before deciding to assess liability against any party or parties.

25. Comment: The final rule should provide a means to appeal or question a retest or compliance action as the result of a failed audit. EPA should provide oversight authority to referee such situations while one commenter suggested a procedure to require the audit sample be reanalyzed by the AASP. (0016, 0026, 0028)

Response: Audit samples are not the only criterion use to evaluate the quality of the test data; therefore, we do not expect disputes to be common. EPA believes that disputes involving failed audits can be negotiated by the parties.

26. Comment: Delays in obtaining audit samples due to problems with the AASP could result in a failure to successfully complete the required source test within the specified time. (0026)

Response: All parties must make the appropriate efforts to ensure that all requirements are satisfied on time as required. Where samples are simply not available or delayed due to problems in the system, compliance difficulties should be discussed with state or EPA officials to determine the best course of action.

27. Comment: The proposed rule does not allow flexibility for the case where the Audit Sample Provider(s) cannot, for whatever reason, provide the owner/operator an audit sample in sufficient time to meet the applicable compliance test deadline. The proposed rule unreasonably

creates a legal obligation or liability for which the source owner/operator would have no control. We therefore request that EPA revise the proposed rule to waive the requirement for audit sample analysis if a) the source owner/operator requests the audit sample from an Audit Sample Provider no later than 30 days prior to the test date and b) if the Audit sample provider fails to provide the samples to the owner/operator in time to analyze the sample during the performance test. This language is fully consistent with language already promulgated in Section 63.7(c)(4)(i) and (iii), except currently the request for samples must be made to the responsible enforcement agency. (0020, 0027)

Response: Owners and operators should plan in advance to meet their obligations. If they contact the Audit Sample Provider and it is determined that more than 30 days' advance notice is needed, then arrangements should be made to give sufficient advanced notice. By eliminating EPA from the service of providing the audit samples, EPA hopes that private parties will do a better job of providing audit samples, to the benefit of all parties.

Reporting period

28. Comment: Reporting schedules in the final rule should be modified to include an additional 15 days for reporting and a tolling period of 90 days if additional testing or retesting is required as a result of a failed audit sample. The basic procedures and the retesting procedures may interfere with meeting 30 day requirements for supplying QA/QC'ed data to the compliance authorities. (0020)

Response: Since the purpose of an audit sample is to support the credibility of a particular test result, it is important that the pass/fail result of the audit sample be included in the final test report. By privatizing the audit program, facilities will be able to get audit results directly from the AASPs which will be much quicker then obtaining them from the compliance authorities as in the past. Since the procedure for obtaining audit results will now be quicker, the final rule does not include additional time to submit a final report.

29. Comment: Additional time may be needed to obtain information on how all the audit sample faired compared to the acceptance criteria before completing and submitting the final report. (0008)

Response: See the response to Comment 28.

30. Comment: EPA should delete the requirement for the final repot to include the pass/fail result. A second option is to delete the proposed requirement to submit "a summary of the emission test results" at the time when the audit sample results are initially reported to the compliance authority and the audit sample provider. Additional reporting steps will directly prevent owners/operators from meeting their compliance report deadlines and/or create an unnecessary condition where enforcement negotiations for additional reporting time is needed for many compliance test. (0027)

Response: See the response to Comment 28.

Choosing correct concentration for an audit sample

31. Comment: There is a risk that the audit samples will fail because they may not be in the same concentration range as the actual samples and therefore would be out of the calibration range of the method. EPA should consider this in the final rule. (0018)

Response: EPA does not believe this is an issue because a test sample can also turn out to be in a concentration range outside of the calibration range and laboratories must take steps to deal with the issue.

32. Comment: The proposal does not provide for regulator input into the supplied audit concentration levels. This is critical. Currently, regulators request audit concentrations based on what they believe is applicable for a given test program. While the proposal specifies that the source provide an estimate of the pollutant concentration(s), there is no regulatory confirmation, nor the option for the regulator to make specific requests based on the needs for the given test program. (0010)

Response: EPA agrees that the compliance authority should have the opportunity for input into the supplied audit concentration level. The rule was revised to require that an acceptable criteria document provides the opportunity for the compliance authority to comment on the supplied audit concentration levels.

33. Comment: Section 60.8(g)(1) states: "When ordering an audit sample, the source operator, or representative shall give the sample provider an estimate for the concentration of each pollutant that is emitted by the source and the name, address, and phone number of the compliance authority." This requirement will cause confusion because a source may or may not know the concentration of the pollutant of concern. Since EPA's interest is in ensuring that the emission standards are being met, the requirement should be to provide information on the standard the facility has to meet and the concentration that would be expected in the stack gases if the emissions equaled the permitted level. The sample provider can then supply an audit sample that is within the target range for the specific pollutant. (0026)

Response: EPA agrees that the facility could provide information based on the facility standard or permit level instead of exact stack emissions. The sentence was revised to read "When ordering an audit sample, the source operator, or representative shall give the sample provider an estimate for the concentration of each pollutant that is emitted by the source or the estimated concentration of each pollutant based on the permitted level and the name, address, and phone number of the compliance authority."

34. Comment: One sentence reads, "When ordering an audit sample, the source owner, operator, or representative shall give the sample provider an estimate for the concentration of each pollutant that is emitted by the source and the name, address, and phone number of the compliance authority." After this sentence, EPA should insert the sentence, "The owner, operator, or representative shall provide the compliance authority with evidence for approximate ranges of expected concentrations of each pollutant to be tested." We have found that sources and their representatives usually provide such estimates with little or no evidence. Unless required, they have often not been willing to get the evidence from past tests or tests of similar emissions equipment. (0021)

Response: The rule language requires them to provide such information to the audit sample provider. If the facility does not know the emission concentrations of interest then they can provide information based on the permitted level. See response to Comment 33 for revised language allowing the information based on permitted levels.

35. Comment: When ordering an audit sample, the source owner, operator, or representative shall give the sample provider an estimate for the concentration of each pollutant that is emitted by the source…" For a given pollutant sampling time may vary from test to test. Instead of providing an estimate of pollutants emitted, the information provided to the AASP should be the estimated concentration of the pollutant collected. (0021)

Response: We believe that it is sufficient for the source owner, operator, or representative to give the sample provider an estimate for the concentration of each pollutant that is emitted by the source. The sample provider can use the estimated concentration along with the minimum sample volume to calculate the expected sample concentration.

EPA cost estimate is not accurate

36. Comment: The EPA cost estimates for audit samples are low. The cost will be more than the EPA's estimate of approximately 1% of a source test. One commenter cited an example where a NELAC Proficiency Test (PT) sample initially cost $150 and quickly increased to over $900 for just a standard SO_2 gas audit sample. (0010, 0011, 0016, 0028)

Response: The commenter did not present any evidence to support this cost and we were not able to substantiate the claim. According to discussions with the Executive Director of The NELAC Institute (TNI), the current cost range of SO_2 PT samples is approximately $95 to $108 and we expect the cost for the SO_2 audit samples to be about the same because they are made exactly the same only used for different purposes. The cost estimates discussed in the proposed rulemaking are based on the last ten years that EPA has operated the program.

37. Comment: EPA needs to provide other means to get samples that will be affordable if the proposed means is too expensive. However EPA must not allow such an alternative to enable cheaper alternatives to remove enough customers that accredited providers of audit samples become less feasible and prices for sample from accredited providers get even higher. (0021)

Response: EPA looked at several different scenarios for privatizing the SSAP and believes the use of AASPs is the best means to ensure consistently high quality audit samples. EPA is willing to consider other ideas when presented with a detailed proposal.

