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*

A. Project Management

This section addresses project management, including project background and purpose, roles and responsibilities, and key research questions and objectives.

A1. Title and Approval Sheet

QA Category: **A (HISA)**

Date Original QAPP submitted: August 30, 2012
Number of Pages: 16
Revision No: 2 (Replaces Previous HF Literature Evaluation QAPP)

Signatures indicate approval of this Quality Assurance Project Plan and commitment to follow the applicable procedures noted:

/s/ 11/18/2014
Caroline Ridley, Overall Literature Review Lead Date

/s/ 11/18/2014
Jeff Frithsen, Report Synthesis Lead Date

/s/ 11/18/2014
Cheryl Itkin, Director of Quality Assurance, Date
National Center for Environmental Assessment (NCEA)

/s/ 11/18/2014
Maureen Gwinn, Acting Deputy Director, NCEA-Washington Division Date

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. 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 HF Research Study

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 QA staff decide a program is of sufficient complexity to benefit from a QMP, as was done for the 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 quality assurance (QA) and quality control (QC) responsibilities, and describes the processes and procedures used to plan, implement and assess the effectiveness of the quality system. The HF QMP is then supported by project-specific QA project plans (QAPPs). The 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 as described in the *Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources* (EPA/600/R-11/122/November 2011/www.epa.gov/hydraulic fracturing). The results of the research projects will provide the foundation for EPA's 2014 study report.

This QAPP provides information concerning evaluation of the literature identified to help answer the HF research program's fundamental research questions as found in Figure 1 of the HF QMP and as described in the HF Study Plan.

A2. Table of Contents

A3. Distribution List

This QAPP will be distributed to the US EPA employees listed in Table 1.

Table 1. QAPP distribution list.

Name	Role in Synthesis Report	Organization	Contact Information
Jeanne Briskin	HF Study Coordinator	ORD/OSP	briskin.jeanne@epa.gov (202) 564-4583
Jeff Frithsen	Report Synthesis Lead; HF Background Literature Review Lead	ORD/NCEA	frithsen.jeff@epa.gov (703) 347-8623
Caroline Ridley	Overall Literature Review Lead	ORD/NCEA	ridley.caroline@epa.gov (703) 347-8506
Stephen LeDuc	Water Acquisition Literature Review Lead	ORD/NCEA	leduc.stephen@epa.gov (703) 347-8962
Chris Knightes	Chemical Mixing Literature Review Lead	ORD/NERL	knightes.chris@epa.gov (706) 355-8326
Susan Burden	Well Injection Literature Review Lead	ORD/OSP	burden.susan@epa.gov (202) 564-6308
Jim Weaver	Flowback and Produced Water Literature Review Lead	ORD/NRMRL	weaver.jim@epa.gov (580) 436-8550
Chris Impellitteri	Wastewater Treatment and Waste Disposal Literature Review Lead	ORD/NRMRL/WSWRD	impellitteri.christopher@epa.gov (513) 487-2872
John Stanek	Chemical Hazard Evaluation Literature Review Lead	ORD/NCEA	Stanek.john@epa.gov (919) 541-1048
Cheryl Itkin	NCEA Director of Quality Assurance	ORD/NCEA	itkin.cheryl@epa.gov (703) 347-8557
Vicki Soto	NCEA QA Manager (NCEA QA Alternate for HF)	ORD/NCEA	soto.vicki@epa.gov (703) 347-0290

A4. Project Organization

The organization chart for this project is depicted in Figure 1.

