Supplemental Programmatic Quality Assurance Project Plan For Work Assignment 4-58:

National Hydraulic Fracturing Study Evaluation of Existing Production Well File Contents

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

Organization Implementing the Project:
The Cadmus Group, Inc.
57 Water Street
Watertown, MA 02472

To support the
Office of Science Policy (OSP)
Office of Research and development (ORD)
U.S. Environmental Protection Agency (EPA)

March 6, 2012

GROUP A: PROJECT MANAGEMENT

A1. Title and Approval Sheet

Programmatic Quality Assurance Project Plan Supplement
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Approving Officials:	Approval Dates:
(Signature on file) Chi Ho Sham Program Manager, The Cadmus Group, Inc.	3/5/2012 Date
(Signature on file) Glen Boyd WA 4-58 Project Manager, The Cadmus Group, Inc.	3/5/2012 Date
(Signature on file) Patricia Hertzler QA Lead Reviewer, The Cadmus Group, Inc.	3/5/2012 Date
/s/ Jeanne Briskin Contracting Officer's Representative, OSP/ORD, EPA	3/12/2012 Date
Stephen Watkins Digitally signed by Stephen Watkins DN: cn=Stephen Watkins, o=EPA, ou=OSP, email=watkins.stephen@epa.gov, c=US Date: 2012.03.06 09:59:28 -05'00' Stephen Watkins Quality Assurance Officer, OSP/ORD, EPA	3/6/2012 Date

Effective Date: March 6, 2012

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 quality assurance/quality control activities and technical requirements that will be used during the research study. EPA plans to publish the research study results in a draft report, which will be reviewed by the EPA Science Advisory Board. The final research report would be considered the official Agency dissemination. Mention of trade names or commercial products in this planning document does not constitute endorsement or recommendation for use.

A2. Table of Contents

A3. Distribution List

The Cadmus Group, Inc.

Dr. Chi Ho Sham, Program Manager
Dr. Glen Boyd, Project Manager
Gene Fax, QA Manager
Patricia Hertzler, QA Lead Reviewer

U.S. Environmental Protection Agency

Cathy Basu, Contract Officer
Jeanne Briskin, Contracting Officer's Representative
Nancy Parrotta, Project Officer
Stephen Watkins, OSP Quality Assurance Officer

A4. Project/Task Organization

Work Assignment (WA) 4-58 issued under Contract No. EP-C-08-015 requires Cadmus to prepare a supplement to the Programmatic Quality Assurance Project Plan (PQAPP) for this contract to ensure the quality of secondary data collected and used under this work assignment. This supplement describes how Cadmus will collect, compile, and analyze data to assess whether there may be impacts on drinking water resources due to hydraulic fracturing activities. Cadmus will also download and analyze well records from the FracFocus system to compile basic statistics and information on the use of chemicals in hydraulic fracturing fluids. This work assignment follows work begun under Cadmus WA 3-58. Therefore, this PQAPP is an update to the PQAPP submitted on November 4, 2011 under WA 3-58.

Exhibit 1 identifies the quality assurance (QA) elements that are addressed in the PQAPP for this contract, the elements that are addressed in this project-specific supplement, the elements that are addressed in the work plan for this work assignment (submitted on January 12, 2012[1]), and the elements that are not addressed because they are not relevant to this work assignment.

In addition to Cadmus' PQAPP supplement, the Environmental Protection Agency (EPA) has developed a Quality Assurance Project Plan (QAPP) dated January 4, 2012 that covers all activities on this project as a whole. From Cadmus' perspective, this EPA project-wide QAPP, *National Hydraulic Fracturing Study Evaluation of Existing Production Well File Contents: Quality Assurance Project Plan*, is incorporated into the Cadmus supplemental PQAPP. In addition to following the QA provisions in this supplemental PQAPP, Cadmus will follow applicable quality assurance provisions in the project-wide QAPP.

A4.2 Roles and Responsibilities

Glen Boyd will serve as the Project Manager for WA 4-58. Dr. Boyd 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.

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 4-58, Patricia Hertzler will serve in this capacity as the QA Lead Reviewer. Ms. Hertzler is the QA Manager for Dr. Boyd's Operating Group. She has no direct operational function on the project, which preserves her independence in performing reviews of the products of this work assignment or for ensuring the that QA activities are carried out.

