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Supplemental
Programmatic Quality Assurance Project Plan
For Work Assignment 5-83
Technical Support for the Hydraulic Fracturing Drinking Water Assessment

Issued Under
Contract No. EP-C-08-015

Organization Implementing the Project:
The Cadmus Group, Inc.
100 5th Avenue, Suite 100
Waltham, MA 02451

To support the
National Center for Environmental Assessment (NCEA)
Office of Research and Development (ORD)
U.S. Environmental Protection Agency (EPA)

September 12, 2013

GROUP A: PROJECT MANAGEMENT

A1. Title and Approval Sheet

Programmatic Quality Assurance Project Plan Supplement
For Work Assignment 5-83:
Technical Support for the Hydraulic Fracturing Drinking Water Assessment

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Approving Officials:	Approval Dates:
/s/ Caroline Ridley Contracting Officer's Representative, ORD-NCEA, EPA	9/27/13 Date
/s/ Cheryl Itkin Director of Quality Assurance, ORD-NCEA, EPA	9/27/13 Date
/s/ Chi Ho Sham Program Manager and Senior Technical Advisor, The Cadmus Group, Inc.	9/27/13 Date
/s/ Jonathan Koplos Project Manager, The Cadmus Group, Inc.	9/27/13 Date
/s/ Donna Jensen QA Lead Reviewer, The Cadmus Group, Inc.	9/27/13 Date

Effective Date: September 12, 2013

Disclaimer

EPA does not consider this internal planning document an official Agency dissemination of information under the Agency's Information Quality Guidelines because it is not being used to formulate or support a regulation or guidance or to represent a final Agency decision or position. This planning document describes the overall quality assurance approach that will be used during the research study addressed under work assignment 5-83 (WA 5-83). Mention of trade names or commercial products in this planning document does not constitute endorsement or recommendation for use.

The EPA Quality System and the Hydraulic Fracturing Drinking Water Assessment (EPA Office of Research and Development Quality Assurance Category 1)

EPA requires that all data collected for the characterization of environmental processes and conditions are of the appropriate type and quality for their intended use. This is accomplished through an Agency-wide quality system for environmental data. Components of the EPA quality system can be found at http://www.epa.gov/quality/. EPA policy is based on the national consensus standard ANSI/ASQ E4-2004 *Quality Systems for Environmental Data and Technology Programs: Requirements with Guidance for Use*. This standard recommends a tiered approach that includes the development and use of Quality Management Plans (QMPs). The organizational units in EPA that generate and/or use environmental data are required to have Agency-approved QMPs. Programmatic QMPs are also written when program managers and their Quality Assurance (QA) staff decide a program is of sufficient complexity to benefit from a QMP, as was done for the EPA's *Study of the Potential Impacts of Hydraulic Fracturing (HF) on Drinking Water Resources*. The HF QMP describes the program's organizational structure, defines and assigns QA and quality control (QC) responsibilities, and describes the processes and procedures used to plan, implement, and assess the effectiveness of the quality system. EPA's HF QMP is then supported by project-specific QA project plans (QAPPs). The EPA QAPPs provide the technical details and associated QA/QC procedures for the research projects that address questions posed by EPA about the HF water cycle and are described in the *Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources* (EPA/600/R-11/122 dated November 2011[1]). The results of the research projects will provide the foundation for EPA's 2014 HF report.

This Cadmus project-level Programmatic Quality Assurance Program Plan (PQAPP) supplements Cadmus' contract-level PQAPP and complements EPA's National Center for Environmental Assessment's (NCEA's) "Quality Assurance Project Plan (QAPP) for Data and Literature Evaluation for the EPA's Study of the Potential Impacts of Hydraulic Fracturing (HF) on Drinking Water Resources" (Revision 1, September 2013).

This PQAPP Supplement provides information concerning efforts to collect, compile, and analyze data; organize and identify literature and contributed comments relevant to the Hydraulic Fracturing Drinking Water Assessment (HFDWA); evaluate and track data, literature, reports, and other documents considered for use in the HFDWA; and provide technical subject matter and writing assistance for the HFDWA.

[1] http://www2.epa.gov/sites/production/files/documents/hf_study_plan_110211_final_508.pdf

A2. Table of Contents

List of Acronyms

CFR	Code of Federal Regulations
COR	Contracting Officer's Representative
DQOs	Data Quality Objectives
EPA	U.S. Environmental Protection Agency
HERO	Health and Environmental Research Online
HF	Hydraulic Fracturing
HFDWA	Hydraulic Fracturing Drinking Water Assessment
NCEA	National Center for Environmental Assessment
NGO	Non-Governmental Organization
NTRL	National Technical Reports Library
ORD	Office of Research and Development
PQAPP	Programmatic Quality Assurance Project Plan
QA	Quality Assurance
QAPP	Quality Assurance Project Plan
QAO	Quality Assurance Officer
QC	Quality Control
QMP	Quality Management Plan
SAB	Science Advisory Board
SDWA	Safe Drinking Water Act
TRID	Transport Research International Database
U.S.C.	United States Code
WA	Work Assignment

A3. Distribution List

U.S. Environmental Protection Agency

Cathy Basu, Contract Officer
Caroline Ridley, Contracting Officer's Representative
Stephen LeDuc, Alternate Contracting Officer's Representative
Nancy Parrotta, Project Officer
Cheryl Itkin, Director of Quality Assurance, ORD-NCEA, EPA

The Cadmus Group, Inc.

Dr. Chi Ho Sham, Program Manager and Senior Technical Lead
Dr. Jonathan Koplos, Project Manager
Anne Jaffe Murray, Assistant Project Manager
Gene Fax, Quality Assurance Manager
Donna Jensen, Quality Assurance Lead Reviewer
Patricia Hertzler, Task Leader
John Martin, Task Leader
Dr. Glen Boyd, Task Leader
Shari Ring, Task Leader
Dr. Mary Ellen Tuccillo, Task Leader

A4. Project/Task Organization

Under Contract Number EP-C-08-015, The Cadmus Group, Inc. (Cadmus) developed a Programmatic Quality Assurance Project Plan (PQAPP) covering the entire contract. As described by EPA's Requirements for Quality Assurance Project Plans (EPA QA/R-5, available at www.epa.gov/quality, March 2001, page 8), a PQAPP "addresses the general, common activities of a program that are to be conducted at multiple locations over a long period of time." Because this plan may not cover all aspects of all work assignments issued under the contract, EPA may require supplements to the contract-level PQAPP upon issuance of the statements of work for applicable work assignments. Work Assignment 5-83 (WA 5-83) issued under Contract No. EP-C-08-015 requires Cadmus to prepare a PQAPP Supplement to ensure the quality of secondary data collected and used under this work assignment. This PQAPP Supplement describes how Cadmus will collect, compile, and analyze data to organize and identify literature and contributed comments relevant to the Hydraulic Fracturing Drinking Water Assessment (HFDWA); evaluate and track data, literature, reports, and other documents considered for use in the HFDWA; and provide technical subject matter and writing assistance for the HFDWA.

