Quality Management Plan
Revision No. 2
Study of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources

SUBMITTED BY:

Name: Jeanne Briskin Phone: (202)564-4583
Title: Study Coordinator

Signature:_____/s/_____ Date: 04/20/2014

Name: Michelle Henderson Phone: (513)569-7353
Title: Program Quality Assurance Manager

Signature:_____/s/_____ Date: 06/10/2014

APPROVAL TO IMPLEMENT:

Name: Jennifer Orme-Zavaleta Phone: (919)541-2106
Title: Director, National Exposure Research Laboratory

Signature:_____/s/_____ Date: 06/06/2014

Name: Russell (Rusty) Thomas Phone: (919)541-5776
Title: Director, National Center for Computational Toxicology

Signature:_____/s/_____ Date: 04/10/2014

Name: Ken Olden Phone: (703)347-0283
Title: Director, National Center for Environmental Assessment

Signature:_____/s/_____ Date: 03/25/2014

Name: Cindy Sonich-Mullin Phone: (513)569-7923
Title: Director, National Risk Management Research Laboratory

Signature:_____/s/_____ Date: 03/13/2014

Name: Fred Hauchman Phone: (202)564-3151
Title: Director, Office of Science Policy

Signature:_____/s/_____ Date: 03/14/2014

Name: Jerry Blancato Phone: (919)541-2854
Title: Senior Information Official/ Quality Assurance Executive Lead, Office of Research and Development

Signature:_____/s/_____ Date: 06/10/2014

REVISION HISTORY:

Revision Number	Date	Revision
0	October 2011	New document
1	January 2012	1. Replaced Robert Puls with David Jewett as Overall Technical Research Lead (TRL) and TRL for Case Studies 2. Replaced Steve Vandegrift with Stephen Watkins as the Program Quality Assurance Manager (PQAM) 3. Updated Figures 3 and 4 to reflect the changes in 1 and 2 4. Section 1.3: Added program quality assurance (QA) as an oversight function of the Office of Science Policy 5. Section 1.4: Replaced Steve Vandegrift with Stephen Watkins as the PQAM
2	June 2014	1. Edited submitted signatures: Edited signatures to reflect current organizational changes 2. Edited approval signatures: Edited signatures to reflect current organizational changes 3. Revised Figure 3 – Hydraulic Fracturing (HF) Organizational Chart 4. Removed Figure 4 – HF Report Writing Team 5. Section 1 – Added text clarifying systematic planning, the approach to quality, and the independence of the PQAM. Added discussion of stakeholders, the OSP summary of projects, and an updated reference from draft to final version of the HF Study Plan (also updated in References, Section 12). 6. Section 2 – Included text concerning the QAM review of products, the Office of Research and Development (ORD) QA Product Review and Approval form, geospatial data policy procedure and the reporting of deviations, field sample chain of custody in the quality system tools and components. Clarified text concerning the graded approach and responsibility of technical staff to implement the HF Quality Management Plan. 7. Section 3 – Included text concerning process to ensure that quality related qualifications are maintained, supervisor and investigator are responsible for retraining and management is responsible for the qualification and training of personnel. 8. Section 4 – Included text concerning COR and PO required to verify contractors meet requirements, transfer of final project documentation to EPA. 9. Section 5 – Included text concerning email management, format of controlled documents, identification of quality related documents and records, training requirements for information managers, and the Investigators' responsibility for proper handling of documents and records. Added to the text were discussions concerning PQAM QAPP review, QAPP boilerplate language and the requirement that QAPPs are to be available at the work site.