[1] As discussed in Section A4.1 of the PQAPP prepared for this contract, some of the required elements of the QA plan are presented in work plans. Therefore the work plan is also included here by reference as a component of the project-specific supplement to the PQAPP.

A5. Problem Definition/Background

In the 2010 Congressional Appropriations report, Congress asked EPA to prepare a study of the potential impacts of hydraulic fracturing (HF) on water resources. EPA researched and prepared the draft study plan; the EPA Science Advisory Board completed its review of the draft study plan in July 2011. EPA intends to report initial study results in 2012, with follow-up results to be reported in 2014. Under this work assignment, Cadmus will conduct analyses that will be used by EPA in its development of these reports.

EPA's Office of Research and Development is leading a study to assess whether drinking water resources are impacted by HF. EPA contacted nine companies that conduct HF and obtained information from them regarding their practices. This information included the location of all wells for which the companies provided HF services during a one-year period. Under this work assignment, Cadmus will review and evaluate the well files obtained from the owners/operators of the wells that were hydraulically fractured in order to assess the key drinking water resources risk factors potentially related to well design, construction, operation, and maintenance.

A6. Project/Task Description

This work involves the collection and use of secondary data. If tasks are added that require additional QA procedures, Cadmus will develop appropriate procedures in consultation with the EPA COR at that time. In addition, Cadmus will follow the QA procedures in EPA's project-wide QAPP, which is incorporated by reference.

Background

Cadmus will review the files collected by EPA from nine production companies regarding initial baseline and follow-up water quality monitoring data collected from ground water resources, offset water wells, and nearby surface water resources. Cadmus will use available water quality data and information to assess potential impacts of HF on drinking water resources. Cadmus will also review the files for evidence of nearby neighbor complaints. In addition, Cadmus will assist with other tasks at the direction of EPA.

For each task described below and in the project-wide EPA QAPP, Cadmus will enter available information into an Excel worksheet along with a well identifier (e.g., American Petroleum Institute (API) well number and field name). The worksheet will include elements as defined in Appendix 3 of the project-wide EPA QAPP and the worksheet will be formatted in accordance with EPA instructions for compatibility with Access software for processing. Updated electronic files of the Excel worksheet will be sent periodically to the project team by courier mail (e.g., FedEx) or electronically for non-CBI well files as requested and instructed by EPA. Cadmus will perform this work and transmit deliverables at the direction of EPA and in accordance with the EPA project-wide QAPP and CBI plan.

Water Quality Monitoring (including Baseline and Follow-up Sampling)

Cadmus will review files for evidence of initial baseline and follow up water quality monitoring. Initial baseline monitoring refers to water quality samples collected before drilling or prior to fracturing of the production well. Follow-up monitoring refers to water quality samples collected after drilling, completion and fracturing of the production well. Cadmus will review files for monitoring information associated with ground water resources, offset water wells, and nearby surface water resources as described below.

Ground Water Resources

Cadmus will review files for evidence of identified ground water resources identified within the wellbore during the drilling and completion production well. Recorded data will include, if available, a description of the Underground Source of Drinking Water (USDW) (10,000 mg/L) and the depth to base of the USDW, available data and information about sampling date(s), analytical results (i.e., major anions and cations, organic chemicals, gases,

and other analyses), and documentation regarding quality assurance and quality control. In addition, files will be reviewed to record any other defined ground water resources (e.g. 3,000 mg/L) described as penetrated by the production well, the depth to the ground water resource base, and available water quality sampling results.

Offset Water Wells

Cadmus will review files for evidence of offset water wells near the production well. Recorded data will include, if available, the source of information, a description of the offset well (e.g., well ID, state of construction or abandonment), the location of the offset well (latitude, longitude, street address, other), total depth, and the available data and information about sampling date(s), analytical results (i.e., major anions and cations, organic chemicals, gases, and other analyses), and documentation regarding quality assurance and quality control.

Nearby Surface Water Resources

Cadmus will review files for evidence of surface water resources near the production well. Recorded data will include, if available, the source of information, a description of the surface water resource (e.g., lake, stream, other water resource), the location of the surface water resource, and available information about any sampling date(s), the sampling location (latitude, longitude, street address, other), analytical results (i.e., major anions and cations, organic chemicals, gases, and other analyses), and documentation regarding quality assurance and quality control.