Appendix A identifies the quality assurance (QA) elements that are addressed in the PQAPP for this contract, the elements that are addressed in this PQAPP Supplement, the elements that are addressed in the work plan for this work assignment, and the elements that are not addressed because they are not relevant to this work assignment.

From Cadmus' perspective, the QAPP developed by EPA's National Center for Environmental Assessment (NCEA), "Data and Literature Evaluation for the EPA's *Study of the Potential Impacts of Hydraulic Fracturing (HF) on Drinking Water Resources"* (NCEA Data and Literature Evaluation QAPP), Revision 1 (September 2013) is incorporated into this Cadmus PQAPP Supplement by reference, with critical content also included in this PQAPP Supplement for ease in referral. In the event that the NCEA Data and Literature Evaluation QAPP is revised, Cadmus will modify QA activities and this document accordingly. If there are any conflicts among the documents, Cadmus will work with NCEA to resolve the conflicts.

A4.1 Roles and Responsibilities

Dr. Jonathan Koplos will serve as the Project Manager for WA 5-83 and as the Task Leader for certain work assignment tasks. Dr. Koplos is responsible for the day-to-day management of the work assignment and for the technical quality of the products to be provided. He will provide administrative and technical leadership throughout the duration of the work assignment, and will direct all activities of the project team, including the development of techniques and methods to meet the work assignment's objectives. Dr. Koplos will be responsible for maintaining the official, approved PQAPP Supplement and ensuring Cadmus personnel working on the work assignment receive the most updated version of the PQAPP Supplement and are trained on the procedures and requirements described herein.

Dr. Chi Ho Sham, a Cadmus Senior Vice President, will serve as the Program Manager

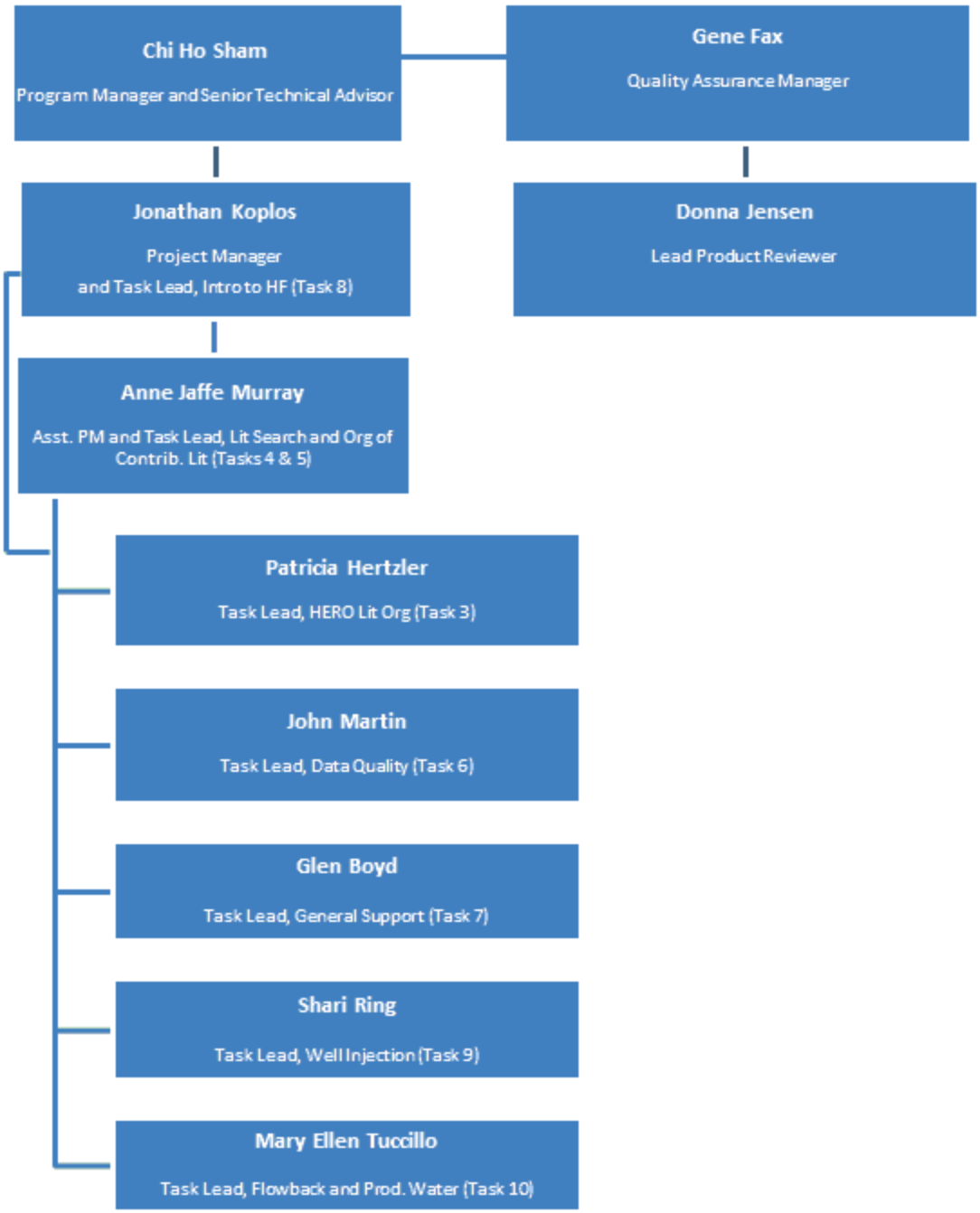
for this contract and will provide contractual and senior technical oversight for this work assignment. Dr. Sham has more than 20 years of experience with regulatory development and implementation in support of the Safe Drinking Water Act (SDWA) and is an expert in the development and implementation of new drinking water and underground injection control regulations.

As described in the PQAPP for this contract, the QA Officer (QAO) may assign a senior technical reviewer based on that person's field of expertise, education, and experience as they relate to the objective of the project. For Work Assignment 5-83, Donna Jensen will serve in this capacity as the QA Lead Reviewer, sometimes referred to as the Lead Product Reviewer. Ms. Jensen has no direct operational function on the project, which preserves her independence in performing reviews of the products of this work assignment and for ensuring the that QA activities are carried out.

