

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES
2. AMENDMENT/MODIFICATION NO. PR-CI-09-10466/0001	3. EFFECTIVE DATE 11/16/09	4. REQUISITION/PURCHASE REQ. NO. PR-CI-09-10466	5. PROJECT NO. (if applicable)
6. ISSUED BY Environmental Protection Agency Cincinnati Procurement Operations Division 26 W. Martin Luther King Drive Cincinnati, OH 45268		7. ADMINISTERED BY (If other than item 6) CODE Not Applicable.	

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) To All Offerors/Bidders.	(✓)	9A. AMENDMENT OF SOLICITATION NO. PR-CI-09-10466
		9B. DATED (SEE ITEM 11) 10/28/09
		10A. MODIFICATION OF CONTRACT/ORDER NO.
		10B. DATED (SEE ITEM 13)
CODE	FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended, is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning 1 copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

(✓)	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor is not, is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

The purpose of this amendment is to correct the numbering in the Performance Work Statement. Section 3.4 and 3.5 have been updated to reflect the correct sequential numbering. Changes are indicated with bold type.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) MARK E. CRANLEY	
15B. CONTRACTOR/OFFEROR <i>(Signature of person authorized to sign)</i>	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA <i>(Signature of Contracting Officer)</i>	16C. DATE SIGNED

AMENDMENTS TO THE SOLICITATION

1. The attachment entitled "PERFORMANCE WORK STATEMENT" has been modified. The text is as follows:

PERFORMANCE WORK STATEMENT
TECHNICAL AND REGULATORY SUPPORT FOR THE DEVELOPMENT
OF CRITERIA/LIMITS FOR WATER MEDIA (TOXICOLOGY EMPHASIS)

1.0 INTRODUCTION

1.1 Background

The mission of the United States Environmental Protection Agency's Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act includes protecting the public health from the adverse effects of pollutants (e.g., chemicals and pathogens) in media such as ground and surface waters, drinking water, wastewater, sewage sludge, and sediments. In fulfillment of this mission, OW's Office of Science and Technology (OST) develops effluent guidelines, human health criteria, health advisories, maximum contaminate level goals, and limits for pollutants in various water media.

1.2 Purpose of Contract

The purpose of this contract is to provide technical and regulatory support services to the Health and Ecological Criteria Division (HECD) in OST for the development of human health criteria, health advisories, maximum contaminant level goals, and pollutant limits. This support includes activities such as conducting literature search and literature reviews; conducting hazard, exposure and risk assessments; performing statistical analyses; evaluating pollutants selected for review by the United States Environmental Protection Agency (EPA); assessing the potential impact of criteria on sensitive populations; preparing criteria documents; preparing health advisories, preparing technical guidance documents, preparing technical support documents for regulatory requirements; preparing the index of references for proposed and final regulations; summarizing comments on proposed regulations; and arranging and conducting workshops.

2.0 GENERAL TASKS

2.1 The Contractor shall furnish all facilities, materials, equipment, and necessary professional, technical, and support personnel in support of the effort delineated below. The initial submission of all documents shall be in draft form for EPA review and comment. Required revisions will be provided to the Contractor by EPA for incorporation into a final document.

2.2 The Contractor shall possess or have access to appropriate equipment/software to perform mathematical modeling and statistical analyses in support of criteria development.

2.3 The Contractor shall develop documents and data bases using EPA standard software (e.g. Word, Excel, Lotus Notes and Power Point), as specified in a work assignment. Software documentation shall be accessible to the EPA Work Assignment Manager (WAM) and other persons authorized by the EPA Project Officer (PO).

2.4 The Contractor shall possess or have access to a laboratory that can analyze pollutants (e.g., organic pollutants using gas chromatography/mass spectrometry, metals using atomic absorption) in water media (e.g., wastewater, surface water, drinking water, and sewage sludge), as specified in a work assignment.

2.5 The Contractor shall prepare a Quality Assurance Project Plan (QAPP) for work assignments that require environmental measurements or the use of secondary data.

2.6 The Contractor shall handle all Toxic Substances Control Act (TSCA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) confidential business information (CBI) in accordance with the clauses in Section H of this contract. The Contractor shall also comply with the security requirements found in the FIFRA Information Security Manual and the TSCA Confidential Business Information Security Manual.