Revision Number	Date	Revision
		10. Section 7 – Included text concerning how goals and objectives are linked to the Quality Assurance Project Plans (QAPPs) in Appendix A and the systematic planning process. 11. Section 8 – Included text concerning Laboratory/Center/Office Technical Systems Audit's coverage of affected Interagency Agreements, extramural, and contract organizations 12. Section 9 – Included text concerning how audit results are to be submitted to affected program managers and line managers and a process for the verification and documentation of corrective action. 13. Appendix A – Added: links the QAPPs to key primary and secondary research questions 14. Appendix B – Added ORD QA Product Review and Approval Form and Instructions 15. Appendix C – Added Components of a QA Summary 16. Appendix D – Added Data Qualifiers 17. Appendix E – Added Audit of Data Quality Checklist 18. Appendix F – Added Deviation Report 19. Appendix G – Added QAPP Boilerplate Language

The U.S. Environmental Protection Agency 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 used during the research study. Mention of trade names or commercial products in this planning document does not constitute endorsement or recommendation for use.

Table of Contents

List of Appendices

List of Tables

List of Figures

Abbreviations and Acronyms

AA	Assistant Administrator
ADQ	Audit of Data Quality
ANSI	American National Standards Institute
ASQ	American Society for Quality
Br-DBP	Brominated Disinfection By-Products
CBI	Confidential Business Information
CFR	Code of Federal Regulations
CIO	Chief Information Officer
COR	Contracting Officer's Representative
DCN	Document Control Number
DOE	U.S. Department of Energy
DQA	Director of Quality Assurance
DQO	Data Quality Objectives
DW	Drinking Water
ECMS	Enterprise Content Management System
EPA	U.S. Environmental Protection Agency
FTP	File Transfer Protocol
HF	Hydraulic Fracturing
HISA	Highly Influential Scientific Assessment
IA	Interagency Agreement
ISO	International Organization for Standardization
LCO	Laboratory, Center, and Office
NCCT	National Center for Computational Toxicology
NCEA	National Center for Environmental Assessment
NERL	National Exposure Research Laboratory
NGDP	National Geospatial Data Policy
NRMRL	National Risk Management Research Laboratory

OEI	Office of Environmental Information
ORD	Office of Research and Development
OSIM	Office of Science Information Management
OSP	Office of Science Policy
PE	Performance Evaluation
PO	Project Officer
PQAM	Program Quality Assurance Manager
QA	Quality Assurance
QAM	Quality Assurance Manager
QAPP	Quality Assurance Project Plan
QARF	Quality Assurance Review Form
QC	Quality Control
QMP	Quality Management Plan
QSA	Quality System Audit
RLO	Records Liaison Officer
SAB	Science Advisory Board
SIO	Senior Information Officer
SOP	Standard Operating Procedure
SOW	Statement of Work
SRO	Senior Resource Official
SSWR	Safe and Sustainable Water Resources
TRL	Technical Research Lead
TSA	Technical Systems Audit
TSCA	Toxic Substances Control Act
USGS	U.S. Geological Survey

1. Management and Organization

1.1. Introduction

Congress requested the U.S. Environmental Protection Agency (EPA) conduct research to examine the relationship between hydraulic fracturing (HF) and drinking water (DW) resources. As domestic onshore natural gas and oil production has increased, so have concerns about the potential environmental and human health impacts of HF in the United States. The HF process involves the pressurized injection of water, chemical additives, and proppants into a geologic formation. This induces fractures in the formation that stimulate the flow of natural gas or oil, thus increasing the volume of gas or oil that can be recovered from coal beds, shales, and tight sands—the so-called "unconventional" reservoirs. Many concerns about HF center on potential risks to DW resources, although other issues also have been raised.

The overall purpose of the EPA Study of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources (HF for O&G DW Study) is to understand the relationship between HF and DW resources. More specifically, the HF for O&G DW Study is designed to examine the conditions that may be associated with the potential impacts on DW resources and to identify the factors that may lead to human exposure and risks. The scope of the proposed research includes the full lifecycle of water in HF, from water acquisition through the mixing of chemicals and actual fracturing to the post-fracturing stage, including the management of flowback and produced water and its ultimate treatment and/or disposal. Figure 1 illustrates the HF water lifecycle's relationship to the key research questions EPA will address through the HF for O&G DW Study. Appendix A contains a table that provides the relationship of each currently approved HF DW Quality Assurance Project Plan (QAPP) to the primary and secondary research study questions.

