



# ITRC PROJECT PROPOSAL:

## Environmental Molecular Diagnostics

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**Call for Proposals Topical Area**

- Site characterization and remediation (CHAR/REM)

**Problem Statement**

Over the last decade, molecular biological and chemical diagnostic techniques (or tools) have been developed for applications in medicine, defense and various industrial applications. These techniques consist of both laboratory and field methods. Some of these techniques have already been adapted for use in environmental restoration, and others are expected to enter the market place in the near future. The most important of these “environmental molecular diagnostics” (EMDs) are various molecular biological tools (MBTs) that can identify and quantify key microorganisms (taxonomy) and their genes (function), and compound specific isotope analysis (CSIA), a chemical method that measures the relative abundance of different isotopes. These techniques are combined in this proposal because they are both innovative aspects of a common platform – the direct and unique measurement of specific biological and chemical processes directed to reducing uncertainty regarding natural attenuation mechanisms and the performance of remediation technologies.

These diagnostic techniques are becoming increasingly powerful and standardized methods are being developed, so their use is increasing rapidly. Using these tools can improve the management of contaminated sites in several ways. The results can be used to assess when natural attenuation as a stand-alone remedy is sufficient, or whether enhancements such as chemical amendments or bioaugmentation are necessary. However, these techniques can also be misused and misinterpreted, and there are limitations that regulators and practitioners need to understand. Ultimately the regulatory community will be the gatekeeper of the acceptance and impact of EMDs, but consultants and regulatory staff lack objective information about how to apply EMDs in consistent and effective ways that maximize their utility in site design, management and resolution of contaminated sites.

As the use of these diagnostics grows, regulators are increasingly being faced with plans that include EMD analyses, or with recommendations for site management based on their results. However, many regulators and practitioners lack objective information about how to apply molecular diagnostics in consistent and effective ways that maximize their usefulness. Many regulators have little comfort or experience with these techniques, and can benefit from objective guidance on their appropriate uses, the factors to consider when reviewing sampling or analysis plans, and proper interpretations of the results.

There is clearly a growing need for technical information and training on the EMDs that are currently available, including the appropriate uses of these diagnostics and their strengths and limitations. Objective technical and regulatory guidance should foster the appropriate uses of these tools and help regulators faced with requests to use them to better understand a site, or to make decisions based on the results of EMD analyses. This proposed team meets the ITRC mission of developing information resources and breaking down barriers to the acceptance and use of technically sound innovative solutions to environmental challenges through an active network of diverse professionals.

## Proposed Scope to Address Problem

The proposed EMD team will summarize the fundamental background and current status of available EMDs. The team will provide objective guidance on the best practices for using EMDs and for evaluating, applying and interpreting the results of EMDs. Technical and regulatory guidance should lead to greater use and confidence in these diagnostics, and help site managers faced with major decisions about site design, management and resolution.

The team includes some of the leading vendors, consultants and academic researchers in this area and the resulting guidance will draw on their collective experiences. In addition, recent efforts, such as several SERDP and ESTCP projects designed to test environmental molecular diagnostic tools and to develop guidance for their use, will provide a solid technical basis for the proposed team's efforts and ensure that the resulting product is current and credible. The resulting guidance should expand the use of EMDs and improve decision-making. EMDs may be helpful in several ways, such as deciding whether or not to terminate a pump and treat system, assessing the effectiveness of *in situ* chemical oxidation treatment, optimizing an *in situ* bioremediation system, determining when natural attenuation is sufficient as a stand-alone remedy or even determining when site closure is appropriate.

Questions the Environmental Molecular Diagnostics (EMD) Team will address include:

- What are the capabilities of the various EMD techniques available?
- Which EMDs are applicable to specific contaminants and environmental matrices?
- How can EMDs improve site management (including characterization, remedy selection, treatment optimization and resolution)?
- What should managers be aware of when reviewing the use and interpretation of EMD results?
- To what degree have EMDs been used to date and what are future growth trends?
- What are the strengths and limitations of each of the EMDs?

Further, there is no standardization of EMD's, so there are many questions regarding a particular test:

- What data quality objectives must be met to support actionable data?
- How can the EMD data be validated?
- What is the significance of the various "tweaks" available for each EMD method?

## Targeted Users

The primary users for this project are state and federal regulatory agencies that select, review and monitor remedial actions at contaminated sites. DOE and DOD site managers and technical consultants will also benefit directly from the project information in the day-to-day management of remedial systems, and when completing periodic performance evaluations of operating remedies.

Secondary users include responsible parties and members of affected communities who will benefit from independent and unbiased information on the performance evaluation of remedial systems they own or that provide protection for their communities. In addition, the resulting guidance should be useful to consultants and environmental practitioners, who would ultimately produce better work products to streamline the regulatory review process.