2.7 The Contractor shall provide information that will be used by EPA for quick responses and analyses of options, issues, and policy decisions as they relate to the tasks in this Performance Work Statement (PWS). Quick responses are those that require completion in one to seven days, or as specified in a work assignment. EPA will review results of all Contractor analyses, and make a final determination with regard to program objectives and policy decisions.

2.8 The Contractor shall comply with the requirements for studies and rulemaking records contained in authorities such as the Administrative Procedures Act, the Paperwork Reduction Act, the Clean Water Act, OMB Circular A-1 30 for management of Federal Information Resources, and the Federal Rules of Appellate Procedure (Rules 16 and 17, 28 U.S.C. Appendix).

2.9 The Contractor shall perform the specific tasks in the PWS in accordance with the appropriate EPA risk assessment guidance and science policy guidance (e.g., guidance on the development of a risk reference dose for a non-carcinogen), as indicated in a work assignment.

3.0 SPECIFIC TASKS

3.1 Human Health

3.1.1 The Contractor shall prepare summaries of peer-reviewed literature on toxicity, clinical and epidemiological endpoints, as specified in a work assignment. Each summary shall discuss the test protocol (e.g., endpoints measured; test animal; the number, sex, and species of animals in the control group and dosing groups; the method, frequency, and duration of dosing; and sacrifice and pathology data), and shall evaluate the test protocol with respect to EPA published test requirements under TSCA and FIFRA. Similarly, for epidemiological studies, the Contractor shall evaluate the protocol, type of study (e.g., case-controlled, community, prospective, or retro prospective), analyses, and conclusions according to Bradford-Hill criteria.

3.1.2 The Contractor shall prepare screening analyses that display and compare all available data for a pollutant, and build on the summaries in subsection 3.1.1. If required by the work assignment, these analyses shall be presented as electronic data bases.

The Contractor shall be able to develop figures, tables or other graphics to display the array of available data for a pollutant building on the summaries in subsection 3.1.1. The requested data arrays may be requested to assist in risk communication, facilitate the dose-response assessments and improve the transparency of health effects support documents.

The Contractor shall collect data, prepare screening analyses and participate in the development of screening methodologies for chemical contaminants that will be useful in the development of future Contaminate Candidate Lists (CCLs), prioritizing resources, and in identifying emerging contaminants.

3.1.3 The Contractor shall be familiar with the EPA Toxics Release Inventory data base, and other Federal and private release and exposure data bases. The Contractor shall document the methodology, assumptions, and rationales used in the analyses. EPA will make the final decision concerning a finding based on the appropriate technical information and Agency policy.

3.1.4 The Contractor shall prepare, evaluate, and revise health effects documents. These documents provide information on the criteria that protect human health from exposure to a chemical in water media. The Contractor shall document the methodology, assumptions, and rationales used for this task. EPA will make the final decision concerning a health effects document based on the appropriate technical information and Agency policy.

A health effects document for a chemical shall address, as specified in a work assignment: (1) physical and chemical properties of the chemical; (2) occurrence in water and other media, (3) environmental fate and transport; (4) toxicokinetics; (5) human exposure to the chemical; (6) health effects in animals and humans; (7) mechanisms of toxicity; (8) magnitude of carcinogenic and non- carcinogenic effects including the relative source contribution ; (9) risk characterization, and (10) any other areas set forth in the work assignment. Examples of documents the Contractor shall prepare include the documents that support CCL Regulatory Determinations, documents for six-year review of regulations which may be considered for revision if new data suggests revision, drinking water regulations and development of human health criteria for ambient water. Standard EPA formats for these documents will be provided by the EPA PO/WAM. During the development of a health effects document, the Contractor shall conduct literature reviews to augment the file of references provided by the EPA WAM with other references.

3.1.5 The Contractor shall prepare, evaluate, and revise health advisories for chemicals. A health advisory provides information that public health officials use to help determine control priorities for pollutants in water media (e.g., drinking water, surface water, and sediments) as well as general information for the public. The Contractor shall document the methodology, assumptions, and rationale used to prepare, evaluate, and revise a health advisory. EPA will make the final decision concerning a health advisory based on the appropriate technical information and Agency policy.