Change in Ground Water or Surface Water Quality

Cadmus will review and evaluate files for water quality change by comparing available initial baseline and follow-up water quality data collected from ground water resources, offset water wells, and nearby surface water bodies. This evaluation will include assessment of the quality of available data based on available quality assurance and quality control information.

Complaints

File contents will be reviewed for evidence of any complaints made by nearby residents or other interested parties. If present, these reports will be reviewed to determine the date of the complaint, the nature of the complaint and what type of environmental medium was alleged to have been impacted (e.g. air, water, soil, etc.), what response was taken and whether any determination was made regarding the source of the alleged impact.

Other

Cadmus will assist with other tasks at the direction of EPA. This includes Geographic Information System (GIS) overlay exercises. The purpose of these exercises is to locate drinking water resources within a half mile from approximately 335 production well point locations within 13 different states, and provide counts and certain descriptions of those resources for each location. Cadmus will modify the GIS analysis as directed by EPA's technical expert and COR and continue to use GIS analyses to evaluate water resources within a half mile from production well locations. This activity will utilize a GIS overlay of each production well's surface location with layers containing water resources identified in databases of known quality.

Cadmus will also assist with the acquisition and analysis of well record data contained in files that have been submitted to FracFocus, a public disclosure database maintained by the GWPC and IOGCC. Cadmus will write a computer program to first download the files from FracFocus and then extract data and information from those downloaded well record files. There are an estimated 11,000 plus well record files each containing 17 parameters (e.g., well location, depth, fracture date(s), product names and chemicals used as injection fluid ingredients, etc.). For each well record, some parameters (such as chemicals used) will themselves contain tens or perhaps hundreds of separate data entries. Cadmus will conduct a data quality review (identifying duplicate records, different spellings

of the same chemical, etc.), then summarize and analyze available data and information. Example analyses include a list of the chemicals used nationally and by state, frequency of use of chemicals nationally, by state, and by operator, etc.). Cadmus will provide updates of the FracFocus analysis at the direction of EPA.

A7. Quality Objectives and Criteria

All of the analysis Cadmus will perform for the production company well file analyses will be based on initial baseline and follow-up water quality monitoring data as well as data on nearby surface water resources, which are compiled by the production companies. These data will be provided by the EPA COR. In some cases, Cadmus may supplement these data with data from EPA or the U.S. Geological Survey (USGS). In addition, for the GIS overlay exercise, Cadmus will also use data from the Safe Drinking Water Information System (SDWIS), available state databases, and USGS databases such as the National Hydrological Dataset (NHD). For the analysis of the FracFocus well record data, Cadmus will obtain the well record files that are publicly available online from the FracFocus website, which reflects information voluntarily supplied by well operators to the GWPC-maintained website. Cadmus will consider the elements listed below when assessing the quality of any data reviewed under this task. In addition, Cadmus will consider the elements listed in the EPA project-wide QAPP. In addition, the EPA project-wide QAPP describes the procedures used to select the well files subject to review under this work assignment and describes how these selection procedures help ensure that the projects meets EPA's data quality objectives.

- ***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. The well file reviews will be based primarily on data generated by production companies and provided by EPA. Cadmus will review these files and extract as much relevant information as possible and record the data on standard reporting forms. To help ensure accuracy, the standard reporting form will be a spreadsheet that contains data elements that will clearly identify important well inventory information (unique well ID, etc.), as well as all construction, operational, logging, remediation, and other factors that might relate to potential risks to water resources due to the HF well, HF activities, and well operations.

  During our analysis of the data, Cadmus will make note of any apparent errors in the accuracy of the data. In some cases, we may help ensure the accuracy of data by using 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 USGS).

  The EPA well file review team member will review a random subset of ten percent of the well files different from the first reviewer, in order to ensure that the correct well file was reviewed and to compare data recorded by the different reviewers. In the event of discrepancies in data interpretation between the reviewers, the well file review team will meet to discuss the issues and agree to a common approach. These reviews will be documented using the form shown in the EPA project-wide QAPP. The goal is to have 100 percent accuracy of data transcription from the industry submitted files to the well file reviewer's spreadsheets to the well file database.

