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Ronald O. Kagel, PhD

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Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460

Attn: Docket ID no. EPA-HQ-OAR-2008-0531

The Coalition for Responsible Waste Incineration (CRWI) appreciates the opportunity to submit comments on *Stationary Source Audit Program; Notification of Availability and Request for Comments*. 84 FR 47,882 (September 11, 2019). CRWI is a trade association comprised of 27 members representing companies that own and operate hazardous waste combustors and companies that provide equipment and services to the hazardous waste combustion industry.

As a part of this notice, the Agency asked for comments on certain aspects of the program. Attached are CRWI's responses to those requests.

Thank you for the opportunity to submit comment. If you have any questions, please contact me at (703-431-7343 or mel@crwi.org).

Sincerely yours,

Melvin E. Keener, Ph.D.
Executive Director

cc: CRWI members
N. Shappley, EPA

Specific comments

1. The effectiveness of the program prior to suspension.

The audit sample program was originally intended as an audit of sampling technique, sample handling, sample preparation, and sample analysis so that regulators could determine the measurement biases relative to all steps of the process. However, the current program is not effective or comprehensive because of way it is conducted, the limited number of accredited providers, and the limited number of available audits sample types. The current program does not address sampling technique, sample handling or sample preparation and serves as little more than another audit program for the laboratories.

For example, a hazardous waste combustor preparing for their comprehensive performance test would order HCl and metals samples from one of the two suppliers. These are the only two audit samples available. Once received, these samples would be packaged with the field samples and submitted to the laboratory for analysis. These HCl and metals audit samples only minimally mimic the field samples recovered from sampling trains primarily because the media fraction configurations often do not match those of the actual field samples recovered from sampling trains. In addition, the concentrations that are available for audit samples do not match the range of concentrations anticipated in the field samples. Thus, even at the laboratory level, audit samples can provide only limited meaningful information relative to biases that may exist with the normal sample preparation, handling, and analysis processes within the laboratory.

Laboratory facilities already have a governing body that polices the standard analytical testing quality assurance and their policies. The National Environmental Laboratory Accreditation Council (NELAC) performs onsite facility audits for participating laboratories. This nationally recognized organization examines procedures, training records, proficiency test records, internal auditing records, external auditing records, and all instrument maintenance records. Laboratories are required to procure annual proficiency test (PT) samples in duplicate and provide the testing results to NELAC for evaluation. These analytical tests are blind audits for accuracy, and are required for each analytical procedure that is performed, assuming a PT is available. Every aspect of the laboratory's operation is open for periodic inspection, and certifications are provided after each detailed evaluation from NELAC. Regarding the issue of samples being submitted to the laboratory to evaluate a particular analyst on a specific instrument and with a specific project, the NELAC process is set up to address these concerns. Analysts are trained on specific methods following standard operating procedures controlled by the laboratory Quality Assurance departments. The certification process requires that the analysis is conducted by a proficient analyst with records that display their training. All other EPA compliance programs deem this to be a

sufficient process for tracing competency and Quality Assurance. In addition, at least three states (California – ELAB, Louisiana – LELAP and New York – ELAP) offer state laboratory accreditation programs.

Laboratory accreditations are made available to clients and regulatory agencies as proof that these nationally recognized auditing groups have recently performed the evaluation. The scores of the proficiency testing samples as blind audits are included as part of the performance proof to all who desire to check on an individual laboratory prior to using their services.

Thus, there is already a program in place to ensure the quality of the data from accredited laboratories. CRWI believes the NELAC and state processes are more than adequate. The requirement to purchase audit samples as part of the performance test and have the laboratory analyze these samples does not provide any additional assurances on the quality of the data. It simply increases testing cost with no discernable improvements in data quality. CRWI believes that the audit sample as currently implemented to be a duplication of effort that adds cost and hassle to the testing process without adding any benefit. We see no reason to continue it in the future should additional audit sample providers become available.

Finally, CRWI would like to point out that at the local state agency level, there seemed to be a lack of awareness about the stationary source audit program and how the process actually works. And even after education on how the process works, the process itself is cumbersome.

2. Should EPA continue the program as currently defined?

   CRWI does not believe the program should be continued. As explained above, the sample audit program is a duplication of existing laboratory accreditation programs. The laboratory accreditation programs are more extensive than the sample audit program and provide better data quality assurances. CRWI believes the Agency should remove this requirement from the regulations. This could be used to meet the Agency's requirements under E.O. 13771.

3. Did the audit program improve the quality of the data produced during performance testing?

   CRWI does not see how this program has made any impact on the quality of the data. The audit program does one thing, measures the ability of the laboratory to accurately analyze a blind sample. The NELAC and state processes already do a better job accomplishing this objective.

4. EPA currently defines "commercially available" as requiring 2 or more companies providing audit samples. Should EPA consider revising that definition?

Should the Agency retain the audit sample program, it is important to keep the requirement to have at least two suppliers. First, having only one supplier will increase the uncertainty for timing of a particular performance test. Having at least two suppliers will give the facility a second option should the first not be able to provide audit samples on a timely basis. Second, having two suppliers creates a level of competition that helps keep costs down. Finally, it should be noted that federal procurement processes require at least two suppliers. Sole source suppliers are allowed but must be justified. Given that the audit program is duplicative of other laboratory certification processes, we cannot see how the Agency could justify a sole source provider for this service.

5. Are there ways the Agency can make this program more effective?

   CRWI believes that the program should be eliminated. However, if the Agency chooses to continue the program, here are three ways we believe it could be improved.

   a. Ship the audit samples directly to the laboratory. A more efficient method would be for the facility to simply order the required audit samples and have the provider ship them directly to the laboratory. There is no reason to have audit samples shipped to the site and then have the testing company ship them to the laboratory for analysis. Cutting out an unnecessary step saves time, money, and reduces possible lost or damaged samples. There are methods of keeping the chain of custody adequate so that matching the audit sample to the test should not be problematic.

   b. Remove the regulatory language that the failure of an audit sample can be used as evidence of non-compliance. Audit samples are not representative of actual field samples (e.g., sample matrix are not the same, concentrations are not in the proper range, etc.) and a “failure” could occur for a variety of reasons that are not indicative of the laboratory’s performance as it relates to the accurate and precise analysis of the field samples. As such, failure of an audit sample should not trigger a non-compliance finding. Instead, the audit sample should be used as one of several pieces of QA/QC information to evaluate the usefulness and validity of the data. These include matrix spikes, surrogates/surrogate spikes, laboratory control samples, and other QA/QC samples appropriate for a given analytical method. CRWI believes that there is something fundamentally unfair about finding a facility in violation based on an analysis of an audit sample that was not collected from the source and, therefore, cannot be representative of the pollutants emitted by that source. Thus, CRWI suggests that this part of the regulatory language be removed.

c. Remove the regulatory requirement that the audit sample must be analyzed by the same analyst using the same analytical reagents and analytical system as the compliance samples. This is not how accredited laboratories operate. The 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 is used to analyze an individual sample. All should give the same answer. When the samples from a test come in, they may be divided among a number of analysts using different analytical systems. This proposed requirement would modify current procedures and increase costs without adding to the quality of the data. We suggest this requirement be removed from the regulatory language.