Ms. Anne Jaffe Murray, a Cadmus Senior Associate, will serve as Assistant Project Manager for this work assignment and the lead for Tasks 4 and 5. Additional Task Leaders on this work assignment include Ms. Patricia Hertzler, Mr. John Martin, Dr. Glen Boyd, Dr. Mary Ellen Tuccillo, and Ms. Shari Ring.

Exhibit 1 presents the organization and reporting and communication lines for the tasks addressed by this PQAPP Supplement.

Exhibit 1: Project Organization



A5. Problem Definition/Background

In the 2010 Congressional Appropriations report, Congress asked EPA to prepare a study of the potential impacts of HF on water resources. EPA researched and prepared the draft study plan; the EPA Science Advisory Board (SAB) completed its review of the draft study plan in July 2011. EPA published a study "progress report" in December 2012 (http://www.epa.gov/hfstudy/pdfs/hf-report20121214.pdf), with the final report scheduled for completion in late 2014.

The HFDWA is anticipated to draw upon a broad group of data and information sources, including peer-reviewed journal articles, federal and state reports, research conducted by EPA as part of the HFDWA, publications from non-governmental organizations (NGOs), and the HF industry. Under this work assignment, Cadmus will search for and compile data and information from the scientific literature, provide expertise on the impacts of HF on drinking water resources, develop and maintain a working knowledge of EPA's Health and Environmental Research Online (HERO) database, assist in the management and upload of all HFDWA literature citations to the HERO database, compile and organize public comments regarding HF and drinking water supplies, track and record data quality evaluation information for compiled data and information sources, and provide technical writing and editing to assist EPA in the development of the HFDWA.

A6. Project/Task Description

WA 5-83 includes eight technical tasks (Tasks 3 - 10) that involve the collection and use of secondary data, data management, and/or modeling. The remaining tasks involve either administrative activities (Task 1: Work Plan, Progress Evaluations, and Monthly Progress Reports), HERO database training (Task 2: Develop and Maintain Working Knowledge of the HERO Database), or editorial contributions (Task 11: HFDWA Technical Editing Assistance) that do not involve data gathering, data management, or modeling, and to which this PQAPP Supplement does not apply. In addition to the QA procedures described in this PQAPP Supplement, Cadmus will follow the QA procedures in the NCEA Data and Literature Evaluation QAPP, which is incorporated by reference. It is not anticipated that the generation of new environmental measurements (i.e., primary data) will be required under this work assignment. Cadmus will revise this PQAPP Supplement if the generation of primary data is required.

The eight technical tasks to which this PQAPP Supplement applies vary in terms of their need for use of secondary data, data management, and modeling:

- Task 3 involves the compilation of, development of uniform citations for, and uploading to the HERO database of the approximately 2,000 citations related to HF, which have already been obtained by EPA. EPA will provide the reference titles to Cadmus. At the direction of the EPA COR, those articles that have undergone peer review will be flagged as such by Cadmus. This task requires data management and

compilation of the reference citations in Microsoft® Excel (a model). Documentation of secondary data quality is not expected for Task 3, other than designation of peer-reviewed documents.

- Task 4 involves a literature search for additional data and information regarding the five areas of the HF water cycle: water acquisition, chemical mixing, well injection, flowback and produced water, and wastewater treatment and disposal. This work involves assessment of secondary data quality. Data management and modeling, compilation of the reference citations in Microsoft® Excel (a model), are also anticipated for this task.
- Task 5 involves the organization of data sources indicated in public comments that are submitted to Docket ID EPA-HQ-ORD-2010-0674. Relevant documents and data sources may also be submitted to EPA as a result of SAB meetings, workshops, stakeholder meetings, etc. This task involves data management and modeling (Microsoft® Excel). Documentation of secondary data quality is not expected for Task 5 other than possibly the designation of peer-reviewed documents.
- Task 6 involves evaluating and tracking the quality of data sources in the context of the NCEA Data and Literature Evaluation QAPP. EPA has indicated this document is likely to be revised and Cadmus will adopt and incorporate all applicable updates to this support effort. This task will involve assessment of secondary data, data management, and modeling.
- Tasks 7, 8, 9, and 10 involve technical writing in four different subject areas for the HFDWA. While these tasks involve reading and extracting information from the relevant literature, they may also involve data management. The data and information used in the technical writing conducted under these tasks will be obtained from data sources identified and evaluated under Tasks 3, 4, 5, and 6 of this work assignment; thus, further documentation of secondary data quality is not anticipated for those data and information. However, it may be necessary to conduct literature searches and assess secondary data quality of materials generated through those searches under these Tasks 7, 8, 9, and10 if the literature work conducted under Tasks 3, 4, 5, and 6 is not completed in time for the writing conducted under Task 7, 8, 9, and 10. Since conceptual models are anticipated for each chapter of the HFDWA, Tasks 7, 8, 9, and 10 will also involve development of flow charts or other graphics to represent an environmental system and/or HF process (in contrast to traditional mathematical modeling).

A7. Quality Objectives and Criteria

All of the analyses that Cadmus will perform for this work assignment will be on data relating to the five steps of the water cycle of HF or related topics, including: drilling for oil and gas; hydraulic fracturing; petroleum engineering; surface water and groundwater chemistry; environmental- and geo-chemistry; chemical fate and transport chemistry; toxicology; surface hydrology; groundwater and vadose zone hydrology; groundwater-surface-water interactions; and geology. These data will be obtained directly from EPA and through literature searches, database searches, recommendations from the SAB and the EPA hydraulic fracturing workshop participants, and/or public comment submissions and may originate from peer-reviewed journal articles, federal and state reports, publications from NGOs, and the HF industry.

As discussed in Section A6, work assignment tasks addressed by this PQAPP Supplement involve documenting information that can be used to assess the quality of secondary data (Tasks 3-5), evaluating secondary data quality (Tasks 4 and 6, and perhaps Task 7-10), and/or preparing technical written materials using secondary data that have been evaluated under other tasks of this work assignment (Tasks 7-10).

Cadmus will assess data quality in the context of the requirements documented in the NCEA Data and Literature Evaluation QAPP. The NCEA Data and Literature Evaluation QAPP describes the procedures used to select data sources from the literature to help ensure that the project meets EPA's data quality objectives. In addition, Cadmus will document data to allow evaluation in the context of these requirements, and, for technical writing tasks, Cadmus will use secondary data meeting these requirements.

- ***Accuracy.*** Statistically, accuracy is a measure of the overall agreement of a measurement to a known value. It includes a combination of random error (precision) and systematic error (bias) components of both sampling and analytical operations. Since accuracy comprises data precision and bias, see the two bullets below for a discussion regarding how accuracy will be assessed for this work assignment.