38. Comment: EPA underestimated the cost of the audit program because they did not take into account the future usage rate which will be significantly more if audit sampling is required for all compliance testing. (0008)

Response: The cost estimates discussed in the proposed rulemaking are based on the last ten years that EPA has operated the program taking usage rates into account. Audit samples have been required for compliance testing for many years. It would be difficult if not impossible

for EPA to try and guess how much if any additional demand there will be for the program. Even if the demand for samples increases, we still believe the cost of the samples will be approximately 1% of the total cost of the compliance test.

39. Comment: EPA significantly underestimated the cost of the audit program because EPA did not include the analytical fees associated with the audit. (0008, 0011, 0014, 0015, 0016, 0020, 0028)

Response: The analytical fees are not a new cost. Facilities have always been required to pay for the analysis of the audit samples even under the current program where EPA has provided the audit samples free of charge. Therefore EPA does not believe it is appropriate to add analytical fees to the estimated cost for the program.

Should set a limit on the cost of audit samples

40. Comment: EPA must also administer and control the cost of blind audit samples and establish a maximum upper bound cost for each type of blind audit sample. Suggested caps are: $250 for gas samples, $400 for liquid samples, and $600 for metal and PBT samples. (0016, 0028)

Response: EPA does not have the authority to set the prices that a private company can charge for their products.

ICR cost estimates are incomplete

41. Comment: EPA's cost estimates and the Information Collection Request (ICR) are woefully incomplete. EPA's estimate should include the total costs and burdens imposed on sources and the agency by the proposed new SSAP, not just the cost incurred by the AASP to report the true value of the audit sample. The burden estimate should include, among other things, the cost to sources of purchasing audit samples, analyzing (and in some cases reanalyzing) audit samples, reporting audit sample results and other information, developing and implementing the other aspects of the proposed "external QA program," and participating initially and every two years thereafter in the proposed VCSB "public process" to ensure that criteria developed by those organizations are reasonable. The burden estimate also should include the cost to EPA of reviewing and approving proposed "written technical criteria documents" and otherwise participating in the process.

EPA's suggestion that it's ICR is limited to that one task because it is the only "new" requirement under the proposed restructuring is misplaced. EPA could only lawfully limit its estimate to this new requirement if the other burdens already were covered under an approved ICR for the period in question. But, as far as UARG can tell, EPA has never submitted, let alone received approval of, another ICR related to the SSAP. As a result, EPA cannot exclude those costs nor can EPA exclude the additional costs associated with its proposed expansion of the program. (0024)

Response: The ICR estimate of burden includes the estimated cost for the AASP to

report the results of the audit to the compliance authority. In addition, the ICR has been revised to include the cost of the audit sample since in the past the audit samples were free. The cost of the requirement to analyze (and in some cases reanalyze) audit samples and reporting audit sample results has already been taken into account in past ICRs for each emission limit under the New Source Performance Standards which contained a burden estimate for reporting emission testing results to demonstrate compliance with emission limits. EPA believes that not all compliance tests that should be audited are being audited under the current program. We believe under the restructured program the rate of compliance with the audit requirement will be higher; therefore, we have revised the ICR to reflect the fact that more audit samples will be purchased. The final rule does not require anyone to participate in the VCSB "public process" and therefore, the cost of participating was not included in the ICR.

Requiring same analyst and analytical system for sample analysis

42. Comment: We are concerned about the proposed requirement that the audit sample must be analyzed by the same analyst using the same analytical reagents and analytical system as the compliance samples. We anticipate that the off-site laboratory will have a number of different analysts using the same type of equipment. For example, there may be several gas chromatograph/mass spectrometry instruments in a particular lab. All of these instruments are calibrated and certified. For all practical purposes, it does not matter which of these instruments are used to analyze an individual sample. All should give the same answer. (0015, 0023)

Response: While EPA agrees that identical instruments calibrated by the same reagents should give the same answer within repeatability limits, EPA also believes that it is important to limit all sources of imprecision and; therefore, the audits should be analyzed using the same analyst and the same analytical system as the compliance test samples.

43. Comment: The requirement that the audit sample must be analyzed by the same analyst using the same analytical reagents and analytical system as the compliance samples" should be expanded to specify analyzing them with the batch of compliance samples in the same batch and, if they are collected in the field, to collect them with the same person(s), using the same reagents and collection system. An example could be, "The audit sample must be collected, if it is an audit sample collection, and analyzed with the compliance samples by the same persons using the same field and analytical reagents, sampling and analytical systems, and procedures as for the compliance samples. Collection with the compliance samples means at the same location immediately before, after, during, or between test runs collecting compliance samples." If field testers use different sampling trains to collect compliance samples during different test runs, the question could arise how to fulfill this requirement, aside from collecting the sample with all the trains and analyzing the samples from the different trains separately or as a composite. This appears to be the best practice. If there is a defect or contaminant in one train, the audit will not detect it unless it uses that train to collect the audit sample. (0021)

Response: The final rule was revised to clarify how field audits should be collected when the audit sample is designed to check the sampling system. The final rule requires that field audits must be collected using the same field testing person who collected the field samples using one of the field sampling systems that was used to collect the compliance samples. If

multiple sampling systems were used, the rule does not require that each sampling train used during the field test be used to collect an audit sample. The revised rule also requires that the audit samples must be analyzed at the same time as the test samples unless the compliance authority waives this requirement.

44. Comment: We have concerns with EPA's premise in it's fact sheet that suggest audit samples must be analyzed alongside test samples in order for the regulatory agency to approve the compliance results. This approach could create uncertain and invalid source test results. (0008)

Response: EPA does not understand how analyzing the audit sample along side the test samples could create uncertain and invalid source test results. The audit samples contain the same pollutants in the same matrix as the source test samples and should be analyzed in the same manner as the sources test samples.

When are audit samples required?

45. Comment: It makes more sense for the company and the compliance authority to discuss the need for an audit sample on a case-by-case basis instead of EPA making it mandatory for each individual test. (0019, 0023)

Response: The requirement for an audit sample is nothing new. Current regulations require audit samples if they are available and we do not see a need to change this requirement. We believe that the program should be administered consistently across the Nation and the only way to do that is to require the tester to include an audit sample with all compliance tests using methods for which audits are available. The compliance authority can always waive the requirement to include an audit sample for a specific compliance test if they believe the audit sample is not necessary.

46. Comment: EPA's proposed regulatory text is not clear with respect to how many audit samples may be required during a given performance test. If the same method is used and same pollutant is sampled, only one audit sample should be necessary for the entire set of samples collected during a test program. EPA should clarify in the final rule to require one audit sample per method per testing activity regardless of the number of individual test runs. (0010, 0011, 0023, 0027)

Response: EPA agrees that only one audit sample per method used during a performance test is needed so long as all pollutants measures using that method are covered by the audit sample. We have clarified this in the final rule.

47. Comment: Requirement to analyze audit samples should be limited to no more than three performance tests (i.e., three test methods per performance test). Otherwise an authority could require audit samples for every pollutant, every run, and every test condition, going well beyond the spot check on accuracy of the performance test that EPA envisions. (0016, 0028)

Response: EPA does not agree that the audit samples should be limited to no more than three performance tests although we did clarify in the rule that only one audit sample per method used during a performance test is needed so long as all pollutants measures using that method are covered by the audit sample.

48. Comment: We hope that it is EPA's intent for delegated agencies to also have some discretion over the audit program implementation since it will be included in the reference method language. We foresee specific problems when facilities are performing multiple test methods and are required to obtain audit samples for each method. We recommend that state and local agencies be permitted to have discretion in determining how many audit samples are required for each testing situation. (0013)

Response: This rule in no way changes a delegated agency's discretion in implementing the audit program as it currently stands. We did clarify in the rule that only one audit sample per method used during a performance test is needed so long as all pollutants measures using that method are covered by the audit sample.

