22 YEARS OF ISOTOPE DILUTION ANALYSIS: FROM COMMAND CONTROL TO FITNESS FOR PURPOSE

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The environmental analysis industry sprang up in the 1970s and 1980s from a recognition that pollution had reached levels that were unacceptable. In other words, the industry developed as a reaction to an urgent situation. The urgency required quick action, and most of the analytical methods developed for environmental analysis were developed in this context of urgency. The community developed isotope dilution methods in this context.

A need for urgent action precludes thoughtful consideration of the situation. Further, in these early days, some external assurance that data were useful was necessary. In much the same way a child needs its parents for education, the early environmental industry needed externally-imposed structure. As the industry matured, the need for strict external structure diminished, just as it does for a child. Yet, unlike the analogy with a child, the strict external structure often remains in the environmental analysis industry.

Today's challenges require something more. Today, the industry has grown sophisticated enough to know its needs. The performance of an analytical method now needs to be defined by the particular requirements of a program. The concept of fitness-for-purpose was introduced in the mid-1990s. In 1997, the EPA called for a performance-based measurement system. The EPA's definition of a performance-based measurement system was laid out in the Federal Register that year (62 FR 52098, October 6, 1997). Per that document, the EPA defined a performance-based measurement system as a "set of processes wherein the data quality needs, mandates or limitations of a program or project are specified, and serve as criteria for selecting appropriate methods to meet those needs in a cost - effective manner. "

While these concepts sound good, no one in 1997 had yet laid out what they meant in specific terms, particularly for isotope-dilution methods. Dr. Tondeur began working that year to determine what fitness-for-purpose and a performance-based measurement system would mean for isotope dilution methods. Soon enough, he realized that no one (himself included) had defined well the technology. He also realized that, even a decade after he wrote the first isotope-dilution method (EPA Method 8290), no one fully understood the technology. The fundamental technology is not HRGC/HRMS. Rather, isotope-dilution is the key technology.

Understanding what the key technology really is, Yves started asking questions about whether the control samples that make sense for other technologies make sense for isotope dilution. He also examined how to best assess performance for isotope-dilution analyses, given the questions regarding control samples. Another decade passed, with various experiments leading the way to better ways to assess performance in isotope-dilution assays. Yves' company, Analytical Perspectives, introduced new control samples and modified others. It also introduced numerous enhancements to improve the quality of measurements.

Over the past few years, Analytical Perspectives – now SGS Analytical Perspectives – introduced a new tool, built upon the concepts, controls, and enhancements developed since 1997. This new tool, the performance-based criteria analysis (PBCA), utilizes information obtained during the analysis of each and every sample. Using this information, the PBCA generates holistic assessments of method performance in an analyte- and sample-specific manner. The PBCA begins with the specification by the end data user of its needs. Based on those needs, the appropriate method and method parameters can then be chosen.

The PBCA provides accurate and meaningful feedback about method performance. Using detection limits and measurement uncertainty, the PBCA clearly indicates whether lab performance is satisfactory, given the end data user's needs. When the feedback indicates that performance is not acceptable, feedback is also provided about how to address the performance problems.

With this tool, the power of isotope-dilution can be fully utilized to meet the needs of the end data user. A truly meaningful perspective is gained on the impact of laboratory performance on the end results. A lab no longer demonstrates performance solely by jumping through static hoops defined by recovery limits. A lab demonstrates performance by demonstrating that the end result is not adversely impacted by lab performance, in a very specific and well-defined manner.

The end goal of fitness for purpose comes to fruition by using this tool to provide an assessment of lab performance relevant to a particular measurement's purpose. Knowing the purpose of the measurement, a lab can determine clearly whether its performance was adequate for the measurement at hand, rather than assuming so because it meets static criteria defined years ago.