- ***Precision.*** Precision is the measure of agreement among repeated measurements of the same property under identical or substantially similar conditions, and is calculated as either a range or standard deviation.

- ***Bias.*** Bias is the systematic or persistent distortion of a measurement process that tends to yield an erroneous outcome or incorrect representation of the system being described.

  Precision and bias are often associated with chemical analysis data (e.g., chemical concentrations in environmental media), but can be applied to other environmental information. To accomplish this, Cadmus will consider available information regarding peer-reviewed sources or established governmental or international agencies to ensure the referenced materials and data meet the needs of EPA and this

work assignment. Although no specific numerical criteria for accepting or rejecting data/information based on Precision and Bias have been established (given the broad range of subjects for which data gathering will be performed), Cadmus will confer with the EPA COR to confirm whether specific numerical Data Quality Objectives (DQOs) are required to address Accuracy, as established by Precision and Bias. If numerical DQOs are required, these will be developed and documented in the written Literature Search Protocol that is to be delivered to EPA prior to implementation of the literature searches. In lieu of numerical DQOs, use of EPA's Assessment Factors to evaluate the quality of data sources, as described in Section B9 of this PQAPP Supplement as taken from the NCEA Data and Literature Evaluation QAPP, serve as qualitative DQOs.

While reviewing the various data either obtained from the literature or provided by EPA for analysis, Cadmus will make note of any apparent errors in the accuracy of the data in the various sources.

- ***Completeness.*** Statistically, completeness is a measure of the amount of valid data needed to be obtained from a system that enables a true representation of that system. Assembling a complete set of valid information for the broad range of research topics associated with this work assignment might involve the use of data sources that do not meet the primary criterion of peer review. Even in this case, a complete set of valid data may not be possible given the proprietary nature of certain HF processes and the large number of research topics. Cadmus will rely primarily on peer reviewed data sources and established governmental or international agencies for information on the five areas of HF water cycle and related topics. Since some of the data required for this WA may not be available from EPA, peer-reviewed sources, federal and state reports, NGOs, or the HF industry, Cadmus will confer with the EPA COR to confirm which additional data sources meet their needs for Completeness. Thus, it is anticipated that a set of representative, rather than necessarily complete, data can be obtained.

- ***Representativeness***. Representativeness is in most cases a qualitative term used to express the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition. Representativeness is closely related to completeness. In using data and information from peer reviewed data sources, federal and state reports, NGOs, or the HF industry, Cadmus will balance the need for completeness with that of representativeness. Cadmus will work with the EPA COR to determine whether the data and information used in this WA meets the criteria of representativeness.

- ***Comparability.*** Comparability is a qualitative term that expresses the measure of confidence that one data set can be compared to another and can be combined for the decision(s) to be made. Where feasible, comparability will be assured by using standardized units in any data reduction processes. Conversion of original data from

one set of units to another will be documented.

- ***Sensitivity.*** Sensitivity is the capability of a method or instrument to discriminate between measurement responses representing different levels of the variable of interest. Cadmus does not anticipate any problems with sensitivity in its sources of data.

A8. Special Training and Certification

Cadmus will ensure staff working on this work assignment exhibit competency to meet the requirements outlined in the performance work statement for this work assignment. While special training and certification related to the technical details of hydraulic fracturing is not required, Cadmus will assign specific task work to individuals with relevant expertise in the five stages of the water cycle of hydraulic fracturing (water acquisition, chemical mixing, well injection, flowback and produced water, and wastewater treatment and disposal) as well as the fields of drilling for oil and gas; hydraulic fracturing; petroleum engineering; surface water and groundwater chemistry; environmental- and geo-chemistry; chemical fate and transport chemistry; toxicology; surface hydrology; groundwater and vadose zone hydrology; groundwater-surface-water interactions; and geology.

Cadmus will ensure staff participating in tasks that require proficiency in the use of EPA's HERO database will attend EPA's one-hour initial training session for new HERO database users or receive internal training from Cadmus staff that completed this EPA training. Cadmus will also ensure applicable personnel are proficient in organizing reference materials and preparing Microsoft Excel files in a format suitable for uploading citations into the HERO database. Additionally, because several tasks of this work assignment require thorough knowledge of the NCEA Data and Literature Evaluation QAPP, staff will be required to participate in internal meetings to review the requirements of this QAPP Supplement and any revisions.

A9. Documentation and Records

All personnel working on this project will receive this PQAPP Supplement as well as the NCEA Data and Literature Evaluation QAPP, which is incorporated by reference. If there are revisions to the PQAPP Supplement or the NCEA QAPP, updates will be posted on Cadmus' internal SharePoint site for this project, and all personnel will receive notification of the updates by electronic mail to ensure that they have the most recent version.

Throughout this work assignment, Cadmus will provide draft and final reports to EPA in electronic and hard copy formats. Cadmus will discuss the computer file formats to be used for reference compilations, word processing, spreadsheet development, database management, and graphics with the EPA COR prior to file preparation. Electronic files required for upload to the HERO database will be prepared in formats suitable for integration into HERO. For Tasks 7-10, Cadmus will utilize the "Cite while you write" functionality of Endnote X6 which will embed

references in the chapters and link them back to EPA's HERO database. While Endnote X6 will be supplied by Cadmus, EPA will provide Cadmus with the LitCiter plug-in for Endnote that will be supported by and compatible with the HERO database. Cadmus will follow any specific file-naming conventions provided by EPA, if needed.

GROUP B: DATA GENERATION AND ACQUISITION

B1. Sampling

Sampling is not relevant to this work assignment; therefore, a sampling design process is unnecessary for this PQAPP Supplement.

B2. Sampling Methods

This section does not apply this PQAPP Supplement because no direct measurements are anticipated for this work assignment.

B3. Sample Handling and Custody

This section does not apply to this PQAPP Supplement because no direct measurement/experiments are anticipated for this work assignment.

B4. Analytical Methods

This section does not apply to this PQAPP Supplement because no direct measurement/experiments are anticipated for this work assignment.

B5. Quality Control

This section does not apply to this PQAPP Supplement because no direct measurement/experiments are anticipated for this work assignment.

B6. Instrument/Equipment Testing, Inspection, and Maintenance

This section does not apply to this PQAPP Supplement because no direct measurement/experiments are anticipated for this work assignment.

B7. Instrument/Equipment Calibration and Frequency

This section does not apply to this PQAPP Supplement because no direct measurement/experiments are anticipated for this work assignment.

B8. Inspection/Acceptance of Supplies and Consumables

This section does not apply to this PQAPP Supplement because no direct measurement/experiments are anticipated for this work assignment.