  For the GIS overlay exercises, Cadmus will limit its sources of data to datasets such as SDWIS, comparable state datasets, and the NHD. These datasets are known to have been compiled using quality assurance steps to help ensure their accuracy. Nonetheless, Cadmus will make note of any apparent errors in the accuracy of the data. If necessary, Cadmus will establish methods for correcting any persistent errors (e.g., inaccurate source locations in SDWIS).

  For all work regarding FracFocus data, Cadmus will limit its sources of data to information available online from the FracFocus website. Cadmus will make note of any apparent errors in the data (e.g., different spellings or misspellings of chemical names). The FracFocus work consists of two separate

areas of data quality concerns: the download and extraction of information from the FracFocus website, and the analyses of the data obtained. The first area of accuracy refers to how well the well record data that were obtained through an automated download and extraction of well record PDF files data compares to the original well record data that are contained in the original PDF files as created by the operators submitting the data originally to the FracFocus website. Cadmus will conduct an accuracy QA of the download and extraction by randomly selecting 100 to 200 well records (based on the unique well record number), manually downloading the corresponding PDF files from FracFocus for those well records, and comparing parameter values in those files to the parameter values in the well records obtained through the automated download and extraction. Confidence intervals and margins of error for the data download and extraction will be calculated to characterize how well the automated data download and extraction reproduces the original data contained in the well record PDF files in the FracFocus database. To check the accuracy of the data analyses (simple non-parametric frequency counts national and by state), some portion of the analyses will be conducted by two separate staff (the same findings by both analysts indicates accurate analyses) and some portion of the analyses conducted will be spot-checked for accuracy.

- ***Data 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. Cadmus will primarily be using data generated by production companies and provided by EPA for the file review task. The EPA well file review team member will review a random subset of ten percent of the well files different from the first reviewer, in order to ensure that the correct well file was reviewed and to compare data recorded by the different reviewers.

  For the GIS overlay exercises, Cadmus will limit its sources of data to datasets such as SDWIS, comparable state datasets, and the NHD. These datasets are known to have been compiled using quality assurance steps to help ensure their precision. Nonetheless, Cadmus will make note of any apparent errors in the precision of the data. If necessary, Cadmus will attempt to remedy any shortcomings of the data and will document the steps it takes.

  For the analysis of FracFocus data, Cadmus will limit its sources of data to information available online from the FracFocus website. The records in the FracFocus system are individual records and not repeated measurements. Thus, evaluations of precision of the original dataset do not apply. Cadmus will, however, note any issues that emerge that could indicate a problem with precision as analyses proceed. Quality checks will be conducted as described under accuracy.

- ***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. As noted above, Cadmus will primarily be using data generated by production companies and provided by EPA for the file review task. However, in order to help mitigate any bias in the data, Cadmus may in some cases supplement the data with other publicly available data. The EPA well file review team member will review a random subset of ten percent of the well files different from the first reviewer, in order to determine whether any significant bias was introduced by the review team.

  For the GIS overlay exercises, Cadmus will limit its sources of data to datasets such as SDWIS, comparable state datasets, and the NHD. These datasets are known to have been compiled using quality assurance steps to help prevent bias. Nonetheless, Cadmus will make note of any apparent bias in the data.

  For the analysis of FracFocus data, Cadmus will limit its sources of data to information available online from the FracFocus website. Cadmus will attempt to use all records available from the FracFocus website. Because Cadmus will use established procedures for summary statistics and other analyses using all available data, Cadmus does not foresee the data analysis introducing bias. Cadmus

will, however, note any apparent bias in the dataset itself (e.g., geographical bias) and report such issues as appropriate. If it becomes necessary to exclude certain records from analysis due to technical difficulties, Cadmus will evaluate whether such exclusion introduces geographic or other bias in the analysis.

- ***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. As noted above, Cadmus will primarily be using data generated by production companies and provided by EPA for the file review task. Data will not be rejected unless they obviously are inconsistent with the well file being reviewed. However, if data in these files are incomplete, Cadmus may in some cases supplement the data with other publicly available data. For the GIS overlay exercises, Cadmus will limit its sources of data to datasets such as SDWIS, comparable state datasets, and the NHD. Use of multiple data sets will help ensure completeness (i.e., help ensure that all water sources are located). For the work using the FracFocus data, Cadmus will limit its source of data to information available online and data will not be rejected unless they obviously are inconsistent with the well file being reviewed. The quality checks for the download and extraction, as described above under *Accuracy*, will also enable assessments of completeness (in the sense of downloading and extracting the complete well record data sets that are contained in the original well record PDF files in the FracFocus database).