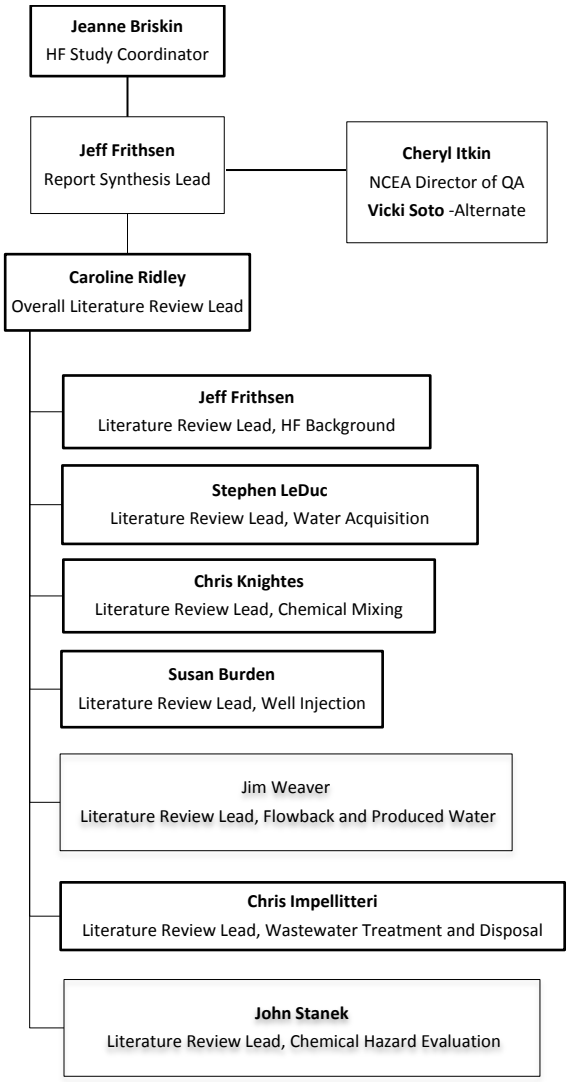

Figure 1. Organization chart for the "Data and Literature Review" project.

The Report Synthesis Lead is responsible for:

- Review and approval of this QAPP; and
- Keeping the HF Study Coordinator apprised of any quality problems that arise during this project.

The Overall Literature Review Lead is responsible for:

- Keeping the OSP QA Manager, NCEA QA Director, and Report Synthesis Lead apprised of any quality problems that arise during this project; and
- Approving and maintaining the QAPP throughout the course of this project.

All Literature Review Leads are responsible for:

- review and concurrence of this QAPP;
- identification, review and assessment of data and literature relevant to the research questions posed in the EPA's *Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources* (Study Plan) (US EPA, 2011);
- tracking and recording data and literature associated with this literature review using HERO; and
- conducting the verification and validation checks described in Section D2.

The NCEA Director of QA is responsible for:

- review and approval of all HF QA/QC documents generated by or for NCEA;
- submitting NCEA HF QAPPs to the HF PQAM for concurrence;
- performance of QA Technical System Audits, without conflict of interest; and
- review of QA problems and audit of corrections.

A5. Problem Definition and Background

The objective of this project is to identify and assess data and literature relevant to the research questions outlined in the Study Plan (US EPA, 2011).

This objective will be met through two sub-objectives:

1) Reviewing published literature and publically available data related to the five aspects of the water cycle that define the EPA's study: water acquisition, chemical mixing, well injection, flowback and produced water, and wastewater treatment and disposal.
2) Incorporating completed parts of the EPA's research results on the five topics into the synthesis report.[1]

This QAPP focuses on sub-objective (1) and outlines guidelines for assessing and reviewing existing data and literature. Given the potential national significance of the results of this study, the EPA researchers will need to apply a consistent, defensible approach to deciding when to include or exclude secondary data and information in the EPA's synthesis report.

A6. Project/Task Description

Literature Review Leads have been identified for each stage of the HF water cycle described in the Study Plan (US EPA, 2011). The Literature Review Leads listed in Section A4 are responsible for identifying

[1] The EPA-funded research described in the *Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources* is being conducted under Category 1 QAPPs, which ensures that this work is done under the Agency's most rigorous QA requirements. Additional information on QA categories can be found at http://www.epa.gov/nrmrl/qa/chapter2.html.

existing data and literature relevant to the research questions associated with their stage of the water cycle.

The Literature Review Leads will identify existing literature and data using a variety of methods, including:

- Recommended by the Science Advisory Board, including from
    - Review of EPA's *Draft Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources*
    - Consultation on EPA's *Progress Report: Potential Impacts of Hydraulic Fracturing on Drinking Water Resources- December 2012*
- Recommended by stakeholders during EPA-organized workshops and roundtables
- Submitted in response to FRN (Docket ID No. EPA-HQ-ORD-2010-0674)
- Literature reviews relevant to one or more of the hydraulic fracturing water cycles previously conducted by EPA or contractors to EPA
- Literature already accessed by EPA researchers to date
- Search of online, scientific databases plus federal, state, and stakeholder websites for recent materials (articles, technical papers, reports, and abstracts) and materials addressing topics not covered by sources listed above, but potentially relevant to the HFDWA. These databases and websites could include, but will not be limited to
    - Databases: Web of Science, Google Scholar, Transport Research International Documentation (TRID), OnePetro, National Technical Reports Library (NTRL), PubMed
    - Federal websites: DOE, DOI, DOT
    - State websites: CA, MT, ND, WY, CO, UT, NM, SD, OK, TX, AK, LA, MI, KY, OH, NY, PA, WV, MD
    - 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

