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April 23, 2015

Eurofins Eaton Analytical's (EEA) South Bend laboratory has recently experienced trouble meeting quality control recovery criteria for On-Going Precision Recovery (OPR) samples for EPA Method 1623. The recoveries for some of the OPR samples over the past two weeks were inconsistent, with some results below required EPA recovery limits. As a result, these non-conforming OPR samples have impacted associated client samples and matrix spike samples. As passing OPR is required, these impacted samples and matrix spikes require re-collection.

A Corrective Action Request (CAR) was initiated by EEA's Quality Assurance group to investigate, document and determine a root cause of this incident as well as institute any appropriate preventative measures. After many hours and days of investigative testing we believe a single reagent lot is the root cause of the problem.

On April 22, 2015, EEA was contacted by CB&I Federal Services, LLC who is a contractor with the EPA who asked if we were using a specific lot of a reagent and if we had any trouble meeting QC requirements. We confirmed that we were using the specific lot in question and noted we also had trouble meeting QC requirements. After consulting with the EPA today, the EPA recommended that re-collection events should not occur until the laboratory is confident that the performance of the procedure is in control. We have also been in contact with the manufacturer of the reagent, who also is in contact with the EPA. Unfortunately, they do not have a replacement lot for this reagent available at this time.

Once we are confident our procedure is in control your Analytical Services Manager (ASM) will coordinate re-collection events. EEA will cover costs of return shipping for this re-collection event by providing a pre-paid shipping label along with appropriate collection supplies.

Below is an excerpt from the LT2 regulation:
http://www.ecfr.gov/cgi-bin/text-idx?SID=03dd8d9d428c207848e2caca22feb97c&mc=true&node=se40.23.141_1702&rgn=div8

(2)(i) If a system is unable to report a valid analytical result for a scheduled sampling date due to equipment failure, loss of or damage to the sample, failure to comply with the analytical method requirements, including the quality control requirements in §141.704, or the failure of an approved laboratory to analyze the sample, then the system must collect a replacement sample.

(ii) The system must collect the replacement sample not later than 21 days after receiving information that an analytical result cannot be reported for the scheduled date unless the system demonstrates that collecting a replacement sample within this time frame is not feasible or the State approves an alternative resampling date. The system must submit an explanation for the delayed sampling date to the State concurrent with the shipment of the sample to the laboratory.

(c) Systems that fail to meet the criteria of paragraph (b) of this section for any source water sample required under §141.701 must revise their sampling schedules to add dates for collecting all missed samples. Systems must submit the revised schedule to the State for approval prior to when the system begins collecting the missed samples.

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I want to apologize on behalf of EEA for the inconvenience that this pending request to re-collect samples has created. Attention to quality continues to be our highest priority and we are continuing to work and consult with the EPA by providing our laboratory quality control data and supporting internal investigative results to help address this issue as soon as possible.

Please do not hesitate to ask us if additional assistance is needed with your state regulatory agency.

Sincerely,

Matthew Hartz
Laboratory Director

William Reeves
Quality Assurance Manager

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