B9. Non-direct Measurement Data

The following list of secondary data sources is taken from the NCEA Data and Literature Evaluation QAPP. This list identifies the types of data sources that may be obtained during this work assignment:

- Peer-Reviewed Literature
  a. Journal publications
  b. Reports, white papers, fact sheets, and similar publications developed by federal and state agencies
  c. Reports on industry-sponsored research, including white papers, fact sheets, and similar publications
  d. Symposium/conference proceedings
- Non Peer-Reviewed Literature
  a. Non peer-reviewed government documents
     i. Regulations (Code of Federal Regulations (CFR) or state)
     ii. Statutes (United States Code (U.S.C.) or state)
     iii. Court cases
     iv. Congressional documents
     v. Hearing proceedings
     vi. Contractor reports
     vii. Government reports
  b. Other types
     i. Workshop proceedings, including the EPA-sponsored Hydraulic Fracturing Technical Workshops presented in the spring of 2010
     ii. Master's/Ph.D. theses
     iii. Reports and white papers from private companies, associations, or NGOs
     iv. Conference presentations or papers
     v. Textbooks
     vi. Maps
     vii. Publications with unknown peer-review status
- Unpublished Data
  a. Online databases
  b. Personal communications
  c. Unpublished manuscripts
  d. Unpublished government data

The search strategy includes the following elements:

1) Assemble data and literature from the following sources:
   a. Recommended by the SAB, including from
      i. Review of EPA's *Draft Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources*
      ii. Consultation on EPA's *Progress Report: Potential Impacts of Hydraulic Fracturing on Drinking Water Resources - December 2012*
   b. Recommended by stakeholders during EPA-organized workshops and roundtables
   c. Submitted in response to Federal Register Notice (Docket ID No. EPA-HQ-ORD-2010-0674)
   d. Literature reviews relevant to one or more of the hydraulic fracturing water cycle stages previously conducted by EPA or contractors to EPA
   e. Literature already accessed by EPA researchers to date
   f. Literature produced by EPA researchers under the Study Plan
2) Import the citations into the HERO database and document the source using 'tags' (e.g., SAB, EPA HF workshops, etc.). [2]
3) Complement the aforementioned sources of data and information using several new search efforts.
   a. Search of online, scientific databases plus federal, state, and stakeholder websites for recent materials (articles, technical papers, reports, and abstracts) to update literature assembled in (1) and materials addressing topics not covered by sources listed in (1), but potentially relevant to the HFDWA. These databases and websites could include, but will not be limited to:
      i. Databases: Web of Science, Google Scholar, TRID, OnePetro, NTRL, PubMed
      ii. Federal websites: Department of Energy, Department of Interior, Department of Transportation
      iii. State websites: CA, MT, ND, WY, CO, UT, NM, SD, OK, TX, AK, LA, MI, KY, OH, NY, PA, WV, MD
      iv. Stakeholder websites: National Academy of Sciences, Susquehanna River Basin Commission, The Nature Conservancy, Environmental Defense Fund, Resources for the Future, Union of Concerned Scientists, National Resources Defense Council, American Petroleum Institute, Center for Sustainable Shale Development, America's Natural Gas Alliance
   b. Import the citations into the HERO database and document the source using 'tags' identified by EPA and as available in HERO

[2] Health and Environmental Research Online (HERO) is an online repository of scientific studies and other references used to develop EPA assessments. It was created and is maintained by ORD's National Center for Environmental Assessment. It is somewhat similar to an Endnote Web database, except that access to the repository is controlled and secure. 'Tags' are a way in HERO to keep track of additional information concerning the references cited in an assessment. For the HFDWA tags will be used to track (1) the source a reference was retrieved from and (2) conformance to quality criteria. A reference can be tagged in as many ways as is appropriate (i.e., tags are not mutually exclusive).

During our analysis of the data, Cadmus will make note of any apparent errors in the accuracy of the data. In some cases, Cadmus may supplement the data with other publicly available data (e.g., determining the distance of a well to a nearby surface water body by using locational information provided by the company and topographic maps from the United States Geological Survey).

Data collected by Cadmus will be evaluated for acceptability based on the five assessment factors (soundness, applicability and utility, clarity and completeness, uncertainty and variability, and evaluation and review). The following discussion and questions that will be used in the assessment of data source quality are excerpted from EPA's Science Policy Council's Assessment Factors Handbook[3]. These questions also appear in the NCEA Data and Literature Evaluation QAPP, and will serve as the basis for Cadmus' execution of Task 6. The assessment factors and related questions below will also serve as data source quality assessment tools under Task 3, Task 4, and Task 5 of this work assignment.

"Example questions that could be raised by the consideration of each of the assessment factors for various types of information are provided below. Given the very general nature of these assessment factors, the agency felt that a compilation of such illustrative questions would most clearly convey the intended nature and breadth of the assessment factors, and how they would be reflected in an evaluation of various types of information. However, the applicability of these factors depends on the individual situation, and the EPA retains discretion to consider and use factors and approaches on a case-by-case basis that may differ from the illustrative considerations presented below.

Soundness: *The extent to which the scientific and technical procedures, measures, methods or models employed to generate the information are reasonable for, and consistent with, the intended application.*

a) Is the purpose of the study reasonable and consistent with its design?
b) To what extent are the procedures, measures, methods, or models employed to develop the information reasonable and consistent with sound scientific theory or accepted approaches?
c) How do the study's design and results compare with existing scientific or economic theory and practice? Are the assumptions, governing equations and mathematical descriptions employed scientifically and technically justified? Is the study based on sound scientific or econometric principles?
d) In the case of a survey, have the questionnaires and other survey instruments been validated (e.g., compared with direct measurement data)? Were checks for potential errors made during the interview process?
e) How internally consistent are the study's conclusions with the data and results presented?

[3] USEPA. 2003. A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information. Science Policy Council, EPA 100/B-03/001, June 2003.

Applicability and Utility: *The extent to which the information is relevant for the agency's intended use.*

a) How useful or applicable is the scientific or economic theory applied in the study to the agency's intended use of the analysis?

b) How relevant are the study's purpose, design, outcome measures and results to the agency's intended use of the analysis (e.g., for a chemical hazard characterization)?

c) Are the domains (e.g., duration, species, exposure) where the model or results are valid useful to the agency's application?

d) How relevant is the study to current conditions of interest? For example, in the case of a survey, are conditions likely to have changed since the survey was completed (i.e., is the information still relevant)? Is the sampled population relevant to the agency's current application? How well does the sample take into account sensitive subpopulations?