Once the Literature Review Leads identify a potential reference for inclusion in the literature review, they will use the decision process diagramed Figure 2 and assess the quality of that reference according to five assessment factors recommended by the EPA's Science Policy Council (US EPA, 2003): soundness; applicability and utility; clarity and completeness; uncertainty and variability; and evaluation and review. These factors are described in more detail in Section A7. They will store citations and assessment factor classification in the EPA's Health and Environmental Research Online (HERO) database (this process is discussed in more detail in Section A9).

A7. Quality Objectives and Criteria

Evaluating Data and Literature Sources for Inclusion: Factors for Consideration

Literature and data identified in the course of the search strategy above will be evaluated using the five assessment factors outlined by the Science Policy Council in *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information* (US EPA, 2003): Applicability and Utility; Evaluation and Review; Soundness; Clarity and Completeness; and Uncertainty and Variability. Those factors are defined by the following criteria for the purposes of the HFDWA.

Table 1. Criteria for each quality factor used for assessing data and literature for the HFDWA.

Factor	Criteria
Applicability	Document provides information useful for assessing the potential pathways for hydraulic fracturing activities to change the quality or quantity of drinking water resources, identifies factors that affect the frequency and severity of impacts, or suggests ways that potential impacts may be avoided or reduced.
Review	Document has been peer-reviewed.
Soundness	Document relies on sound scientific theory and approaches, and conclusions are consistent with data presented.
Clarity/completeness	Document provides underlying data, assumptions, procedures, and model parameters, as applicable, as well as information about sponsorship and author affiliations.
Uncertainty/variability	Document identifies uncertainties, variability, sources of error and/or bias and properly reflects them in any conclusions drawn.

Our objective will be to cite literature in the HFDWA that conforms in full to all five criteria. However, from previous search efforts, we have learned that the preponderance of literature on some topics does not fully conform to some aspect of the outlined criteria. For instance, there are many white papers and reports in technical areas in which independent peer-review is not standard practice or is not well documented. Should non-peer reviewed references address topics not found in the peer reviewed literature, provide useful background information, or corroborate conclusions in the peer reviewed literature, we may cite them with clear explanation. The same kind of explanation will also be offered should references be cited in the HFDWA that do not fully conform to one of the other criteria.

Evaluating Data and Literature Sources for Inclusion: Process for Consideration

Literature identified by the Literature Review Leads will undergo a review process to determine whether an information or data source will be considered and/or citable by the synthesis report. The following decision tree (Figure 1) will be used that incorporates the quality factors referred to in the section above.