EPA has consulted with and is continuing to engage experts in the field through peer review, technical workshops, and roundtables. The public and key stakeholder groups have provided input and received status updates throughout the course of the study. The *Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources*[1] was developed to describe the specific research activities that will be performed. The research includes generalized scenario evaluations involving modeling, evaluation of existing data, laboratory studies, toxicity studies, and case studies.

The draft HF study plan was reviewed by the Science Advisory Board (SAB), and EPA has established a Web site for the HF for O&G DW Study activities and associated documents at http://www2.epa.gov/hfstudy/.

The research will culminate in a report that will include the results from individual research projects, together with a broad assessment of the relevant scientific literature. The draft assessment report will be made available for public comment and will be peer reviewed by the SAB.

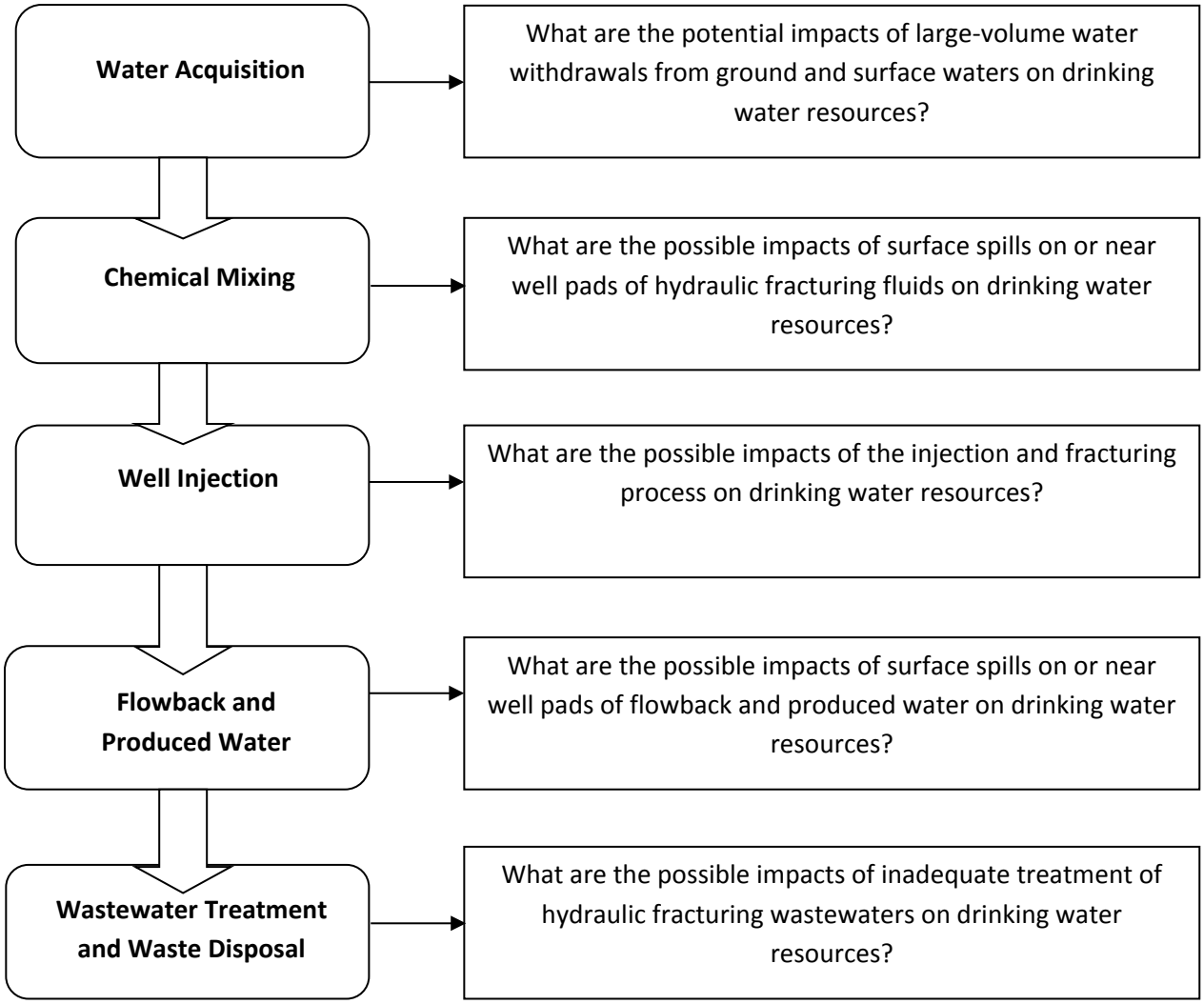


Figure 1. Hydraulic Fracturing Drinking Water Study Water Cycle's (left) Relationship to Fundamental Research Questions (right).

The significant national interest in this HF for O&G DW Study requires a rigorous quality assurance (QA) approach with the following elements:

- research projects that comply with Agency requirements and guidance for QAPPs, including the use of systematic planning;
- Technical Systems Audits (TSAs), Audits of Data Quality (ADQs), and Quality System Audits (QSAs) conducted as described in this Quality Management Plan (QMP) and project-specific QAPPs;
- performance evaluations (PEs) of analytical systems conducted, if available;
- QA review of all products that include environmental data (including existing data and models);

- reports that have a readily identifiable QA section; and
- research records managed according to EPA's record schedule 501 for *Applied and Directed Scientific Research.*[2]

1.2. Quality Policy

To ensure that results are scientifically defensible, the HF for O&G DW Study will comply with the EPA Quality Policy CIO 2106,[3] the EPA Procedure for Quality Policy CIO 2106-P-01.0, [4] and the other quality requirements are listed below.

EPA Policy and Procedure CI0 2105.0 and CIO 2105-P-01-0[5, 6]
EPA's Information Quality Guidelines[7]
EPA's Laboratory Competency Policy[8]
EPA Quality Standard for Environmental Data Collection, Production, and Use[9]
EPA Guidance on Quality Management Plans[10]