ITRC conducted a survey in December 2008 of the (then) 48 member states. There were 41 qualified respondents. Several topic areas related to this proposal were rated as high priority issues. These topics were site characterization, which fifteen (15) states listed as a high priority; groundwater contamination, which 10 states listed as a high priority; DNAPL, which 5 states listed as a high priority; and remedial technology, which 4 states listed as a high priority. This survey demonstrates that there is a national recognition of a need that this project can fulfill, which has a high potential for impact in several different areas of regulatory concern.

## Summary of Deliverables

There will be three distinct deliverables for this team:

- A document which answers the questions listed in the scope.  
The document will provide users a consistent set of answers to the questions proposed in the scope of work given above and will explore and document a wide variety of case studies that exemplify various ways in which EMD's have been applied.
- An interactive website that provides users with guidance on the above-listed questions, case studies and references that support the guide.  
While the document needs to be stand-alone and available in a hard-copy format, there are several potential benefits to developing the guidance as an interactive web-site. The proposed project team will do so as the second deliverable (taking cues from, and expanding upon, the ITRC's Enhanced Attenuation of Chlorinated Organics: Electronic Resource Guide).
- Internet-based training  
The final deliverable will be an Internet training program, which will be a means for teaching the public to utilize the guidance.

The team will also consider a live course if funds and time permit.

## Impact

The project will produce many tangible tools which will make the use of EMD's more accessible and understandable to stakeholders. The appropriate use of EMDs should reduce the uncertainty associated with traditional methods for characterizing sites and for making regulatory decisions related to the fate and transport of groundwater contaminants. This project will provide users a basis to critically assess the validity of the interpretations of EMD test results, so that regulators and other stakeholders can feel more confident in their own use of EMDs. In addition the use of EMDs should support the goal of 'greener' or more sustainable cleanups by reducing the energy needed for cleanups.

The hardcopy of the guidance will provide users a tangible product to reference and to learn from, while the on-line version will allow users to learn more interactively. Specifically, they will learn that EMDs are not routine tools but are meant to answer specific questions. They will learn which EMDs can answer which questions and what can reasonably be expected from such analyses. They will learn how those answers can help regulators and other stakeholders assess questions of safety and can help consultants assess remedy potential or effectiveness. These two points clearly illustrate that the function of this project is to increase both environmental protection and remedial technology effectiveness while increasing the cost-effectiveness of monitoring and characterization activities. This team is intended to increase the appropriate use of these innovative techniques, as well as the comfort level of potential users, and thereby benefit the entire ITRC community.

## Project Schedule

### **Initial Poster (January – March 2010)**

This poster is intended to market the team's mission and to be used as a starting point for collecting the case studies required below. This poster will be exhibited at the 2010 ITRC Spring meeting. This poster will be done in parallel with other efforts identified below.

### **Information Collection (January – June 2010)**

Technical information and case studies will be collected to establish that a particular EMD is supported by field applications that include defensible data which document its proper application, expected performance, and reliability. The team will use this information to evaluate whether an EMD has enough information to be considered a potential application in the environmental industry. For EMDs that have adequate information and application, a more detailed evaluation will occur in the technology/methodology overview phase of the project.

### **Technology/Methodology Overview (July – October 2010)**

Each EMD application will be evaluated based on the team's criteria to determine if the technology and methodology of the application has a credible potential to achieve performance claims. The overview will assess the current state of the art and any lessons learned from prior uses of these techniques. The overview will also summarize the existing EPA guidance on CSIAs as well as guidance on MBTs that is currently in development through SERDP- and ESTCP-funded projects that will be completed by 2010.

### **Technical and Regulatory Guidance (October 2010-August 2011)**

A technical and regulatory guidance document will compile the information from the case studies and the technology/methodology overview phase of the team's research in preparing a guidance document aimed at assisting regulators faced with reviewing and interpreting EMD uses. The guidance document will summarize for regulators and consultants the appropriate questions and criteria needed to make supportable decisions when developing and reviewing applications for use. The guidance document will also summarize several critically-reviewed case studies that demonstrate a wide variety of EMD applications and discuss both their attributes and limitations. The technical and regulatory guidance will provide an ITRC customer with tools to use EMDs to make better decisions than they could make either without EMD's or without an independent, critical assessment of EMDs. This guidance will be initially produced as a hard-copy document but will subsequently be developed into an interactive web-site.

The Technical & Regulatory Guidance will be coupled with the development of internet training for two specific purposes:

1. Inform the State POCs of the use and usability of the guidance prior to ITRC concurrence review
2. Teach ITRC Customers how the guidance should be used.

### **Final Poster & Related Marketing Material (August - September 2011)**

The team will prepare visual and concise narrative material to be used to introduce the environmental industry to the project, the results and the products of ITRC. Team members will be encouraged to make presentations at conferences to distribute the information developed by the team.