Audit sample availability

49. Comment: Timing for checking on availability of a specific pollutant audit sample does not mesh with the 60 day requirement to submit a test protocol for approval by the permitting authority. Cut-off date for sources to locate and incorporate audit sample requirements into a performance test plan must be at least 3 months prior to submitting the test protocol to their permitting authority. (0016, 0028)

Response: There is no requirement under the amended SSAP program to submit a test protocol for approval by the compliance authority. If a source chooses to voluntarily prepare and submit a test protocol, the protocol could incorporate audit sample requirements that would have to be met only if an audit sample became available 60 days prior to the scheduled test date.

50. Comment: The restructured audit program must have a mandatory requirement that there will be more than one provider of each type of audit sample (gas, liquid, metal) in order to have healthy competitive pricing and alternative sourcing. Program requirements for a specific type of audit sample should not be effective until after clear demonstration of at least two qualified U.S. sources for the type of audit sample. (0016, 0023, 0026)

Response: EPA agrees that there needs to be at least two sources of an audit samples before it is considered commercially available. Also see response to comment 18.

51. Comment: If audit samples are ultimately required for each test, we suggest that each test plan should clearly indicate how the facility intends to comply with this requirement during the test event. There would be no need to specify which AASP will provide the audits. Conditional language in the approved plan could protect a facility from unexpected unavailability of an audit sample. For example: Audit samples will be provided for the following test methods [list of methods] provided such audits are available from an accredited provider. In the event audit samples are not available for one or more test methods from an accredited

provider, the Permittee will notify the Administrator within 60 days of testing that a method audit sample is not available for one or more methods from an accredited provider and no audit sample will be provided for the subject method in accordance with [insert regulatory citation]. (0015)

Response: Except for the existing rules in Part 63, there is not requirement for a test plan. Sources may choose to submit a test plan under Parts 51, 60 and 61. Whether the test plan submitted is required or not, EPA agrees that test plans do not need to specify which AASP will provide the audit samples, so long as AASPs being considered are listed in the plan.

52. Comment: EPA presumes that there will be AASPs or Accredited Proficiency Test Sample Providers willing to get in the business of supplying the necessary audits for all applicable methods. What if this is not the case for some or all of the methods? Are there plans for a transition period if there is a delay in getting Providers accredited? If audit materials become unavailable, an important quality assurance tool of the Regulators will be lost. (0010)

Response: We anticipate that audit samples will be available for most if not all the methods for which EPA currently provides audit samples. We know that TNI is currently developing criteria documents and accreditation standards to produce audit standards (www.nelac-institute.org/standards.php) so we know there is interest in the private sector. We believe there will be an accredited audit program in the future. Therefore, we do not believe that there is a need for a transition period during which EPA would continue to provide audit samples until an AASP is approved. Again, if an audit sample is not available, there is no requirement for use of an audit sample.

53. Comment: The proposal does not deal with kinds of audit samples that accredited providers choose not to provide. They will not provide samples that cannot be sold for a profit. The EPA should add to the rule allowance of other ways to obtain samples when they are not available through accredited providers. (0021)

Response: EPA cannot require an AASP to provide all types of audit samples. EPA looked at several different scenarios for privatizing the SSAP and believes the use of AASPs is the best to ensure consistent high quality audit samples. EPA is willing to consider other ideas when presented with a detailed proposal.

54. Comment: The EPA document uses language such as “if available” and “if no gas phase audit samples are available” which indicates that it is anticipated that audit samples may not be available, and that it is unclear which audit samples would need to be performed with each method. (0007)

Response: EPA believes audit samples will not be available for all methods for which audit samples could be applicable as is with the current program therefore the phrase “if available.” is used. It would not be reasonable to require audit samples knowing some may not be available for purchase. The only method that currently has a gas audit sample is Method 25 and we do not foresee any other gas audit samples in the near future. We will post on the EPA

web site listed in the rule what audit samples are available and in what format (gas, filter, etc.) they are available.

55. Comment: Under EPA's proposed new SSAP, notice of availability of audit samples would be the sole means of determining whether a test method requires use of an audit sample. All test methods would require audit samples unless EPA's website does not identify a provider 60 days before the test. Sources would have to check EPA's website prior to every performance test to determine whether a new requirement might apply. We object to this use of the availability criterion. Whether an audit sample is required should be based on a determination, made after notice and comment rulemaking, that analysis of an audit sample is appropriate for a particular test method and not on whether EPA determines that a sample is "available" 60 days before a test. to promulgate the provision as proposed, EPA would have to explain why analysis of audit samples is appropriate for *all* existing and future test methods in Parts 51, 60, 61, and 63, once EPA determines that an audit sample "is available" from a private provider. EPA has not done that. (0024)

Response: As previously discussed in this rulemaking, EPA believes that the use of audit samples is appropriate and provides an important tool in compliance testing for all test methods in Parts 51, 60, 61 and 63. EPA has not been presented with adequate evidence to the contrary in this rulemaking. Therefore, EPA continues to believe that audit samples are a useful tool. EPA disagrees with the commenter that availability of a new audit sample creates a new requirement. Under this rulemaking, all test methods require audit samples, except where a sample is not available. A new audit sample becomes available once there are two providers willing to supply the audit sample. The criteria for accredited sample providers have been outlined in this rulemaking for notice and comment.

56. Comment: PT samples should not be used in place of audit samples, unless PT Providers follow the Provider requirements and be accepted as an Audit Sample Provider by a Provider Accreditor, as set forth in the Standards defined by the VCSB they are using. There are many differences between Audit Sample and PT Sample standards with respect to ordering, reporting, and analyte concentration ranges, to name a few. If audit sample protocols are not followed, the usefulness of the data may be diminished. Additionally, if PT Providers can participate in the audit sample program without having to comply with the same standards as Audit Sample Providers, there will be no incentive for PT Providers to become Audit Sample Providers. (0012)

Response: We agree with this comment. The rule has been revised to remove the option of using PT samples in place of audit samples if audit samples are not available.

57. Comment: Gaseous sample audits: We perform numerous test programs for gaseous components (NO_x, CO, SO_2, HC). We have been concerned with the lack of availability of audit samples currently, and would like more detail regarding the type and availability of audit samples proposed for gaseous measurements. (0007)

Response: Currently the only gas audit sample available is for Method 25 and we do not foresee any other gas audit samples in the near future. We will post on the EPA website listed in the rule what audit samples are available and in what format (gas, filter, etc.) they are available.

58. Comment: The EPA should not allow sources to forgo using an audit sample if the EPA fails to identify a provider on its website 60 days before a scheduled test. The EPA should limit its informational obligations to informing users how to find information about approved audit-sample programs and leave the job of identifying providers and which samples are available to these programs. (0021)

Response: It takes time to plan and prepare for a source test. We do not want a source to be cited for a violation because an audit sample becomes available a short time before the compliance test. We also do not want sources and testing firms to spend time everyday looking for available audit samples. Therefore, we believe the final rule needs to provide a 60 day time frame so that sources can properly plan a compliance test. In addition, listing the available audits on our website not only benefits the sources but also the compliance authorities. The list provides one location for them to see what is available otherwise they too would have to constantly contact providers for information on available audits.