A health advisory for a chemical shall address: (1) general information and properties of the chemical; (2) occurrence and environmental fate and transport; (3) pharmacokinetics; (4) health effects in animals and humans; (5) quantification for carcinogenic and non-carcinogenic effects, (6) treatment technologies; (7) analytical methods; (8) risk characterization; and (9) any other areas set forth in the work assignment. During the development of a health advisory, the Contractor shall conduct literature reviews to augment

the file of references provided by the EPA WAM with other references.

3.1.6 The Contractor shall provide technical support during the preparation, evaluation, and revision of hazard, exposure, or risk assessment/characterization techniques or methodologies for human health protection. This includes, among other things, providing technical support during the development of methodologies used to develop human health criteria for various water media (e.g., surface water and drinking water). The Contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning a technique or methodology based on the appropriate technical information and Agency policy.

3.1.7 The Contractor shall provide on a rapid response basis analyses of human health risk assessment guidelines, results of human health risk assessments, and treatment technology practices and procedures. This includes, among other things, analysis of the impact of criteria on sensitive populations, and analyses of dose response data, pharmacokinetics data, exposure data, and bioaccumulation data.

3.1.8 The Contractor shall prepare, evaluate, and revise technical guidance documents for chemicals. These documents provide information on the principles for criteria development (e.g., minimum data requirements and exposure assumptions). The Contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning a technical guidance document based on the appropriate technical information and Agency policy.

3.1.9 The Contractor shall evaluate "raw" data generated from a toxicity study. The raw data will be provided by the EPA WAM. The evaluation shall include a complete description of the protocol used to gather the data; analyses of effects observed including tabulation of all observations and pathology for individual test animals; evaluation of biological significance of endpoints according to EPA published guidelines or other technical documents; statistical analyses of significance of observations; and conclusions as to existence of treatment-related effects and their implications for human health. If required by a work assignment, the Contractor shall engage and convene a panel of experts to conduct a review of tissue preparations and slides from the test to characterize and classify lesions observed.

3.1.10 The Contractor shall conduct Monte Carlo or similar statistical uncertainty analyses of toxicity or epidemiological endpoint incidence data or exposure data, as specified in a work assignment. These analyses shall be completed in accordance with EPA published guidance.

The Contractor shall model the dose response data from cancer and noncancer studies using benchmark dose, categorical regression or other similar methodologies developed by the Agency as specified in a work assignment. These analyses shall be completed in accordance with EPA published guidance for the methodology used.

3.1.11 The Contractor shall provide analyses of food consumption patterns and associated intake of pollutants for the U.S. population. These shall include frequency and amount of specific foods consumed by sex, age, and geographical locations. Data to be analyzed shall include data from Federal data collection efforts, State collection efforts, and other available studies. Similarly, the

Contractor shall provide analyses of exposure data from the Center for Disease Control National Health and Nutrition Examination Survey (NHANES) data base and the EPA National Human Exposure Assessment Survey data base.

3.1.12 All of the above tasks and deliverables shall be completed in accordance with EPA published guidelines (e.g., carcinogenic risk assessment guidelines, reproductive risk assessment guidelines, developmental risk assessment guidelines, neurotoxicity guidelines, exposure assessment guidelines, risk characterization policy guidelines, benchmark dose guidelines or Monte Carlo guidelines).

3.2 Sewage Sludge

3.2.1 The Contractor shall provide technical support during the preparation, evaluation, and revision of procedures for selecting pollutants-of-concern in sewage sludge that is used or disposed of, and shall provide technical support during the evaluation of those pollutants. The Contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning the procedure used to select pollutants-of-concern and the evaluation of those pollutants based on the appropriate technical information and Agency policy.

3.2.2 The Contractor shall conduct exposure pathway risk assessments for pollutants in sewage sludge applied to the land, placed on a surface disposal site, or fired in a sewage sludge incinerator. The pathways evaluated for each use or disposal practice shall be the pathways evaluated for each practice when the Standards for the Use or Disposal of Sewage Sludge (40 CFR Part 503) were developed, and other pathways specified in a work assignment. Results of the risk assessments will be used by EPA to develop limits for pollutants in the sewage sludge.