## **Proposed Personnel**

### **Potential Team Membership / Needs**

Robert Mueller from the New Jersey Department of Environmental Protection is the proposed team leader for this project. Mr. Mueller served as co-chair of ITRC from 2004 - 2008. Prior to that, he was a team leader from 1998 - 2004, during which he lead four teams that produced six documents and internet trainings. One project, phytoremediation, also produced classroom training. Mr. Mueller holds an M.S. in Environmental Science from Rutgers University and has worked for the NJDEP for 28 years. Mr. Mueller works in a research group within NJDEP and has had many research projects investigating the fate and transport of contaminants in the subsurface. As ITRC co-chair Mr. Mueller has had the opportunity to interact with federal funding partners, industry affiliates, and the general membership. This will greatly facilitate team building and help to insure that the project moves forward smoothly.

We anticipate that states will be very interested in this project because these EMD technologies are being proposed at sites throughout the country. Indeed, a brief introduction of this topic on a POC call generated a lot of interest. Besides the participation of NJDEP's Mr. Mueller, we already have commitments from the following states that have identified team members:

- Oregon: Ann Levine
- Wyoming: Bonnie Pierce
- Alabama: Larry Bryant

Both Ms. Levine and Dr. Pierce have extensive backgrounds in bioremediation and a strong interest in this team. In addition, we have spoken with California, West Virginia, Michigan and Florida. All are in the process of identifying potential team members. We will provide specific names at the Spring meeting. Each of these states recognize that EMDs are being employed at sites and agree that an ITRC document and training will facilitate their understanding and proper application of these new tools.

The team was initiated by a group of the leading vendors and consultants in this area. These key team members have committed time and funds to work on this effort, and will ensure that the information is

accurate and up-to-date. The origins of this Team effort have been in development for over two years within the industrial sector. These individuals and their affiliations include : 1) Dr. Stephen Koenigsberg (ENVIRON), who was a co-founder of Regenesis and an expert on *in situ* remediation and environmental diagnostics, and has been working with EMDs for almost a decade; 2) Greg Davis President of Microbial Insights and staff members (Dora Ogles, Dr. Brett Baldwin), who have been leaders in the field of MBTs for over a decade; 3) Drs. Robert Pirkle and Patrick McLoughlin (Microseeps), who provide innovative analytical services including CSIA, and were key members of the recent effort - with EPA and industry representatives - to develop guidance on CSIA for environmental uses; and 4) Brian Sogorka (LANGAN), who had a 30-year career at the NJDEP and has since entered into consulting.

In addition, the SERDP/ESTCP program will participate in this project. Dr. Hans Stroo, who works with SERDP/ESTCP and has contributed to this project proposal; he will be a key member of the team. Carmen Lebron (U.S. Navy), and Dr. Erik Petrovskis (Geosyntec), principal investigators for SERDP and ESTCP projects designed to develop guidance on molecular biological tools have also committed to participate on the team. Dr. Frank Loeffler (Georgia Technical Institute) has agreed to assist the team as well. We also have contacted the staff at U.S. DOE, who have expressed support for this project. We will also work with the USEPA to include their expertise, and identify other appropriate academic participants.

This proposal was developed by a group composed of Mr. Mueller and Ms. Levine representing state regulators, as well as the team members identified above. The team already includes several experts in this area, and as the team builds, that expertise will certainly grow. Further, we will then seek to include the perspectives not only of state regulators and consultants but also of federal regulators, responsible parties, public stakeholders and other interested stakeholders.

### **Proposed In-Kind/Direct Project Funding**

#### **Related Work:**

This project is an ideal complement to a host of ITRC documents. The following is a list of ITRC teams that have addressed subjects that will benefit from the proper use of EMDs:

- Bioremediation of DNAPLs
- Diffusion/Passive Samplers
- In Situ Bioremediation
- In Situ Chemical Oxidation
- MTBE and Other Fuel Oxygenates
- Permeable Reactive Barriers
- Remediation Process Optimization
- Sampling Characterization and Monitoring
- Vapor Intrusion

Further, this project is intended to encourage implementation of USEPA works such as:

- "Evaluation of the Role of *Dehalococoides* Organisms in the Natural Attenuation of Chlorinated Ethylenes in Ground Water" (EPA/600/R-06/029)
- "Monitored Natural Attenuation of MTBE as a Risk Management Option at Leaking Underground Storage Tank Sites" (EPA/600/R-04/1790)
- "A Guide for Assessing Biodegradation and Source Identification of Organic Groundwater Contaminants Using Compound Specific Isotope Analysis (CSIA)" (EPA 600-R-08-148)

This project will also draw on the science and engineering driven by the "SERDP and ESTCP Expert Panel Workshop on Research and Development Needs for the Environmental Remediation Application of Molecular Biological Tools". The final report of that workshop was released in October 2005 and is available at <http://www.estcp.org>.