Setting acceptance limits

59. Comment: EPA is relying too much on voluntary consensus organizations to do the job of enhancing data quality. A VCSB should not write standards with regulatory compliance implications without EPA first establishing the acceptability criteria or defining how the acceptability criteria should be established. For example, prior to sending out audit samples, an organization needs to conduct interlaboratory tests to determine the acceptable error range. EPA needs to define its minimum requirements to set regulatory limits and not leave it up to voluntary consensus organizations to define the acceptable level of performance for compliance purposes. (0026)

Response: We agree that EPA needs to define minimum requirements for how the acceptance criteria should be determined in the final rule. The final rule has been revised to specify that acceptance criteria must be based on results from the analysis of audit test samples analyzed by qualified laboratories using the method that is being audited. The final rule requires that acceptance limits must be set so that 90 percent of qualified laboratories would produce results within the acceptance limits for 95 percent of all future audits. This acceptance criterion is consistent with the general goal that EPA established for the program it operated in the past.

60. Comment: The rule should assign responsibility for planning and carrying out research, development, review, maintenance, and improvement of the specifications for audit samples for each test method to the VCSB overseeing accrediting of audit-sample providers. The proposed rule assigns this responsibility to each provider separately. (0021)

Response: EPA does not believe the proposed rule assigns research, development, maintenance or improvement to anyone specifically. The proposed rule does state that the audit sample providers in consultation with the VCSB should periodically review the acceptance

criteria for each audit sample. Since EPA is defining "commercially available" as at least two sources it would be inadvisable for one provider to work alone, not to mention that the providers must be accredited to provide each individual sample and the criteria for accreditation must be approved under the umbrella of the VCSB. This means that the procedure and requirements must be reviewed and approved by the VCSB.

61. Comment: "Evaluating the acceptance limits of samples at least once every two years to determine in consultation with the VCSB if they should be changed." The purpose of the audit program is to evaluate data quality for tests used to determine compliance with governmental regulations. The rule should require that agencies with compliance authority have a significant role in determining the acceptance limits of the audit samples. (0021)

Response: Although EPA thinks it is a good idea for compliance authorities to participate in standard development process, we do not have the authority to require other agencies to participate in VCSB. EPA retains the authority to adopt additional regulatory criteria through rulemaking for the audit program if it is determined in the future it is needed.

62. Comment: EPA proposes to eliminate provisions in existing test methods that identify the criteria for determining acceptability of the PA sample result. Instead, the rule would state only that an audit sample fails if it does not produce "an acceptable result." Proposed §60.8(g). Acceptability of results would be determined, not by rule (or even by EPA), but by the AASP or APTSP "in cooperation with" some "VCSB.". Like the existing test methods, and §63.7(c), the proposed rule would specifically allow the regulatory authority to use the sample results to determine the compliance status of the source. Proposed §§60.8(g) and 60.8(g)(2)(vi). EPA's proposal to allow third party organizations to unilaterally establish (and periodically revise) the acceptance criteria for audit sample results, and therefore, the compliance status of sources, is unlawful. Sources are entitled to notice and opportunity for comment on revisions to the standards that establish their compliance. To the extent EPA believes that the current criteria for acceptability are no longer appropriate, EPA must explain why and propose new criteria. If a VCSB in the future establishes criteria for acceptability of audit results for particular test methods that the Agency deems appropriate, EPA can conduct a future rulemaking to propose incorporation of those criteria rather than develop its own. The opportunity to participate in a future proceeding by some VCSB is not a lawful substitute for a rulemaking proceeding on a determination of acceptability by EPA. (0024)

Response: EPA is not allowing third party organizations to determine the compliance status of sources. Third parties are simply providing audit samples. These samples are not used to determine compliance or even revise standards. They are quality assurance tools that may be used by the compliance authority as evidence of compliance or non-compliance. All audit sample providers are required to meet certain criteria in order to provide samples. These criteria have been provided for notice and comment.

63. Comment: We have concerns regarding EPA's proposal for AASPs, TNI's standard for PT providers contains inappropriate criteria for development and adoption of acceptance criteria. Specifically, the TNI standard provides a group of TNI appointed members (called the TNI PT Board) sole, and apparently unlimited, authority to develop acceptance criteria, which

then are simply published in Tables on the TNI website and applied by PT providers. *See, e.g.*, Volume 3, sections 6.3.1, 10.2.1, and 10.3.1. Contrary to EPA's proposed criterion in §60.8(g)(2)(vi), this particular standard does not appear to provide for review of, or vote by the TNI membership on, audit sample acceptance criteria, let alone require consensus on them. As a result, the standard not only allows establishment of acceptance criteria that could be critical to a source's compliance without rulemaking, it provides for their establishment without any public participation. Thus, even if these TNI standards are relevant to the proposed new SSAP, they should not be incorporated unless that unlawful aspect of the standards is removed or revised. (0024)

Response: See response for comment 59.

64. Comment: EPA must address regulatory, or even peer-reviewed criteria, established by the proposed rule for determining the "true value" and/or acceptable range for the audit sample results, which under the proposal apparently would be left up to either the third-party AASP or the fourth party audit sample provider accreditation. The proposal also does not indicate for the respective Reference Methods, what the QA/QC objective is for the audit sample. The proposal is deficient without delineation and a basis for establishing such a standard. Further, we submit that the proposal also should address means for assuring that audit samples are properly analyzed or prepared or handled during shipping as well as "ownership" of the sample once received, a critical element in reporting and further analysis if there is audit sample failure. (0020)

Response: The criteria for determining the true value and acceptance limit are not determined by the AASP or the audit sample provider accreditor (ASPA) but by the VCB. The technical criteria documents specify how the samples are to be prepared, analyzed and shipped. It is the responsibility of the ASPA to check the AASPs to make sure they are complying with the criteria document procedures. The criteria documents are approved in advance by EPA. The audit samples are owned by the facility once they are received.

Audit samples should not apply to instrumental methods

65. Comment: EPA has not explained how a test method PA would apply to instrumental test methods, to test methods involving human observers (*i.e.*, Methods 9 and 22), or to any of the other test methods that currently do not include audit sample requirements. The instrumental test methods already include QA requirements and specifications for accuracy of the required calibration gases, and EPA never suggested in any of the recent revisions that use of blind audit samples should be required for those methods. For calibration style reference method, it is both duplicative and unnecessary to add a step to the current audit sample analysis process. (0008, 0024)

Response: We agree that it is not necessary to require audit samples for those test methods that use instruments that measure pollutants in the stack gas taken directly from the source. These methods include Method 3C, 6C, 7E, 10, 20, 25A, 318, 320, and 321. These methods already have sufficient calibration and quality assurance requirements that would make an additional audit sample redundant. We believe that Method 18 also has sufficient quality

assurance measures that make an audit sample unnecessary. This method requires that the tester perform a recovery study through the entire sampling system to demonstrate that the combined sampling and analytical system is capable of measuring the target pollutant within specified limits. The measured results are then corrected to account for the empirically determined recovery. We believe that for this method an audit sample would not add significant additional information about the quality of the measured results. We have revised the final rule to specifically exempt Methods 3C, 6C, 7E, 9, 10, 18 20, 22, 25A, 303, 318, 320, and 321 from the requirement to have an audit sample. We also agree that Methods 9, 22, and 303 do not need audit samples. These are all methods for determining visible emissions by observation and, therefore, there is not practical way to audit them. The final rule has been revised to exempt these methods from the audit sample requirement.

66. Comment: We question the need to conduct audits on routine test such as SO_2, NO_x, VOC and others since these tests require the use of certified standards to calibrate and validate results. Mandating audits samples for any and all routine testing performed under the qualifying air programs is redundant and unnecessary. (0014)

Response: See the response to Comment 65. We agree that Methods 6C, 7E and 25A which are the methods that measure SO_2, NO_x, and VOC using certified calibration gas standards do not require audit samples. We have revised the final rule to exempt those methods from the general requirement to include audit samples.