3.2.3 The Contractor shall prepare, evaluate, and revise technical support documents for a standard for the use or disposal of sewage sludge. These documents contain the rationales for the requirements (i.e., general requirements; pollutant limits; management practices; operational standards; and frequency of monitoring, record keeping, and reporting requirements) in a sewage sludge use or disposal standard (see 40 CFR Part 503).

The Contractor shall document the methodology, assumptions, and rationale used for this task. EPA will make the final decision concerning a technical support document based on the appropriate technical information and Agency policy.

3.3 Statistics Support

3.3.1 The Contractor shall have statistical analyses capabilities to perform analyses of environmental data for toxicological pollutants to derive descriptive or interpretative statistics.

3.3.2 The Contractor shall conduct laboratory/field studies to support the development of water quality criteria, maximum contaminant level goals, sewage sludge pollutant limits, and other program requirements, as specified in a work assignment.

3.4 Administrative Record Support

The Contractor shall provide data and documentation to be used by EPA in the

analysis of technical issues and options for proposed and final regulations, as specified in a work assignment. Deliverables under this task include data summaries, technical reports, option papers, issue papers, and public and confidential records and files. The Contractor shall describe and document the data gathering activities; display, characterize, and interpret the data and information collected; obtain copies of any references used; and describe all methodologies used. Written reports and corresponding records and files shall be prepared and organized, indexed, and cross-referenced in an administrative record for a proposed or final regulation so that the analyses and conclusions can be reproduced based on the information in the administrative record for a proposed or final regulation.

3.5 Rule making support

The Contractor shall index and summarize public comments on proposed regulations. Using information provided by EPA (i.e., typically public comments submitted in response to a proposed regulation and information collection requests), the Contractor shall prepare an index of issues in the information provided by EPA, and cross reference those issues to the public comments. For technical issues assigned by the EPA WAM, the Contractor shall, based on knowledge of the appropriate rule making, prepare draft technical responses to the issues in the public comments including all relevant citations to the administrative record. EPA will review the draft technical responses, and prepare the final responses to the comments.

3.6 Preparation of outreach materials

3.6.1 The Contractor shall develop outreach materials in support of the tasks in this PWS. These materials include brochures, presentation boards, slide shows, fact sheets, pamphlets, posters, videos, INTERNET layouts, and models. The materials shall be developed for use in media events (e.g., press releases). In addition, the Contractor shall provide materials for distribution at presentations. All materials shall be provided in accordance with the limitations set for in the Section H clause titled "PRINTING (EPAAR 1552.208-70)." The Contractor shall provide a draft of all materials for approval by the EPA WAM, and shall prepare the final materials based on the EPA WAM's comments on the draft materials. For print products, the Contractor shall provide a camera-ready copy and a disk copy in a disk format that enables the material to be loaded onto the INTERNET. This task only shall be done in direct support of the technical requirements in this PWS.

3.6.2 The Contractor shall provide, when included in a work assignment, a complete and accurate translation of foreign language articles cited in a criteria document, a health advisory, or a technical guidance document. Translations shall be performed by experienced scientific translators well-versed in chemical, toxicological, statistical, biomedical, or epidemiological terminology. The Contractor shall insure that there are no terminology or language usage ambiguities that make interpretation and analysis of the findings difficult. No translations shall be made without the written approval of the Project Officer.

3.7 Arranging and conducting workshops

The Contractor shall provide support in arranging workshops, conferences, training sessions, and public meetings, and obtaining appropriate individuals

to address various issues. Meeting support shall be limited in scope, and shall cover only those meetings required to address the requirements in this PWS. The Contractor shall arrange travel only in accordance with the authority and limitations in the Section H clause titled "APPROVAL OF CONTRACTOR TRAVEL" (i.e., use of contract funds to reimburse travel is strictly limited to logistical support for speakers, scientists, and experts who contribute directly to the requirements of a task in this PWS). The Contractor shall support EPA by: (1) providing information for meeting agendas, including typing the agendas; (2) preparing drafts of technical information for use in preparing briefing materials; (3) identifying and inviting speakers and experts to participate in a workshop; (4) arranging for meeting space when Government space is not available; (5) arranging for the appropriate audio-visual equipment; (6) providing advance announcements, registration support, visual aid preparation, logistical support, case study preparation, interactive and role-playing activity development; and (7) preparing the minutes of the meeting, including the meeting results, for approval by the EPA PO/WAM.