EPA Guidance on Quality Assurance Project Plans[11]
ORD Policies and Procedures Manual, Chapter 13, Quality Assurance[12]

The development, review, approval, and implementation of this QMP is part of the mandatory Agency-wide Quality System that requires EPA and all organizations collecting environmental data for EPA to develop and operate management processes and structures for assuring that data or information collected are of the needed and expected quality for their desired use. This QMP complies with the Agency policy for programmatic QMPs and includes coordination of research across multiple EPA Laboratories, Centers, and Offices (LCOs), as well as extramural research support. This QMP provides the necessary elements to plan, implement, document, and assess the effectiveness of QA and quality control (QC) under the HF for O&G DW Study.

1.3. Technical Approach Summary

The HF for O&G DW Study involves multiple EPA LCOs within the Office of Research and Development (ORD). The HF Study Coordinator provides oversight functions that include overall budget management and study coordination. Organizations with responsibilities for technical research leadership and their projects include the following.

- National Exposure Research Laboratory (NERL)
  - Analytical method development
  - Validation of Rapid Radiochemical methods
  - Subsurface migration modeling
  - Source apportionment study and modeling
  - Water acquisition modeling
- National Risk Management Research Laboratory (NRMRL)
  - Bromide-disinfection by-product precursor studies

  - Retrospective case studies in Bradford County, PA; Dunn County, ND; Las Animas County and Huerfano County, CO; Washington County, PA; and Wise County, TX; and prospective case studies in locations to be determined
  - Surface water modeling
  - Wastewater treatability studies
- National Center for Computational Technology (NCCT)
  - Toxicity assessment
- National Center for Environmental Assessment (NCEA)
  - Literature review
  - Toxicity assessment
- Office of Science Policy (OSP)
  - FracFocus analysis
  - Service company data analysis
  - Spills database analysis
  - Well file review

The ORD LCOs are part of a balanced organizational matrix achieved by balancing the level of authority between the functional manager (vertical dimension) and the program manager (horizontal dimension) within a matrix organization. For ORD, this means a balance of authority between the LCO management and the Safe and Sustainable Water Resources Research Program (SSWR), which includes the HF for O&G DW Study.

