Guidance on Initial Demonstration of Capability for Drinking Water Methods

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1.0 BACKGROUND

Problem Statement: Most EPA drinking water methods require that laboratories conduct an Initial Demonstration of Capability (IDC) which includes verifying the Minimum Reporting limit (MRL) using the Half Range Prediction Interval of Results (HR_{PIR}) for all analytes is within limits published in the method. This requirement has proven difficult to meet for methods which contain many analytes. The EPA drinking water program agrees and only requires that the HR_{PIR} be met for regulated drinking water analytes. State accreditation/certification programs believe any analyte listed within the Fields of Accreditation of the laboratory must meet method requirements.

EPA Response: EPA is not aware of any issued guidance or correspondence that specifically addresses or advises drinking water laboratory Certification Officers (COs) to exclusively focus on regulated parameters when conducting drinking water laboratory audits and/or reviewing IDC data. There are several approved analytical methods that include an extensive list of target analytes that fall within the scope of the procedure, but most often only a subset of these analytes is federally regulated in drinking water. Nothing was ever issued because this position could be inferred from the regulated analytes, the approved analytical methods specific to monitor those regulated analytes, and the lab certification requirement that applies to conducting compliance monitoring for these regulated analytes with those approved methods. EPA allows drinking water primacy states to be more stringent than federal requirements and some may establish state-codified monitoring requirements for these additional non-federally regulated analytes, which then would warrant a state certification officer's finding. States also have the authority to be more stringent than federal regulations in how they implement their laboratory certification/accreditation programs and could require labs to generate IDC data for all analytes included in the method scope. Included within the CO training program are ways for COs to be efficient and prioritize data review during a lab audit. EPA suggests the auditor not include in their lab audit these non-regulatory analytes that fall within the scope of the method, but rather they specifically focus on the drinking water federally regulated analytes and associated QC.

Auditors review a significant amount of information and if during a lab audit the CO would happen to notice poor performance for a non-regulated analyte with failing QC data or poor recoveries in the IDC, they may identify that observation in their report. In this case, the observation would include a recommendation that the lab maintain awareness and consider looking into why the method may be performing poorly for that non-regulated analyte, but they would not make it a finding requiring any corrective action. The observation would be shared with the lab for broad awareness and recognition that the failed IDC for the non-regulatory analyte may represent an early warning of potential future lab performance problems. Oftentimes specific target analytes can be more sensitive and may serve as early indicators/sentinels that the analytical system (extraction and/or analysis) may be teetering and soon may fall out of control for regulated analytes.

EMC Action: This guidance was shared with every state agency that accredits or certifies laboratories that analyze drinking water.

State Response: The National Environmental Laboratory Accreditation Program (NELAP) Accreditation Council represents 14 state programs that accredit laboratories to the TNI laboratory accreditation standard. The Council discussed this guidance and indicated they could not use it since any analyte listed in a laboratory's Accreditation Certificate must meet any method requirements. However, the Council did agree that laboratories could take corrective action as outlined in Section 4.11 of Module 2 of the TNI standard.

2.0 EMC FINAL GUIDANCE

Most EPA drinking water methods require that laboratories conduct an Initial Demonstration of Capability which includes establishing a Minimum Reporting Level (MRL). The methods then require the laboratory to verify that the Half Range Prediction Interval of Results (HR_{PIR}) by analyzing seven replicate samples at or below the MRL. The MRL is validated if both the Upper and Lower Prediction Interval of Results meet criteria of < 150% and > 50% respectively. These values are based on the mean and standard deviation of the seven replicates. The methods then state:

> If these criteria are not met, the MRL has been set too low and must be confirmed again at a higher concentration.

The EPA methods provide no guidance regarding what to do if only a few analytes in a long list do not meet these criteria. Should all analytes be retested at a higher concentration? Should only those that fail be repeated at the MRL concentration?

EMC also recommends laboratories follow the corrective action process in the TNI Standard as summarized below.

1. Start with an investigation to determine the root cause(s) of the problem.
2. Select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.
3. Document and implement any required changes resulting from corrective action investigations.
4. Monitor the results to ensure that the corrective actions taken have been effective.

NOTE: Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes for this situation could include a sporadic random failure, inadequate calibration, incorrect spiking solution, insufficient training, or analyst error.

Once the root cause has been identified and addressed, the corrective action must result in a MRL verification process for only those analytes that didn't pass the HR_{PIR} process, using additional replicates or a higher concentration.