Notice and comment procedure

67. Comment: EPA's proposal, and in particular its proposed use of VCSBs, has many problems. First, EPA's proposal turns the requirements of the "National Technology Transfer and Advancement Act of 1995" (NTTAA) (Public Law 104-113) on its head. The NTTAA requires EPA (and other federal agencies) to use standards already adopted by VCSBs, where appropriate, rather than developing their own government-unique standards, and to participate in the development of such standards to help ensure their usefulness in government applications. It does not authorize EPA to adopt Voluntary Consensus Body (VCB) standards that do not currently exist, to adopt rules that condition sources' compliance with Federal regulations on a VCSB's adoption of standards, or to require regulated sources to participate in future VCSB proceedings in order to protect their interests.

EPA's own regulations regarding incorporation of standards by reference prohibit incorporation of future standards. *See, e.g.,* 40 C.F.R. §51.3. EPA's proposal of a rule specifically designed to allow EPA to approve and incorporate by reference future VCB standards is an unlawful circumvention of notice and comment procedures, and of limitations on incorporation by reference. EPA's proposed rule is no more lawful than a rule authorizing the Administrator to incorporate by reference without further rulemaking any future voluntary consensus standard EPA deems appropriate. (0024)

Response: The NTTAA only requires agencies to use VCS in regulatory actions when VCSs are available. There are no current standards adopted by VCSBs for audit samples. We are allowing VCSBs to develop standards for audit samples and allowing these standards to be

used for government applications. These audit samples are not used to determine compliance. They are quality assurance tools used during compliance testing to assist in determining the accuracy of the compliance testing. The final rule does not condition a source's compliance with Federal regulations on a VCSB's adoption of standards. If audit samples do not exist for a particular compliance test, an audit sample is not required. There is also no requirement that sources participate in future VCSB proceedings. Sources may participate, but there is no requirement.

On the second point, we did not circumvent notice and comment procedures. The final rule establishes minimum requirements for the audit samples, the AASPs and the AASPA. We have proposed these criteria for notice and comment. Although audit samples may be produced in the future, the only audit samples that we will accept are those that meet the substantive requirements of this rule. Accordingly, all commenters have had a full opportunity to discuss their concerns with the requirements set for audit samples by this rule.

68. Comment: We understand through our own research that EPA approached TNI more than a year ago regarding the development of standards that could be used to privatize the SSAP in a manner similar to what EPA now proposes. In July 2008, TNI developed, and for a full year EPA staff participated on, a committee for the express purpose of "developing TNI consensus standards that enable the externalization of EPA's SSAP." We assume EPA hoped that TNI would be able to adopt standards consistent with the criteria EPA now proposes for the AASP and ASPA "written technical criteria documents" in time for EPA to simply propose that those adopted TNI standards be incorporated by reference. That did not happen. TNI had not even completed the voting process on the TNI "Stationary Source Audit Sample" (SSAS) Committee's draft standards when EPA issued its proposal. As a result, EPA moved forward with a proposal that, without even identifying TNI or the draft SSAP standards, appears specifically designed to preauthorize EPA to approve and incorporate by reference those standards if they are adopted by TNI. Rather than discuss the TNI standards in the rulemaking, EPA asked the public to "identify potentially-applicable VCS" and explain why they should be used in EPA's rule. To the extent EPA was suggesting by its solicitation that it might incorporate into the final rule standards, like the TNI standards, identified by commenters, we object. Although the Agency has some discretion to alter its final rule in response to comments, these standards are not an insignificant part of the proposal. They are the entire reason for it. EPA cannot revise its final rule to incorporate such an important element without identifying and soliciting comment on it. (0024)

Response: See response to Comment 67.

69. Comment: To the extent EPA wants to adopt the TNI SSAS Committee standards, if and when they are finalized, EPA will need to develop a new rulemaking proposal that names those standards, describes any relevant issues raised by those standards, and describes the extent to which those standards have resulted in the availability of sufficient AASPs and ASPAs to implement EPA's proposed program. We, specifically, request that any such proposal include in the docket a copy of the tally of votes by the TNI membership on the proposed TNI SSAS standards, a copy of any negative votes received, and a description of how those votes were resolved. In our experience, many standards adopted by VCSB do not generate significant

comment among the VCSB membership and may be developed and adopted by a very small group of individuals with a fairly narrow range of interest. For this reason, adoption by a VCSB is not itself a substitute for rulemaking. VCSB standards must be incorporated through rulemaking before their terms can be imposed on regulated sources. (0024)

Response: EPA does not believe that VCSB standards must be incorporated through rulemaking. EPA has established regulatory criteria for VCSBs. EPA will only approve a VCSB criteria document if it meets all of the requirements in the rule. The NPRM for this rulemaking provides for comment on those criteria.

70. Comment: We object to EPA's incorporation of the two existing TNI standards addressing PT providers. EPA has not sufficiently explained how these standards, which address development and evaluation of PT samples used to evaluate laboratories seeking accreditation, would apply to the SSAP EPA proposes. Incorporation simply to provide an "example" of a standard that meets EPA's criteria is not appropriate. (0024)

Response: EPA provided the TNI standards addressing PT providers as an example of a criteria document that meets EPA's regulatory criteria for audit sample providers. The standards will not be incorporated into the rulemaking.

71. Comment: The Clean Air Act requires that the revision of any standard of performance under sections 111 and 112 of the Act require rulemaking. See §307 (1)(B), 42 U.S.C. §7607(1)(B). This includes procedures for measuring compliance with standards and includes changes to methods for determining compliance. Although the proposed rule discusses third-party field sampling and laboratory accreditation procedures, details on these procedures are not part of the rulemaking. EPA proposes in the future to post a list of purveyors, but does not set forth procedures for certifying these providers. The NPRM does propose to incorporate a number of voluntary consensus standards; however, it is not clear how these standards will be applied, monitored or certified. We do not believe that working under voluntary consensus standards that are not part of a regulatory procedure is sufficient to provide the requisite oversight or assurances that are required as part of a regulated performance testing requirement. Such procedures themselves require rulemaking under law. (0020)

Response: This rulemaking does not change procedures for measuring compliance with standards or change methods for determining compliance. Audit samples are being used just as they were used in the past. They are not used to measure compliance with standards. As discussed previously, audit samples are used with compliance tests as a quality assurance tool.

Field analysis of audit samples

72. Comment: The proposed changes to the Appendix M to Part 51 and the General provisions (60.8, 61.13, and 63.7) contain the following regulatory text for field testing: "If the method being audited is a method that allows the samples to be analyzed in the field and tester plans to analyze the samples in the field, the tester may analyze the audit samples prior to collecting the emission samples provided a representative of the compliance authority is present at the testing site". The rule should allow the owner/operator to obtain a waiver from the

requirement to have the compliance authority present at the testing site on a case-by-case basis. It may not be practical for a representative from the compliance authority to be on-site for every one of these audit analyses. (0015, 0023)

Response: We agree that it may not be practical in all cases for a representative of the compliance authority to be present when an audit sample is analyzed in the field, so we are revising the final rule to allow the owner/operator to obtain a waiver from the compliance authority for the requirement to have the compliance authority present at the testing site.

73. Comment: Is it reasonable to expect that a regulatory agency person will show up prior to the actual stack test just to watch the analysis of an audit sample? If that is not the case, will the results of the audit test be acceptable to all the parties? (0026)

Response: See the response to Comment 72.