EPA Regions are involved in the case study projects to provide technical, logistical, and analytical laboratory and methods development support, in addition to providing support for the source apportionment study. Other Federal entities, such as the U.S. Geological Survey (USGS) and the Department of Energy's (DOE's) National Energy Technology Laboratory, provide research support for case studies through Interagency Agreements (IAs). Contractors provide support for case studies in the field and laboratory for modeling activities, with existing data activities (compiling, evaluating, analyzing, etc.), and for QA. Oversight of extramural programs and contracted activities is the responsibility of the Project Lead, as defined in the QAPP. Project Leads submit an ORD QA Product Review and Approval Form, outlining proposed quality plan requirements of these extramural projects or contracted activities, to Division Quality Assurance Managers (QAMs) for review and approval. Intramural QAPPs also are submitted to the Division QAM for review and approval.

Extramural support is provided by

- Cadmus;
- Eastern Research Group, Inc.;
- Ecology and Environment;
- Lawrence Berkeley National Laboratory;
- Oak Ridge Institute for Science and Education postdoctoral personnel;

- Shaw Environmental, Inc.;
- Student Services Contracts and others as determined according to need;
- USGS; and
- Westat.

Technical Research Leads (TRLs) have been assigned to the following HF research areas: analytical chemistry, case studies, data analysis, scenario evaluation and modeling, toxicology assessment, and wastewater treatment and disposal. These areas are encompassed by the five key stages of the HF water lifecycle: (1) water acquisition, (2) chemical mixing, (3) well injection, (4) flowback and produced water, and (5) wastewater treatment and disposal, as shown in Figure 1. Appendix A provides a summary of the research projects that will be conducted under this HF DW study, the primary and secondary research questions addressed by each project, and the associated planning documents. The list of research projects and associated QAPPs is periodically updated as needed and was current at the time of publication of this QMP. Please see the HF for O&G DW Study QA web site (http://www2.epa.gov/hfstudy/quality-assurance-integrity).

1.4. Quality Approach Summary

This document provides QA guidance to all personnel associated with EPA's efforts to conduct the Congressionally requested HF for O&G DW Study.[(1)] The intent of this QMP is to document QA procedures and practices that are required under the HF for O&G DW Study and to specify roles with respect to QA.

This programmatic HF QMP will be implemented in coordination with existing organizational QMPs. All technical and QA personnel will implement their organization's QMP in all cases where the programmatic HF QMP is either silent or points to the organizational QMPs. Requirements, where specified, in this HF for O&G DW Study QMP must be met to ensure consistency in the QA approach for all participating organizations.

The Acting Principal Deputy Assistant Administrator (AA) and Senior Resource Official (SRO) for ORD has appointed the ORD Quality Assurance Executive Lead for Hydraulic Fracturing. The HF for O&G DW Study also is supported by a Program QA Manager (PQAM), who is independent of the technical work and will assist the QA staff in the implementation of the HF quality program and the requirements of this QMP. Table 1 presents a summary of the responsibilities for both LCO QAMs and the PQAM. The ORD HF Leadership Team, led by the Acting Principal Deputy AA and SRO for ORD, includes the Study Coordinator, Directors of each LCO involved in the HF for O&G DW Study, the ORD QA Executive Lead for HF, and appropriate deputies and the Communication Lead. Members of the leadership team are responsible for updating the LCOs and the HF QA staff on actions and decisions of the team. This two-way relationship also provides staff with a path for bringing issues to management.

The team meets weekly to exchange information among LCO Directors and the Study Coordinator on topics related to the HF for O&G DW Study, including research products, Congressional briefings, research progress, communications, QA, and peer review.