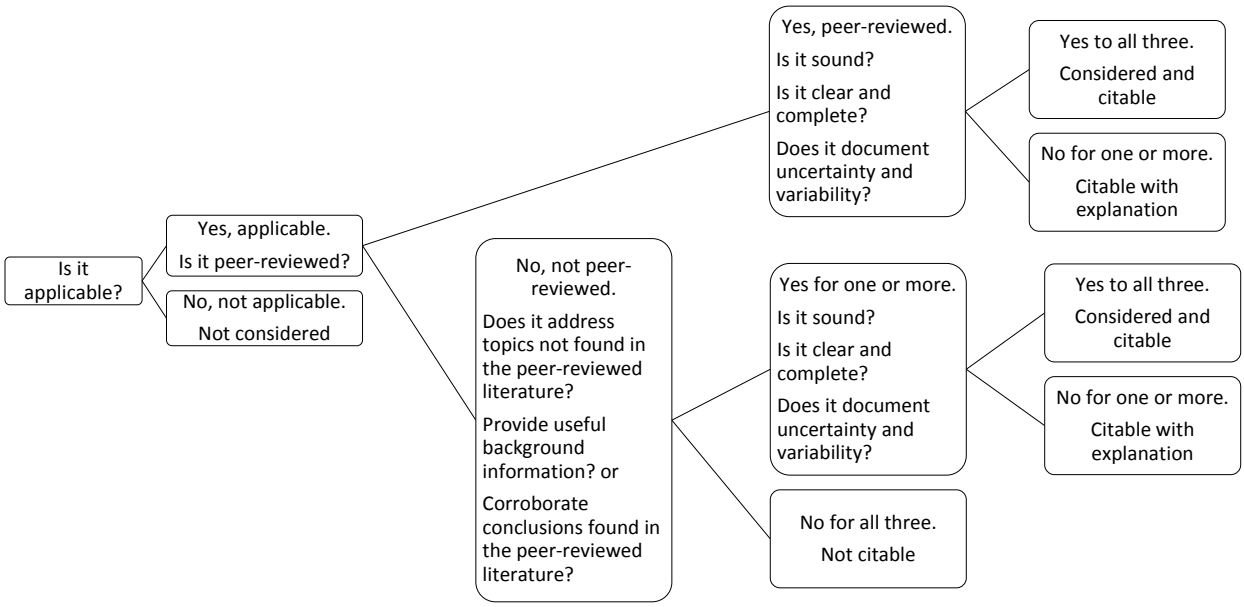

Figure 2. Process for literature consideration and citation.

A8. Special Training/Certification

No special training is anticipated at the time of this writing.

A9. Documents and Records

Final documents and files generated by the Literature Review Leads are "records" and will be moved to the HF project folders on the O:\ drive when work is completed. Reference documents could be either record or non-record material, depending on how they are utilized. Items cited or referenced that support a decision/conclusion should be retained as records, and will be stored in the HF project folders on the O:\ drive. Informational copies of references or data sources are, by agency definition (EPA Schedule 008), "non-records." They will be stored on the O:\ drive if considered relevant (see section A7 applicability and utility); however, as non-records they need not be retained beyond project completion.

B. Data Generation and Acquisition

This section addresses data acquisition and management activities.

B1-B8. Sampling and Measurement Requirements

The following list of sampling and measurement requirements appears in "EPA Requirements for Quality Assurance Project Plans" (US EPA, 2002). These items were considered for this plan, but were judged non-applicable to a literature and data evaluation study.

- B1. Sampling Process 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

The data needed for this project fall under the category of non-direct measurements and may include data from the following types of sources:

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 (C.F.R. or State)
    ii. Statutes (U.S.C.)
    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/PhD theses
    iii. Reports and white papers from private companies, associations, or non-governmental organizations
    iv. Conference presentations or papers
    v. Textbooks
    vi. Maps
    vii. Publications with unknown peer-review status

Datasets

a. Online databases
b. Unpublished government data

All data and existing literature will be evaluated using the guidelines given in Section A7 of this QAPP. It is expected that information included in the synthesis report will be drawn primarily from peer-reviewed publications. These publications will be viewed generally as containing the most reliable information, particularly if all of the criteria in Section A7 are met. High reliability will be ascribed to publications with high levels of review and evaluation and where extensive tabulation of supporting information is often available. Similarly, some agencies (e.g., EPA, USGS, etc.) are known to follow extensive quality assurance and review procedures for documents they produce.

Non peer-reviewed publications may provide useful information as long as they enhance understanding from peer-reviewed sources, or if peer-reviewed sources prove too scarce or insufficient to answer the research questions by themselves. Since workshop and conference papers may be abbreviated, and may present works-in-progress, these are not expected to form the sole basis of conclusions presented in the report. Generally, these publications may be of most use to support results presented from peer-reviewed work, to identify promising ideas of investigation and to discuss further in-depth work needed.

B10. Data Management and Hardware/Software Configuration

Reference Evaluation tracking in HERO

All references included in the report should be tracked using the 'tagging' function in Health and Environmental Research Online (HERO) database. The database 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. 'Tags' are a way in HERO to keep track of additional information concerning the references cited in an assessment. Peer-review status, and fulfillment of the other criteria outlined in Figure 2, and explained in detail in section A7, will be tracked by electronically categorizing each reference using these tags (e.g., peer reviewed, not peer reviewed, etc.). We note that, in general, literature that is not applicable will be screened out before the citations are imported into the database. Therefore, the vast majority of literature in HERO will be applicable.