74. Comment: EPA proposes to specifically allow reporting of audit sample test results prior to collecting emission samples. Proposed §60.8(g)(1). However, if "the method" allows samples to be analyzed in the field and the tester plans to do that, EPA proposes to allow analysis of the audit samples "prior to collecting the emissions samples" only, if a representative of the compliance authority "is present at the testing site." *Id.* EPA does not provide any explanation for this provision and we do not understand it. First, we assume EPA is referring to methods that allow analysis of emissions samples in the field. We also assume that by "testing site," EPA is referring to the emissions source being tested. We do not understand, however, why the presence of a state, local, or EPA observer during source testing is necessary to authorize analysis of audit samples prior to source testing. We also believe that conditioning validity of testing on the presence of a regulatory observer is not reasonable, given that sources have no control over whether or not an observer shows up. In short, EPA also needs to better explain this aspect of the proposal. (0024)

Response: See the response to Comment 72.

75. Comment: We believe that the proposal to restrict when the tester may analyze an audit in the field is unnecessary (74 FR 28456). The proposed rule requires the use of blind audit samples so it is unclear why the agency apparently presumes that the tester (or owner/operator) would somehow "cheat" in determining the audit sample concentration. This provision should be deleted. (0027)

Response: See the response to Comment 72.

Audit sample matrix

76. Comment: There are no requirements regarding method interferents that may or may not be added to the audit sample to make it reflective of the source being tested. The proposal only speaks of gaseous audits in air or nitrogen, or audits in the same matrix (undefined) produced after sample recovery, either of which might not be representative of stack samples.

Some Providers may decide to include interferents, while others may not. This, among other things, leads to concerns regarding the consistency of audits between Providers. (0010)

Response: The term sample matrix was not intended to imply that the audit samples were to be prepared in a manner that would duplicate an emission gas stream. The term matrix was only used in conjunction with those samples that did not consist of the pollutant in the gas phase in air. The term matrix was used to indicate that if a method collected the pollutant in an aqueous solution, then the audit sample should consist of the pollutant in an aqueous solution. The EPA believes that preparing audit samples in a matrix that would include interferents that might or might not be present in the stack is too complex to be workable and is not requiring that interferents be included in the audit samples.

77. Comment: The EPA must specifically require any acceptable audit-sample program to strive to include in audit samples realistic interferences that may be present in emissions tested. The audit sample must audit the measurement of analyte concentrations in emissions as realistically as is feasible, including the challenges that may make measurements of field samples less accurate than measurements of clean lab samples. This applies to audit samples in any container and matrix. The proposal does not interpret "matrix." It seems to mean only the largest components of emission samples. (0021)

Response: See the response to Comment # 76.

78. Comment: The desire to have audits in the sample matrix is troubling. The provider is not necessarily going to know what to mimic, and a difference might give you misleading thoughts about the sample validity. Audit samples are better kept clean and analyzed as an 'absolute' measure of the lab's accuracy in analyzing/measuring the compounds per the method(s). (0021)

Response: See the response to Comment # 76.

Audit results reporting and availability

79. Comment: EPA should share the results of the audit program with the affected community. The commenter believes the data collected over the yeas would be helpful in identifying problem area and developing programs to address them. (0026)

Response: Under the current audit system, we cannot release the true value of the audit samples because it could compromise the integrity of the audit system. The current supply of data can be release to the affected community when the EPA is no longer sending out samples and all outstanding sample results have been reported.

80. Comment: We believe the regulatory agency should be provided a copy of the audit results at the time of shipment from the sample provider. Many times having the results prior to sample analysis helps generate more accurate data and minimizes problems. (0017)

Response: EPA believes that this would be beneficial, but should not be mandatory. Since we did not provide the compliance authorities with the actual concentrations under the current audit program it is hard to justify making it mandatory.

81. Comment: Section 60.8(g)(1) states: "If the method being audited is a method that allows the samples to be analyzed in the field and the tester plans to analyze the samples in the field, the tester may analyze the audit samples prior to collecting the emission samples provided a representative of the compliance authority is present at the testing site. The source owner, operator, or representative may report the results of the audit sample to the compliance authority and report the results of the audit sample to the AASP or the APTSP prior to collecting any emission samples." It seems to us that if the results of the audit are available prior to conducting the emission tests, the facility should be provided with information on the pass/fail status of the audit test results prior to carrying out the source test. This would avoid unnecessary testing and waste of resources when the ability of the testing outfit is in question. (0026)

Response: EPA agrees with the commnenter and there is nothing in the rule to prevent this scenario.

82. Comment: Section 60.8(g)(3)(vii) requires AASPs or APTSPs to maintain "a database, accessible to the compliance authorities, of results from the audit that shall include the name of the facility tested, the date on which the compliance test was conducted, the name of the company that analyzed the compliance samples including the audit sample, the measured result for the audit sample, the true value of the audit sample, the acceptance range for the measured value, and whether the testing company passed or failed the audit."

It is our view that the results being discussed are being obtained as a part of an EPA regulation and should be available to the public. Keeping this information secret from source operators is inappropriate. The language in this section should be changed to read as follows: "Maintaining a database, accessible to the public and the compliance authorities, of results from the audit that shall include the name of the facility tested, the date on which the compliance test was conducted, the name of the company that analyzed the compliance samples including the audit sample, the measured result for the audit sample, the true value of the audit sample, the acceptance range for the measured value, and whether the testing company passed or failed the audit." (0026)

Response: EPA disagrees that this information is being keep secret from the source owner or the public. The source owner will receive a report from the AASP with all the information pertaining to their audit(s). Giving sources full access to the database would compromise the audit program since true values of audit samples could be know a head of time.

83. Comment: The results shall include … the measured result for the audit sample, the true value of the audit sample…" Only pass/fail should be reported. The samples are to be unknowns; if the audit samples are supplied in a limited number of concentrations then, over time, revealing the true value will comprise the unknown status of the audit sample. (0021)

Response: EPA agrees that the sample's true value needs to remain blind to the sources and laboratories at least until the values are reported. The rule has been revised to state that only pass/fail results will be reported unless the AASP ensures that no laboratory receives the same sample twice.

84. Comment: The audit sample provider would be under no compliance (or contractual) obligation to provide a quick turnaround on the audit results, so significant delay could occur during this step, depending on the audit sample provider's availability. We believe EPA would need to add a regulatory provision requiring the audit sample provider to send out the results of the audit within 7 calendar days. (0027)

Response: EPA agrees that it is important that the AASPs provide a quick turnaround of the audit results. The final rule will include a criterion that AASPs submit the results in a timely manner. The AASPs and the sources may decide a more specific time frame.

85. Comment: EPA's proposed reporting requirements are overly complicated and duplicative. Sources conducting "performance test" already are required by rule to report the results of those test to the appropriate regulatory agency. *See*, *e.g.*, 40 C.F.R. §§60.8(a), and 60.51Da. To the extent analysis of an audit sample is required for a particular test method, the results of the source's analysis (including whether the result passed or failed the acceptance criteria) should be included in that report. EPA provides no justification for requiring separate reporting of audit sample results or their acceptability to the regulatory agency or the sample provider. Once the sample analysis is complete, sources should be able to communicate with audit sample providers directly to learn the true value of the sample and calculate the pass/fail result to be included in the performance test report that is sent to the regulatory authority. We can think of no reason why the regulatory authority would need (or want) to receive results prior to that time. We also object to a rule that suggests the audit sample providers could provide audit sample results to a regulatory agency before providing them to the source that purchased the sample.

If EPA has specific reasons for the content and timing of the reporting provisions it proposes, EPA needs to explain those reasons and solicit comment on them. Otherwise, EPA should revise its proposal to include in the general provisions a requirement that all of the information necessary to document the results of the audit sample analysis required in a particular test method be included in the final "performance test" report submitted to the regulatory authority (0024)

Response: The requirement to report the audit sample results to the compliance authority prior to the final test report is to insure the integrity of the audit system. The compliance authority must know the testers results for the audit system prior to the tester receiving the true value of the audit sample from the provider to prevent possible misrepresentation of the results of the audit or compliance test.