Table 1. Responsibilities of Laboratory, Center, and Office (LCO) Quality Assurance (QA) Managers and Program QA Manager (PQAM)

	Planning	Implementation	Assessment	Products
LCO QAM Responsibilities	QA review/approval of QA review forms (QARFs), and QAPPs	QA review/approval of protocols, standard operating procedures (SOPs), and methods	Conduct Technical Systems Audits (TSA), Audits of Data Quality (ADQ), Performance Evaluations, as applicable; prepare audit reports; report status of assessments and corrective actions to LCO management and PQAM	QA review/approval of LCO products
PQAM Responsibilities	Provide guidance for QAPP preparation; provide concurrence that QAPPs meet HF for O&G DW Study requirements; ensure that QAPPs are approved via communication with QAM/Director of QA (DQA) of associated LCO; and track approved QAPPs	Provide consultation as needed.	Track status of all audits and associated corrective actions.	QA review and approval of consolidated HF for O&G DW Study products with assistance from LCO QA staff. Tracks QA review of LCO products.

1.5. Expected Products and Associated Reviews

The primary products from this HF for O&G DW Study include the Progress Report published in 2012 and the Assessment Report on *The Study of the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources* that is to be submitted as a draft report for peer review and public comment in 2014. In addition to these reports, there may be other products, including: EPA technical reports, journal articles, symposium and conference papers, extended abstracts, and computer products (software, models,

databases, and scientific data collections). Prior approval from the ORD AA's office must be obtained before external publication of any products that present HF for O&G DW Study results.

Technical products produced in the HF for O&G DW Study that present environmental data or include models or existing data (also known as "secondary data" [13]) are required to undergo QA review prior to release, as indicated in Table 1 above. The process for QA reviews is stated in the project QAPP and is appropriate for the LCO conducting research. LCO QAMs will conduct a documented review of HF for O&G DW Study products prior to clearance by the Division Director and LCO Director.

All HF research products must be submitted for clearance. QA approval must be documented in the clearance package per LCO procedures using the ORD QA Product Review and Approval Form. The process for completion of the ORD QA Product Review and Approval Form is included with the form in Appendix B.

Each technical report will include a summary of QA activities performed during the research. Appendix C provides guidance for the contents of this QA summary. The data reported in all products will be adequately documented and characterized, including a thorough description of limitations or qualifiers wherever appropriate.

Peer reviews are documented critical reviews of scientific or technical work products by qualified individuals independent of the researchers but having relevant substantive expertise. Peer reviews will be documented and conducted according to the guidance contained in the *U.S. Environmental Protection Agency Peer Review Handbook*, 3rd Edition, 2006,[14] as amended.

Peer reviews and associated responses also are included in the clearance packages. Specific review and clearance requirements, each meeting EPA requirements for product clearance, are described in each of the LCO-specific QMPs. Additionally, all HF for O&G DW Study related products are submitted through the HF Study Coordinator and Acting Principal Deputy AA and SRO for ORD for clearance prior to publication and dissemination to the public.

1.6. Dispute Resolution

Oversight responsibilities for QA/QC may sometimes result in disagreements between the QA staff and project management. Such disputes may occur in situations involving technical issues (e.g., audits, surveillances, data quality assessments) and management issues (e.g., QAPP reviews). QA problems should be resolved at the lowest possible management level. The respective organization's QMP will be followed for dispute resolution within the LCO.

If the issue cannot be resolved within the LCO under the QMP that guides that LCO, then the issue must be elevated outside the LCO to the Quality Assurance Executive Lead. The PQAM must be included in all negotiations of these dispute resolutions if they involve more than a single LCO. This process is illustrated in Figure 2.

The Acting Principal Deputy AA and SRO for ORD is the ultimate decisionmaker for resolving disputes.