- ***Representativeness***. Representativeness is in most cases a qualitative term 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. As noted above, Cadmus will primarily be using data generated by production companies and provided by EPA for the file review task. Data will not be rejected unless they obviously are inconsistent with the well file being reviewed. However, Cadmus will inform the EPA COR if the data — e.g., the sampling data — do not appear representative. Cadmus may in some cases supplement the data with other publicly available data. Issues regarding representativeness do not apply to the GIS overlay exercises.

  For the FracFocus work, the issue of representativeness is addressed above under *Completeness.* All FracFocus well record files will be downloaded, so the data used for the analysis are expected to duplicate the information available in FracFocus (i.e., data will be fully represented). It is beyond the scope of this project to evaluate the quality or representativeness on a national scale of the data submitted to FracFocus by oil and gas operators. Completeness (not representativeness) is the key data quality measure for analysis of the FracFocus records.

- ***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. Comparability will be assured by using standardized units in the reduced data. 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 that staff who work on this individually exhibit competency to understand all well file contents in general.

In addition, EPA is using the Toxic Substance Control Act (TSCA) CBI rules for handling the data. Cadmus has obtained appropriate CBI clearance and will handle all CBI-designated materials under TSCA CBI rules for handling the data. To maintain TSCA CBI access approval, a briefing on the TSCA CBI Security Manual

or completion of the TSCA CBI On-Line Training must be completed annually.

A9. Documentation and Records

All personnel working on this task will receive this supplemental PQAPP. If there are amendments to the supplemental PQAPP, personnel will receive updates by electronic mail to ensure that they have the most recent version. Personnel working on this project will also receive copies of the EPA project-wide QAPP, which is incorporated by reference.

Paper records will adhere to EPA PPM 13.2, "Paper Laboratory Records." The majority of records will require permanent retention under EPA Records Schedule 501, "Applied and Directed Scientific Research." Cadmus will maintain written documentation indicating the data sources to be used in the study (including the source name, data, table or exhibit numbers, page numbers, column headings, Web sites, and dates of Web site access). If Cadmus identifies any potential problems with data sources, Cadmus will develop and send to EPA a written summary of the problem encountered, the impact of the problem on the analysis, and possible options for addressing the problem. CBI data-handling procedures will be followed as applicable.

Throughout the performance of the work assignment, Cadmus will also document and report QA efforts in the monthly technical and financial progress reports that Cadmus submits to EPA. The progress reports will address specific QA-related issues as well as any problems encountered and their resolution.

B1. Sampling

Statistical sampling is the responsibility of another contractor, and sampling procedures are described in the EPA project-wide QAPP. No physical or statistical sampling is anticipated under this work assignment. Therefore, a sampling design process is unnecessary for this PQAPP supplement.

B2. Sampling Methods

Statistical sampling is the responsibility of another contractor, and sampling procedures are described in the EPA project-wide QAPP. This section does not apply because no direct measurement/experiments are anticipated for this work assignment. Therefore, a sampling design process is unnecessary for this PQAPP supplement.

B3. Sample Handling and Custody

"Samples" within this research project refer to data submitted by the nine oil and gas operators sent letters on August 11, 2011, requesting well file information expected to be in their possession. "Sample handling procedures" are the responsibility of another contractor and are described in the EPA project-wide QAPP. This section does not apply to this PQAPP supplement because no direct measurement/experiments are anticipated for this work assignment.

B4. Analytical Methods

Data submitted by the nine oil and gas operators will be analyzed using the methodology described in Section A.6.

B5. Quality Assurance and Quality Control

Cadmus will comply with applicable to QA steps identified in the EPA project-wide QAPP, which is incorporated by reference.

The EPA well file review team member will review a random subset of ten percent of the well files different from the first reviewer, in order to ensure that the correct well file was reviewed and to compare data recorded by the different reviewers. In the event of discrepancies in data interpretation between the reviewers, the well file review team will meet to discuss the issues and agree to a common approach.