86. Comment: We are concerned there may be a fundamental flaw in the proposed plan that may have an impact on cost and/or program administration. Current PT providers that will be AASPs go to great lengths to ensure that true values are not known to the laboratory. PT

programs are typically administered to cover discreet periods of time with a single set of samples issued to a laboratory for analysis and reporting. The participating laboratories report the results back to the PT providers where performance is evaluated. If audit samples are to be submitted by a facility with each compliance test or test event, it is highly likely that a laboratory will receive the same audit sample from the same AASP more than once, especially during periods when many permitted facilities are conducting HWC compliance testing test every 2.5 years while others test annually. This could compromise the program's integrity, especially if results are made available in a timely manner to the Permittee as the Permittee would want. If the AASPs must prepare and provide a different audit sample for every compliance test, this will certainly drive the cost of the audit samples up. (0015)

Response: EPA agrees that the sample's true value needs to remain blind to the sources and laboratories at least until the values are reported. The rule has been revised to state that only pass/fail results will be reported unless the AASP ensures that no laboratory receives the same sample twice.

External QA program

87. Comment: In its restructuring of the SSAP, EPA proposes to replace the audit sample requirements in existing test methods with a requirement in the general provisions of Parts 60, 61, 63, and 51, Appendix M, that each "performance test" include an "external QA program" including, at a minimum, a test method "performance audit (PA)" during the performance test. Thus the Part 60 program would no longer be limited to specific test methods, but instead would apply to any "performance test" and would require something more than analysis of audit samples. EPA does not explain what other requirements might exist for the "external QA program," other than the proposed requirement that it "may also" include "systems audits," which the proposed rule describes using the same vague language in §63.7(c)(2)(iii). UARG objects to EPA's proposal to remove the audit sample requirements from individual test methods and objects to the requirement to develop something called an "external QA program" for each performance test. (0024)

Response: The only mandatory requirement under the restructured audit program is to include an audit sample with each compliance test. EPA has revised the final rule to make this clear.

No justification for program

88. Comment: EPA did not provide a justification for continuing the current program or expanding the program. Three commenters believe that the emergence of private providers is an insufficient rational for the rulemaking. (0014, 0019, 0020, 0024, 0026)

Response: We disagree. The emergence of private providers is one reason for changing the audit program. We discussed other reasons for privatizing the audit program in the Notice of Proposed Rule Making. Also, we believe allowing private companies to provide audit samples will 1) insure a wider range of audit sample concentrations that will better match the working range of the methods, 2) provide a more efficient and responsive system for supplying the

required samples, 3) insure greater transparency in the operation of the audit program, 4) produce higher quality audit samples, and 5) insure a more stable supply of samples.

89. Comment: EPA's proposed privatization of the SSAP is designed to transfer the Agency's obligations with respect to the SSAP to private parties who would then fund what previously were EPA regulatory activities (like establishing future audit sample requirements and criteria), UARG questions whether the restructuring might be an unlawful augmentation of EPA's Congressional appropriation and a violation of the Miscellaneous Receipts statute, 31 U.S.C. §3302(b). If EPA's goal is simply to pass to sources the cost of purchasing audit samples, that goal can be achieved without a total privatization of the program. (0024)

Response: The reason for the restructuring is not budgetary. As we stated in the preamble, there previously were no private entities who supplied stationary source audit samples so EPA provided them. But now there are private sources for these types of samples. EPA is not under any statutory requirement to provide audit samples and therefore does not believe it is appropriate to do so when private providers are available. EPA does not believe the program, as structured, violates the Miscellaneous Receipts Act.

90. Comment: The proposal to restructure the stationary source audit process would significantly increase source owners' and operators' testing costs and time periods for data collection without a discernable improvement in data quality. (0019)

Response: See response to Comment 38 with respect to testing costs. EPA does not see how this rule changes the time periods for data collection from what it is today. In fact, the time it takes for a facility or laboratory to learn if it passed the audit may be shorter than the time to go through a compliance authority.

Consistency

91. Comment: Although the proposed rule does not suggest that in-house source testing firms would be relieved from compliance with the requirements of a source audit program, the audit program should be administered consistently regardless of the affiliation or size of the testing firm and that in-house testing groups should not be exempted. (0011)

Response: EPA agrees that the program should be administered consistently. The proposed rule does not relieve any facility from the requirement of using audit samples during stationary source compliance testing regardless of the size or affiliation of the testing firm or laboratory.

92. Comment: As a national source testing firm, we must conform to or comply with a patchwork of programs, all of which have the stated purpose of "improving emission test data quality." Accordingly, we encourage EPA to use this opportunity to advance data quality programs that are consistent for all source test programs and have applicability in all jurisdictions. (0011)

Response: EPA has different programs because they have their own separate needs and issues whether it be different media, different measurement levels or different data quality needs and therefore, it is not possible to make all the programs consistent in how they evaluate emission data.

93. Comment: On page 38, "Part 60 - Standards of Performance for New Stationary Sources", Section 60.8(g)(1) states in part "...the owner, operator, or representative may report the results of the audit sample to the compliance authority and report the results of the audit sample to the AASP or the APTSP prior to collecting any emission samples." On page 30, "Appendix M to Part 51-Recommended Test Methods for State Implementation Plans", Section 4a, and elsewhere repeated in the proposed rule (pages 65 and 79) state in part: "...the owner, operator, or representative may report the results of the audit sample to the compliance authority and then report the results of the audit sample to the AASP or the APTSP prior to collecting any emission samples." (emphasis added). Note the statement in Part 51 has the additional word "then," which could be interpreted to mean that the results could be reported to the AASP or APTSP at some later time after reporting to the compliance authority, whereas the statement in Part 60 could be interpreted to mean that the results should be reported to the compliance authority and to the AASP or APTSP at the same time. The statement in Part 51 should be amended to remove the word "then" to correspond with the statement in Part 60. (0012)

Response: EPA agrees that the two statements should be consistent. The final rule has been revised so all parts require that the audit sample results be reported to the compliance authority and the audit sample provider at the same time.

94. Comment: EPA needs to revise the NESHAP General provisions for consistency with the proposed audit restructuring program. Provisions in 63.7(4)(i) state that “audit materials may be obtained by contacting the appropriate EPA Regional Office or responsible enforcement authority.” This language conflicts with the proposed rule if audit samples are to be obtained from an Audit sample provider. (0027)

Response: EPA agrees and the final rule has been revised to correct the inconsistency.

Ordering audit samples

95. Comment: It is not clear who is responsible for obtaining the audit samples. The proposed rule allows the source or an agent for the source to request the audit sample for a source test. It is unclear to the requesters what exactly that means. What type of documentation would be needed by the agent to demonstrate to the AASP that it is indeed an agent for the source? (0008, 0011)

Response: This provision was intended to allow the source owner or someone designated by the owner such as a member of a source testing firm to request the audit sample. The agent would need to work with the AASP to provide any documentation necessary to satisfy the AASP that they were an agent acting for the source.

96. Comment: We believe there should be a time-frame for the source to order audits and the regulatory agency should be notified when an audit was ordered. (0017)

Response: The final rule has been revised to provide the compliance authority input into the audit concentration range which in itself provides the compliance authority notification of an audit order. We believe the time frame for ordering audit samples is between the source owner, compliance authority and the AASP, not an issue to be covered by this rule.