Clarity and Completeness: *The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, sponsoring organizations and analyses employed to generate the information are documented.*

a) To what extent does the documentation clearly and completely describe the underlying scientific or economic theory and the analytic methods used?

b) To what extent have key assumptions, parameter values, measures, domains and limitations been described and characterized?

c) To what extent are the results clearly and completely documented as a basis for comparing them to results from other similar tests?

d) If novel or alternative theories or approaches are used, how clearly are they explained and the differences with accepted theories or approaches highlighted?

e) Is the complete data set accessible, including metadata, data-dictionaries and embedded definitions (e.g., codes for missing values, data quality flags and questionnaire responses)? Are there confidentiality issues that may limit accessibility to the complete data set?

f) In the case of a modeling exercise, have the definitions and units of model parameters been provided? To what extent have the procedures for applying the model been clearly and completely documented? How available and adequate is the information necessary to run the model computer code?

g) To what extent are the descriptions of the study or survey design clear, complete, and sufficient to enable the study or survey to be reproduced?

h) Have the sponsoring organization(s) for the study/information product and the author(s) affiliation(s) been documented?

i) To what extent are the procedures for quality assurance and quality control of the data documented and accessible?

Uncertainty and Variability: *The extent to which the variability and uncertainty (quantitative and qualitative) in the information or in the procedures, measures, methods or models are evaluated and characterized.*

a) To what extent have appropriate statistical techniques been employed to evaluate variability and uncertainty? To what extent have the sensitive parameters of models been

identified and characterized?

b) To what extent do the uncertainty and variability impact the conclusions that can be inferred from the data and the utility of the study? What are the potential sources and effects of error and bias in the study design?

c) Did the study identify potential uncertainties such as those due to inherent variability in environmental and exposure-related parameters or possible measurement errors?

Evaluation and Review: *The extent of independent verification, validation and peer review of the information or of the procedures, measures, methods or models.*

a) To what extent has there been independent verification or validation of the study method and results? What were the conclusions of these independent efforts, and are they consistent?

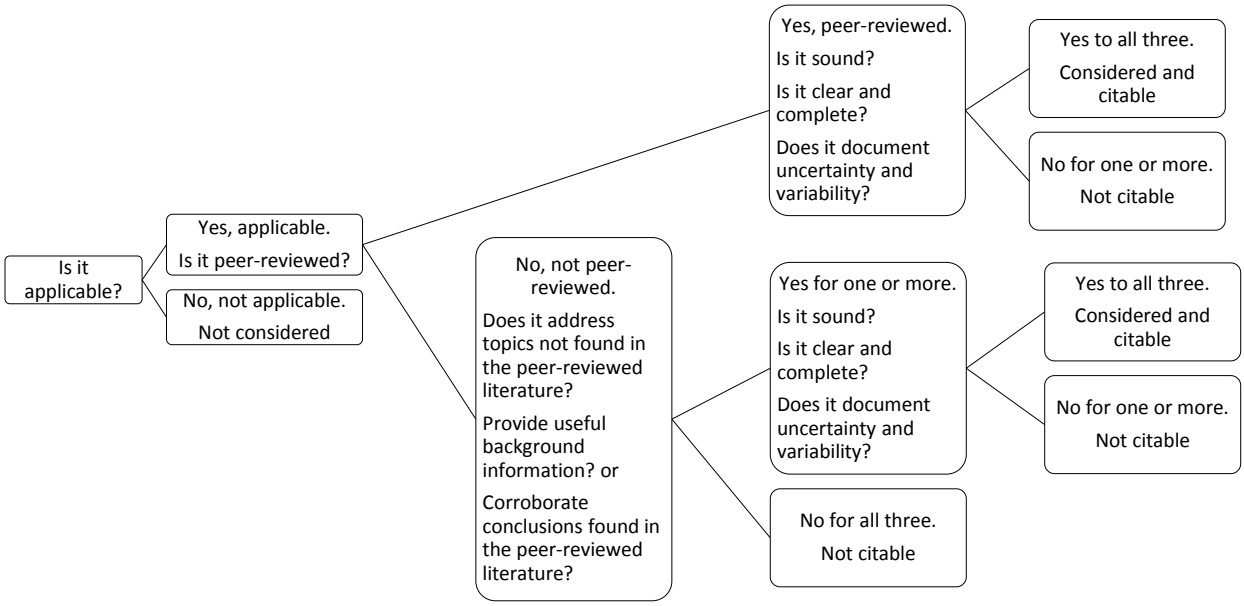
b) To what extent has independent peer review been conducted of the study method and results, and how were the conclusions of this review taken into account?

c) Has the procedure, method or model been used in similar, peer reviewed studies? Are the results consistent with other relevant studies?

d) In the case of model-based information, to what extent has independent evaluation and testing of the model code been performed and documented?"

Exhibit 2 presents a flow chart from the NCEA Data and Literature Review QAPP, which indicates how data sources will be evaluated based on EPA's Assessment Factors and whether a source is deemed to be citable for the HFDWA.

Exhibit 2. Flow Chart for Data Source Evaluation



B10. Data Management

This section of the PQAPP Supplement describes how secondary data will be managed. This PQAPP Supplement addresses data retrieval, transmittal, reduction, analysis, tracking, and storage. As noted in A6 above, Tasks 3-10 require data management efforts (depending upon the technical direction issued). Data management for this work assignment will involve the following processes:

B10.1 Data Retrieval

Cadmus recognizes the importance of ensuring, before conducting analyses, that the applicable data are reliable and directly applicable to the technical tasks in this work assignment. For tasks that involve retrieving data from databases, Cadmus will ensure that the data are not corrupted or damaged. If tasks on this work assignment involve retrieving data from existing databases or other sources of environmental data, Cadmus' approach is to:

- Specify the data retrieval objectives.
- Identify relevant existing databases.
- Specify and test the search and retrieval logic, and refine the logic as necessary.

- Verify (on a random or comprehensive basis) that the retrieval logic is being correctly executed.

- Document the results of each search, including the search criteria, the data and time of the search, and the identity of the specific data files searched.

B10.2 Data Transmittal

This work assignment will involve the transfer of data from various data sets. All data transmittals include potential threats to data quality. Cadmus will minimize the steps necessary to transfer data for each task and will document all data transfers, from raw data through final interpretation. When Cadmus receives data sets from EPA, a summary text document will be prepared and placed on the same internal Cadmus SharePoint site that describes when the data set was received, what that data set contains, and any relevant information concerning the contents of the file. Cadmus will retain an original, unchanged (read-only) version of the data set received from EPA and will perform all analyses, including any modifications to the data set (e.g., adding fields or modifying contents of existing fields) on a duplicate version of the data set. Cadmus will prepare a separate summary text describing all changes made to that data set relative to the original data set received from EPA.