Following is an example of a reference evaluated by the process in Figure 3 under the five criteria in section A7; highlighted boxes indicate the evaluation outcome and the tags that would be applied in HERO to record the evaluation.

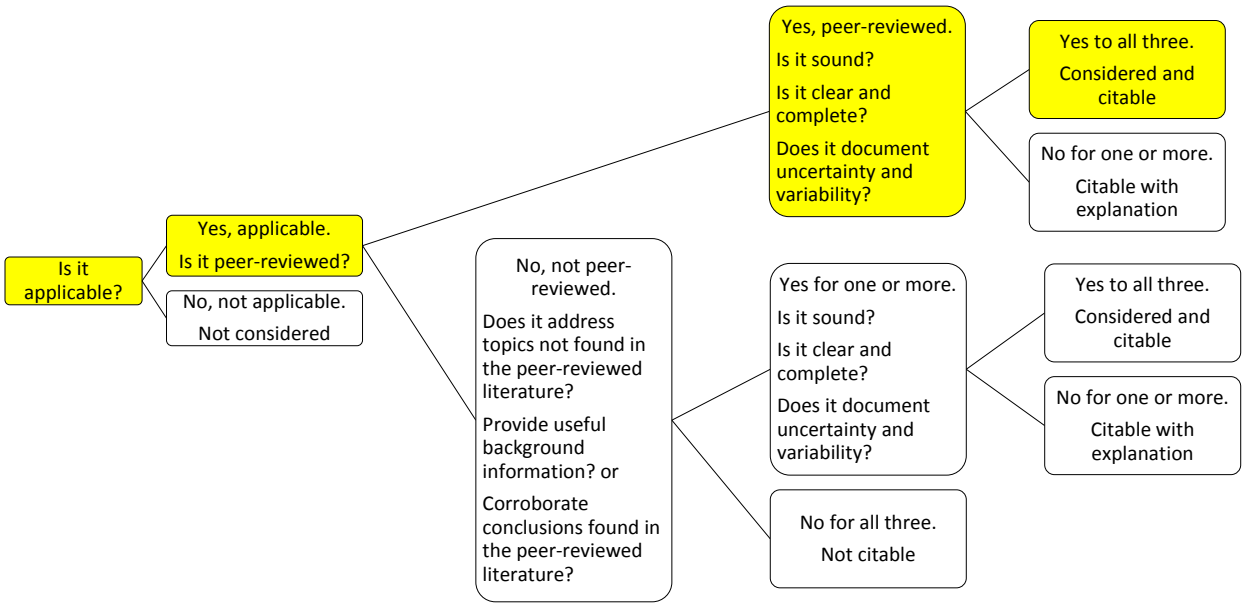

Figure 3. Literature evaluation for Jones, X.Y. 2013.

As an applicable reference, the following citation would be entered into HERO and tagged.

Jones, X.Y. 2013. Example article. Journal of Example 22: 1-10.

Tags: Peer-reviewed

Meets soundness, clarity, and uncertainty criteria

HERO repository

All literature and data sources used in the report should be attached to the citations in the HERO database.

Monitoring Procedures

The Overall Literature Review Lead will review what literature is being identified for inclusion in the synthesis report in order to ensure that selection criteria are being applied to potential sources of information in a balanced and consistent manner. This will involve monitoring the information entered in the HERO database by the other Literature Review Leads, and addressing inconsistencies or disagreements during project conference calls. Any issues that cannot be resolved among the Literature Review Leads will be brought to the attention of the HFDWA Lead. Additionally, the Overall Literature Review Lead will ensure that all data and literature sources are attached to the citations in the HERO database.

Available Datasets

As noted above in Section B9, this report may require information from available datasets, including online databases and unpublished government data. Data management for the assessment will involve data retrieval and transmittal, reduction and analysis, storage, and applications.

Data Retrieval and Transmittal

This work assignment may involve the retrieval and transfer of data from existing databases or other sources of environmental information. We will minimize the steps necessary to transfer data for each task and will document all data transfers, from raw data through final interpretation. We will verify and document that the retrieval has been executed correctly, and will retain relevant metadata. We will retain an original, unchanged version of the data set accessed 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. We will prepare a separate summary text describing any changes made to that data set relative to the original.