For other aspects of this project, such as the GIS overlay exercise and the analysis of FracFocus data, Cadmus will perform multiple levels of QA review to ensure that location data are accurate. This will, in part, involve comparing calculated location values to true values derived from system features whose geographic extents have been mapped. Cadmus will report any data anomalies identified during this process to EPA and will contact the entity responsible for generating the data source to identify reasons for any inconsistencies, resolve problems with changes to the data source, and to answer any outstanding questions as necessary.

B6. Instrument/ Equipment Testing, Inspection, and Maintenance

Laptop computers used to review CBI data have been scanned for viruses. From time to time, as new data may be transmitted to the well file review team, virus scans will be updated through consultation with local information technology support. Back up versions of spreadsheets containing the recorded data will be made by burning the file to a disk.

B7. Instrument/ Equipment Calibration and Frequency

This section is not applicable because no direct measurements are being taken. Therefore, no instruments will be used or calibrated.

B8. Inspection/ Acceptance of Supplies and Consumables

The EPA project-wide QAPP describes procedures to ensure that computers used to record well file data claimed as confidential are configured to ensure they meet protocols in the TSCA CBI Protection Manual, including removing the machine's ability to connect to servers and the internet. Information will be provided to Cadmus in hard copy or using supplied disks. The EPA project-wide explains that each incoming submission from the nine oil and gas companies will be visually examined to determine whether a claim of confidentiality is made.

B9. Non-direct Measurement Data

Cadmus will use the following secondary data sources:

- Production company files analyses that include initial baseline and follow-up water quality monitoring data as well as data on nearby surface water resources. These files will be compiled by the production companies and supplied by the EPA COR.
- Water quality data from EPA or USGS.
- Data on the sources of drinking water from SDWIS, available state databases, and USGS databases such as the NHD.
- Chemical data and information from FracFocus.

During our analysis of the data, Cadmus will make note of any apparent errors in the accuracy of the data. In some cases, we 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 USGS). Data will generally be accepted for inclusion in the review unless an obvious error precludes its use, such as the data is from the wrong well file.

For the GIS overlay exercises, Cadmus will limit its sources of data to datasets such as SDWIS, comparable state datasets, and the NHD. These datasets are known to have been compiled using quality assurance steps to help ensure their accuracy, precision, and lack of bias. Nonetheless, Cadmus will make note of any apparent errors in the accuracy of the data. If necessary, Cadmus will establish methods for correcting any persistent errors (e.g., inaccurate source locations in SDWIS).

For the analysis of FracFocus data, Cadmus will limit its source of data to information available online. Cadmus will note any apparent errors in the accuracy of the data.

B10. Data Management

The PQAPP for this contract sets out the general approach for QA involving data management. In addition, Cadmus will maintain, handle, and transmit CBI in accordance with applicable requirements for contractors, as specified in the *TSCA CBI Protection Manual*.[2]

[2] U.S. Environmental Protection Agency. 2003. *TSCA CBI Protection Manual*, Office of Pollution Prevention and Toxics, Washington DC (7407 M), October 20 (7700A1).

GROUP C: ASSESSMENT AND OVERSIGHT

C1. Assessment and Response Actions

Assessing the quality management system itself is important to maintaining the system's effectiveness and integrity. The Cadmus QA Officer (QAO) oversees quality assurance activities throughout the company, identifies weaknesses, and recommends and implements improvements. As the Cadmus QA Officer, Mr. Gene Fax, is also the QA Officer for this contract. When deemed necessary, the Cadmus QAO will conduct an internal assessment of the work assignment activities and/or deliverables.

All deliverables generated under this work assignment that do not involve CBI will be reviewed by Ms. Patricia Hertzler, the QA Technical Lead Reviewer for this work assignment, or her designee.

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.

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 data such as field or laboratory measurements. Data verification and validation for this work assignment requires the review team to:

- Conduct senior internal review of all work products that do not involve CBI, and
- Revise work products based on the EPA COR's technical direction.

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 the non-CBI deliverables to ensure compliance with criteria set forth in Sections A7 and B9 of the PQAPP.

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. For this work assignment, Cadmus will rely on EPA QA reviewers for the review of data involving CBI.

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.

Exhibit 1. QA Project Plan Elements for Work Assignment 4-58, Task 2

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	✓	✓		