B10.3 Data Reduction and Analysis

Data reduction is an irreversible transformation of data: examples include generation of summary statistics, rounding, etc. When data reduction occurs, Cadmus staff will maintain a copy of the original data set and will keep track of which version of the original data set was used. As in the case of simple data transformation, data reduction will receive QA appropriate to the use and importance of the data.

For tasks under WA 5-83 that involve data analysis, Cadmus will, in final reports submitted to EPA, describe analyses conducted on the datasets and address the reliability of computations. Cadmus will address potential problems in data analysis and how the potential problems might be solved.

B10.4 Data Tracking and Storage

It is essential to track data from generation to end use or storage to establish the quality of all data collected and used in this work assignment. Draft Cadmus documents associated with this project will be stored on Cadmus' internal SharePoint site. In implementing its SharePoint site, Cadmus has adopted protocols to ensure changes to working drafts are tracked and the backup systems are in place. Our document-handling protocols include the following:

- Implementation of a SharePoint infrastructure that follows industry standard best practices for security and is currently undergoing an SSAE16 audit for validation of those security measures.

- Frequent file saves and auto-recover features. Cadmus' QA training courses encourage participants to save their work frequently to Cadmus' SharePoint site or to a network drive. In addition, by default, all Cadmus computers are set up to take advantage of programs' auto-recover features. For example, Microsoft Word files create an auto-recover version every ten minutes and create an auto-recover version if the user quits the program closes without saving.

- Offsite access Cadmus' SharePoint site and networks. Staff working off-site have access to a secure Virtual Private Network (VPN), which allows them to access the firm's SharePoint site and network drives.

- Document flow and version control. Project leaders are able to identify the most up-to-date version of the document, compare the current version of a document to previous versions, identify who has modified the document, and revert to previous versions if needed.

- Daily backups of updated project files from SharePoint to tape and disk. The backup on disk is retained for seven days. Data backed up to tape is rotated weekly and sent off-site on a weekly basis for a one month rotation. In addition, data is backed up to tape and sent off-site on a monthly basis for a three-month rotation. A similar backup routine is in place for network drives.

- Tagging within SharePoint, which allows Cadmus staff to search for pertinent project files.

- Records of comments from the EPA COR, including indications of whether the comment has been implemented and whether there are any issues associated with the comment.

- Systems that allow Program Managers and project leaders to restrict access to sensitive project files.

Draft and final documents will be delivered to EPA electronically, which will allow management of the documents under NCEA's QA protocols (e.g., storage of the documents on NCEA's "O Drive").

B11. Special Requirements

B11.1 Model Specification

The contract-level PQAPP set out the general approach for model specification and model documentation. Under Tasks 3-6, Cadmus may employ Microsoft Excel spreadsheets to

compile, organize, and track literature citations for uploading to EPA's HERO database or for inclusion in technical write-ups under Tasks 7-10. Conceptual models will be developed under Tasks 7-10; however, these "models" are intended to represent potential environmental impacts and/or HF processes in a flow chart or other visual form, and do not constitute "modeling" in the mathematical or data management sense.

B11.2 Model Documentation

Where applicable, Cadmus will provide a complete model description and supporting information. This information will include descriptions and discussions of key model variables, model representation or reflection of reality, whether the model produces credible and logical output, and other information such as the history of model use, level of support by government agencies or other organizations, and whether the models have undergone evaluation and review. The goal of the descriptive information is to make the modeling assumptions and procedures transparent and reproducible for informed readers.

B11.3 QC Review and Style Guide

In matters of style, Cadmus' deliverables produced under this work assignment will follow the Agency's 2009 "Communication Product Standards" Stylebook or instructions from the EPA COR.

GROUP C: ASSESSMENT AND OVERSIGHT

C1. Assessment and Response Actions

All deliverables generated under this work assignment will be reviewed by Ms. Donna Jensen, the QA Technical Lead Reviewer for this work assignment, or her designee. In addition, Ms. Jensen or her designee will develop and oversee a protocol for uploading references or citations to the HERO database and tracking the upload status of each citation under Tasks 3-5.

For Tasks 3 and 4, the upload protocol will follow the process demonstrated by HERO support staff. Cadmus will prepare a written protocol for approval by the EPA COR. The approved protocol will be used by Cadmus staff to upload documents or citations to HERO. Cadmus' protocol will include implementation of a HERO tracking spreadsheet that will list the citation for each reference, the reference source tag (using the source tags on the HERO hydraulic fracturing project page), HERO ID number (if provided after upload), and the update outcome as follows:

- Successful update
- Error message – the error message will be described
- Resolution of message – the resolution of the error will be described (including formatting changes, referral of the error to HERO support staff, and others identified during implementation of the task).

Each Cadmus QA Reviewer will work closely on an on-going basis with a particular staff member who will be uploading documents to confirm the document or citation correctly uploaded to the HERO database and contains the proper source tag. The QA Reviewers will complete their review within one week following upload of the document or citation to HERO. The QA Reviewers will also monitor the tracking sheet weekly to ensure upload issues are resolved and to identify and implement steps that can be taken prior to upload to correct repeated error triggers. Cadmus will seek approval of the protocol from the EPA COR prior to conducting QA. Note that the HERO tracking spreadsheet will be used to develop the biweekly progress report under Task 3; the HERO tracking spreadsheet will undergo QA prior to submission to the EPA COR.

In addition, Cadmus will conduct literature searches under Task 4, and possibly under Tasks 7, 9, and 10. Cadmus will maintain a literature search record using a log sheet stored on Cadmus' internal SharePoint site. An example of the log is included in Appendix B. Information to be included in the research log includes details such as the Cadmus researcher, the site or Internet search engine, the search criteria, the total number of hits, the number of hits evaluated, and the Cadmus internal document identification number of documents retrieved for further review.

Cadmus will obtain the EPA COR's approval of this log sheet and appropriate search terms prior to conducting any literature searches. The Cadmus QA Reviewers will review each

of the retrieved documents and their checklist information investigated by each searcher. If the QA reviewer is satisfied with the outcome of his/her review after at least 20 references have been reviewed, he/she will review a minimum of 10 percent of the remaining literature searches prior to their upload to HERO and based on a weekly random selection of citations. Cadmus QA Reviewers will work with the searcher to resolve any issues and will contact the QA Technical Lead Reviewer or her designee about any concerns regarding the quality of the searches, which will result in additional training or reassignment.