Data Reduction and Analysis

Data reduction and analysis is an irreversible transformation of data: examples include generation of summary statistics, rounding, etc. As described above, we will maintain a copy of the original data and will perform all analyses on a duplicate version. We will verify and document that the data reduction and analysis have been executed correctly.

Storage

Final datasets and accompanying documentation will be stored in the HF project folders on the O:\ drive when work is completed. See Section A9. Documents and Records. Documentation will also address licenses (if required), and any non-quality constraints such as legal, programmatic, and CBI affecting its use in the project.

Model Specification

EPA may employ applications to compile data and generate visual forms of display intended to represent locational information and potential environmental impacts. These do not constitute modeling in the mathematical sense.

C. Assessment and Oversight

This section describes the audits and other assessments needed to determine whether this QAPP is being implemented as approved and to increase confidence in the information obtained and produced as a result of this project.

C1. Assessments and Response Actions

The NCEA QA Director will conduct a Technical Systems Audit of the writing team early on in the literature review process in order to evaluate how the literature selection process outlined in this project plan is carried out and to ensure that the Literature Review Leads are adhering to the practices outlined in the QAPP. As stated in Section B10, the Literature Review Leads are responsible for ensuring that all data and literature sources are entered in the HERO database. Throughout the report writing

process, the QA Director will inspect the report team's tagging of citations in HERO and the literature sources attached to them. Problems will be discussed with the team and reported to the Study Coordinator. Any necessary corrective actions will be monitored by the QA Director.

C2. Reports to Management

Progress will be discussed during project conference calls. Literature Review Leads will ensure that the quality criteria are applied in a consistent manner. Any inconsistencies in applying quality criteria that develop will be discussed with the Overall Literature Review Lead and reported to the Report Synthesis Lead.

D. Data Validation and Usability

This section addresses the quality of the completed final report to see if this product will conform to the objectives outlined in this QAPP, especially given this project's use of existing datasets.

D1. Data Review, Verification, and Validation

This QAPP identifies two areas for data review, verification and validation: data transcription and report citations. Methods for conducting these reviews are described in Section D2.

Additionally, the Overall Literature Review Lead will ensure that the references and data sources listed in the synthesis report have all been evaluated and tagged in the HERO database. This process will ensure that all references and data sources included in the report have been reviewed according to the criteria listed in Section A7.

D2. Verification and Validation Methods

Data Transcription

All tables and figures created from existing literature and data sources will undergo an appropriate review process to ensure that the data were correctly transcribed, which will be organized by the relevant Literature Review Lead. This process will include checking the created tables and figures against the original sources.

Report Citations

References cited in the synthesis report will be verified by the Literature Review Leads primarily through cross-checking of each other's report sections. During the verification process, the report text associated with the selected citations will be checked against the original sources to ensure that the report text accurately reflects the information in the original source. The Project QA Director may also assist in verifying citations in the synthesis report as needed.

D3. Reconciliation with User Requirements

References and data sources that do not strictly meet the criteria listed in Section A7 may still be included in the synthesis report at the discretion of the Literature Review Leads, particularly with respect to data that have not undergone external peer review (e.g., data collected by states or industry).

The Literature Review Leads are responsible for deciding to include these data, documenting the rationale for inclusion and providing all available background information on these data in order to place these results in the appropriate context.

References

U.S. Environmental Protection Agency. 1997. Exposure Factors Handbook: Volume I – General Factors. Washington, DC: Office of Research and Development, National Center for Environmental Assessment; Report No. EPA/600/P-95/002Fa.

U.S. Environmental Protection Agency. 2002. Guidance for Quality Assurance Project Plans. Washington, DC: Office of Environmental Information; Report No. EPA/240/R-02/009.

U.S. Environmental Protection Agency. 2003. A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information. Washington, DC: Office of Research and Development, Science Policy Council; Report No. EPA/100/B-03/001.

U.S. Environmental Protection Agency. 2011. Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources. Washington, DC: Office of Research and Development; Report No. EPA/600/R-11/122.

Revision History

Revision Number	Date Approved	Revision
0	August 2012	New document
1	September 2013	Sections A1, A3, A4: Project Organization changed Section A6 & A7: Data and literature search strategy and evaluation criteria updated Sections A9 and B10: Records and data management updated to reflect use of HERO database
2	November 2014	Sections A1, A3, A4: Project Organization changed Sections B9 and 10: Data management updated to reflect use, documentation, and storage of available datasets