EPA maintain list of Audit providers

97. Comment: If the affected source owners seek the lowest cost AASPs, then there could be audit sample shortages, unforeseeable variations in costs, audit quality issues, and. last minute failures in AASPs supplying audit samples. We encourage EPA to consider the substantial effort and expense that both the regulated source and the AETB must undertake in "preparation for a test, only to find at the last minute that the audit material offered by an AASP is unavailable as offered or advertised. Clearly, an AASP that fails to deliver audit material as offered or promised must be flagged or removed from the list that EPA proposes to post. (0011)

Response: We intend to monitor the progress of this new system of supplying audit samples to ensure that it works as anticipated. We trust that most AASPs will deliver on their contracts, as most businesses want repeat customers.

98. Comment: The rule needs to include a requirement on the part of EPA to maintain an online data base of the current AASP-certified providers. The data base serves to communicate which providers are current relative to certification status and the types of samples provided. The web site location of the database needs to be included in the text of the rule. (0015, 0023)

Response: EPA does not believe a regulatory requirement is necessary and EPA will keep the website updated and accurate.

EPA's 2003 study on quality gas cylinder samples

99. Comment: Reliance on voluntary consensus requirements for accreditation of audit samples does little to improve the reliability of compliance testing, and may threaten the quality of the testing itself without additional procedures for qualifying and auditing private entities. This makes the EPA proposal arbitrary and unreasonable. As proof of this contention, as part of a 2003 study, EPA performed an audit of 42 source-level, tri-blend, EPA Protocol calibration gas cylinders from a total of 14 major gas vendors nationwide. The cylinders contain blends of SO_2, NO, and CO_2 in a N_2 balance. The gas concentrations are (1) 50 ppm SO_2, 50 ppm NO, and 5% CO_2; (2) 500 ppm SO_2, 400 ppm NO, and 12% CO_2; and (3) 1000 ppm SO_2, 900 ppm NO, and 18% CO_2. The cylinders were purchased by a third party so that the gas vendors did not know that EPA was analyzing the cylinders. The purpose of the audit was to help vendors improve gas quality, and to help calibration gas buyers identify good gas vendors. The overall failure rate was 11% on a gas component basis, and 57% on a vendor basis. No additional evidence of the

availability or the quality or calibration of private vendor audit samples has been offered to refute EPA's own study. (0020)

Response: This study is not relevant to the proposed restructuring of the audit program. The gas vendors surveyed in this study were not accredited to produce EPA protocol calibration gases because the protocol gas program does not require accreditation and were not subject to any third party verification. The restructured audit program requires that providers be accredited and that recurring third party verification of the quality of the audit samples be produced.

Audit requirements in methods

100. Comment: Although UARG objects to the proposed expansion of the SSAP to include some other undefined QA program, and the disassociation of the audit sample requirement from individual test methods, UARG would not oppose a requirement in the general provisions to comply with audit sample requirements "where contained in an individual test method," or to a general provision addressing other details of audit sample analysis requirements (such as where and when to send audit sample results), where applicable. Defining and codifying those aspects of the program that are consistent among all test methods would be an appropriate use of the general provisions. In short, EPA should revise its proposal to retain audit sample requirements and acceptance criteria in individual test methods involving manual analysis of samples, and to limit the proposed addition to the general preamble to those implementation details that currently are not defined or are not defined consistently. (0024)

Response: There is already a requirement in 40 CFR Part 63 to use audit samples for all test methods, so we think that this an appropriate amendment to the general provisions of Parts 51, 60, and 61. We have specifically exempted those test methods for which audit samples are not appropriate.

EPA's proposal is premature

101. Comment: To our knowledge, there are no existing third party accrediting bodies for audit sample providers, and therefore there are no AASPs from which to obtain audit samples under this proposed rule. For this reason, EPA's proposal is premature at best. EPA cannot propose a program that requires source compliance when none of the structure required for its implementation exists. It is not sufficient for EPA to simply propose a framework and then to develop the details of the program after the opportunity for notice and comment has passed. (0024)

Response: As stated previously, an audit sample is required with compliance testing only when a sample is available, except where exempted in the regulations. EPA is permitted to develop regulatory criteria for approval of criteria documents from audit sample providers and did this in the proposed rule which provided an opportunity for notice and comment. These are not "details of the program" to be determined at a later date. If an audit sample provider's criteria document meets the regulatory criteria, it will be approved and the sample provider may provide samples for sources conducting compliance tests.

Audit samples should be delivered to lab

102. Comment: A more efficient method is for a plant site to order the required audit samples and have the provider ship the samples directly to an off-site external lab. Since the program does not address the act of sample collection, there is little to no value in having the audit samples shipped to the plant site. In addition, transporting a blind audit sample in and out of a petrochemical facility may cause transportation complications. In many cases, transportation regulations require the identification of the chemicals present along with concentrations and hazards. Thus, the AASP would be required to identify the chemicals present and indicate in a general fashion the approximate concentration of the various chemicals that are present in the blind audit sample. (0015, 0023)

Response: The EPA audit program allowed analytical audit samples to be shipped directly to the laboratory if requested by the compliance authority. We do not see any problem with that option unless it is an audit sample that is intended to be collected out in the field. Those types of audit samples must be collected in the field and sent to the laboratory with the stack samples.

Audit samples on test site during testing

103. Comment: The audits should be required to be at the test site during testing, then handled, stored, packaged and shipped with the stack samples, unless the Compliance authority waives this requirement. (0010)

Response: See response to Comment 102

VCSB standard does not meet EPA's needs

104. Comment: The entire proposal is short on detail. Presumably this will be addressed through EPA's approval of Accrediting Bodies, where EPA would specify additional details. Will it? A VCSB may be able to agree to standards, but what if those standards do not serve the needs of EPA or other Regulators? The Regulators most interested in the audit program may not have the time to be involved in every VCSB that decides to write standards. (0010)

Response: We believe that any program that meets the minimum criteria specified in the final rule will meet the needs of the EPA and other compliance agencies. The criteria in the final rule ensure that any program that is developed by the private sector and approved by EPA will be equivalent to EPA's current audit program.

Gas audit samples entry point

105. Comment: Section 60.8(g) states: "For pollutants that exist in the gas phase at ambient temperature, the audit sample shall consist of an appropriate concentration of the pollutant in air or nitrogen that can be introduced into the sampling system of the test method at the same entry point as a sample from the emission source." In source gas sampling work, calibration gases as well as audit gases are introduced in the probe such that they pass through

most of the probe tube and all filters and other components of the sampling system. However, it is not always practical to introduce the calibration gas at the same entry point as the source gas. We recommend changing the above wording in Section 60.8(g) to the following: "For pollutants that exist in the gas phase at ambient temperature, the audit sample shall consist of an appropriate concentration of the pollutant in air or nitrogen that can be introduced into the sampling system of the test method at or near the same entry point as a sample from the emission source." (0026)

Response: EPA agrees that it may not always be practical to introduce the calibration gas at the same entry point as the source gas. EPA has revised the final rule to allow introduction of the audit sample "at or near" the entry point for the sample from the emission source.

TNI's finalized standards in the EPA final rule

106. Comment: In the June 16 proposed rule, the Agency referenced some existing consensus standards developed by TNI for the accreditation of PT providers and the analysis of PT samples. The recently formed TNI Stationary Source Audit Sample (SSAS) Expert Committee has developed three new TNI standards for EPA's SSAP. These new standards address the overall roles and responsibilities of the entities that participate in the SSAP, the specific responsibilities of SSAS providers, and the specific responsibilities of provider accreditors. In accordance with the TNI *Procedures Governing Standards Development*, these standards are expected to be final on or around August 11, 2009, after the comment period for this proposed rule closes. TNI requests the Agency consider the new TNI standards as it moves forward with this regulation. (0009)

Response: EPA will determine whether the TNI standards meet EPA's regulatory criteria when they are completed and submitted to EPA for approval after EPA's rule is promulgated.