Under Task 6, Cadmus staff will evaluate data, literature, reports, and other documents being considered for the HFDWA to ensure that they meet the quality standards set in the NCEA Data and Literature Evaluation QAPP (see Exhibit 2). Evaluations will be conducted based on a protocol approved by the EPA COR. The Cadmus Lead Product Reviewer will review the findings under this task on an ongoing basis, ensuring that QA is complete within a week of the review of the respective materials.

Under Tasks 7-10, draft deliverables will be reviewed by the Cadmus Lead Project Reviewer or her designee within a week of their completion.

In cases where quality issues are identified, the Cadmus Lead Product Reviewer will work with the project staff to resolve any issues and will contact the Cadmus QAO or Project Manager about any concerns regarding the quality, which will result in additional training or reassignment. In extreme cases or upon direction from the EPA Contracting Officer or Contracting Officer's Representative, the following individuals have authority to stop work on specific work assignment activities or the work assignment as a whole: the Cadmus Program Manager (Chi Ho Sham), the Cadmus Project Manager (Jonathan Koplos), the Cadmus QA Officer (Gene Fax), and the Director of Contracts (John Roman).

C2. Reports to Management

Cadmus will include QA activities in its monthly technical progress report to EPA and will provide verbal updates to the EPA COR, as necessary. QA reports will discuss limitations and constraints in the data sources, identify assumptions made about the information, and describe any information gaps and uncertainties.

In addition, during active phases of Tasks 3, 4, and 5, Cadmus will provide weekly or bi-weekly updates on progress and QA activities to the EPA COR. During active phases of Tasks 7-10, Cadmus experts will attend bi-weekly phone calls of the HFDWA technical writing group, reporting on progress and QA activities.

GROUP D: DATA VALIDATION AND USABILITY

D1. Data Review, Verification, and Validation

EPA requirements for QAPPs specify that there be two types of analysis for each data item:

1. **Process of *verification***. Verification confirms that the required QC acceptance criteria have been met.
2. **Process of *validation.*** Validation confirms that the requirements for a specific intended use have been fulfilled and determines whether specific user needs have been met.

These analyses typically apply to primary data such as field or laboratory measurements that are to be generated as part of a work assignment. However, the purpose of the PQAPP Supplement is to provide metrics to demonstrate that existing (i.e., secondary) data were generated under the same procedures that would apply to primary data generation. As applicable, these procedures include appropriate sampling designs; sample collection and handling procedures, including chain-of-custody requirements; analytical methods; QC processes; and equipment calibration, testing, inspection, and maintenance procedures. Data verification and validation for this work assignment requires the review team to:

- Evaluate data sources that contain data subject to the above QA procedures (i.e., data sources that contain environmental measurements) for adherence to data verification and validation requirements,
- Conduct senior internal review of all work products,
- Revise work products based on the EPA COR's technical direction, and
- Ensure that project DQOs are met.

Methods for verification and validation to be used during reviews of work products are described below.

D2. Verification and Validation Methods

The procedures for verification consist primarily of examination to ensure that the requirements of specific QC acceptance criteria are met. The goal of data verification is to ensure that the data are complete, correct, and conform to the pre-determined collection, transmission, and analysis methods or procedures. Data verification evaluates, through a set of criteria, how closely the project's data quality procedures were followed.

Cadmus will not perform any mathematical or statistical procedures that would determine whether data should be rejected or transformed before statistical analysis. Instead, the QA team will perform independent review of deliverables to ensure compliance with criteria set forth in Section A7 of this PQAPP Supplement. In addition, an inherent part of the technical work under

several tasks of this work assignment (primarily Tasks 4 and 6, and potentially Tasks 3 and 5) is the evaluation of data sources in terms of EPA's Assessment Factors (see Section B9 of this PQAPP Supplement). Cadmus will document data sources in terms of these Assessment Factors for those data sources that rank as citable based on the flow chart in Exhibit 1.

The Cadmus QAO or QA Technical Lead Reviewer assigned by the QAO is responsible for the verification and validation processes and will serve as an independent examiner. QA Technical Lead Reviewers are chosen by the QAO based on the individual's field of expertise, education, and experience as they relate to the objective of the project. A QA Technical Lead Reviewer performing verification or validation of data for a project has no direct operational function on the project. If independence and objectivity cannot be preserved by assigning an in-house reviewer, Cadmus will use an outside expert consultant.

D3. Reconciliation with User Requirements

Cadmus understands that the work products resulting from this work assignment will be used by EPA. To that end, Cadmus will strive to develop and prepare products of high quality that represent the issues facing EPA, which are developed in a manner and style appropriate to the target audience(s). The Agency will determine which information and reports generated under this work assignment are of adequate quality for decision making and may seek peer review or public comment.

Appendix A. QA Project Plan Elements for Work Assignment 5-83

QA Project Plan Element	Addressed in PQAPP	Addressed in this Project-Specific Supplement	Addressed in Work Plan	Not Relevant to this Work Assignment
Group A: Project Management Elements				
A1 Title and Approval Sheet	✓	✓		
A2 Table of Contents	✓	✓		
A3 Distribution List	✓	✓		
A4 Project/Task Organization	✓	✓	✓	
A5 Problem Definition/Background	✓	✓	✓	
A6 Project Task/Description		✓	✓	
A7 Quality Objectives and Criteria	✓	✓		
A8 Special Training/Certification		✓	✓	
A9 Documents and Records	✓	✓		
Group B: Data Generation and Acquisition				
B1 Sampling Process Design (Experimental Design)				✓
B2 Sampling Methods				✓
B3 Sample Handling and Custody				✓
B4 Analytical Methods				✓
B5 Quality Control				✓
B6 Instrument/Equipment Testing, Inspection, and Maintenance				✓
B7 Instrument/Equipment Calibration and Frequency				✓
B8 Inspection/Acceptance of Supplies and Consumables				✓
B9 Non-direct Measurements	✓	✓	✓	
B10 Data Management	✓	✓	✓	
Group C: Assessment and Oversight Elements				
C1 Assessments and Response Actions	✓	✓		
C2 Reports to Management	✓	✓		
Group D: Data Validation and Usability Elements				
D1 Data Review, Verification, and Validation	✓	✓		
D2 Verification and Validation Methods	✓	✓		
D3 Reconciliation with User Requirements	✓	✓		

Appendix B. Checklist for Literature/Sources

Sample research log for Internet search for data sources and literature.

Date	Researcher Initials	Site or Internet Search Engine	Search Criteria	Total Number of Hits	Number of Hits Evaluated	Documents Retrieved for Further Review (list doc id's)
For example:						
07/25/13	CS	Google Scholar	"marcellus" .AND. "mechanical integrity"	62	42	00001-00013