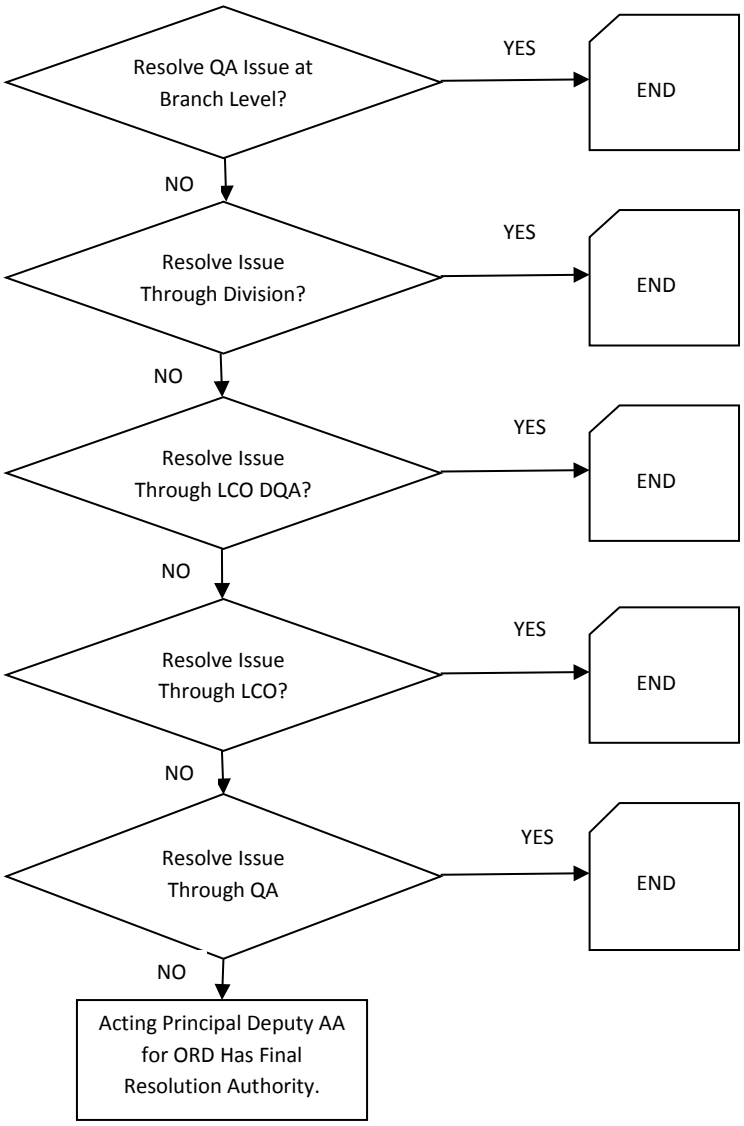


Figure 2. Quality Assurance Dispute Resolution Flowchart.

1.7. Roles and Responsibilities

All HF for O&G DW Study personnel are responsible for the quality of research and the quality of output derived from activities under their control or influence; they also are accountable to appropriate line managers and, ultimately, to the respective LCO Directors. Figure 3 presents the HF for O&G DW Study organization and identifies those personnel with HF for O&G DW Study responsibilities.

Each Investigator with project lead responsibilities (may be a Contracting Officer's Representative [COR] on a contract), as identified in Figure 3, is responsible for ensuring that data collected for their project are of acceptable quality for their intended use. QAPPs must be approved prior to primary data collection to ensure that the data generated by EPA is high quality. In the case of existing or secondary data, QAPPs must be signed prior to the analysis of secondary data collected by the EPA; this ensures that the analyses conducted by EPA are of high quality. It is the responsibility of each investigator's Branch Chief, Division Director, and QAM to ensure project management/QA approval for associated QAPPs and products. The PQAM will work closely with the LCO QAMs, Directors of Quality Assurance (DQAs), and the technical staff to ensure that the QA/QC documents and procedures are adequate to meet the needs and objectives of the HF for O&G DW Study. It is the responsibility of the LCO Division QAMs to audit the projects within their LCO.

Specific roles and responsibilities for personnel involved in these HF research activities are presented in the following sections. Authority for these roles and responsibilities is provided by the individual's line management.

1.7.1. ORD QA Executive Lead

- Reviews and approves this HF for O&G DW Study QMP
- Champions the HF for O&G DW Study Quality Program to management
- Ensures HF for O&G DW Study participants are trained in the requirements of the QMP
- Responsible for dispute resolution when multiple LCOs are involved

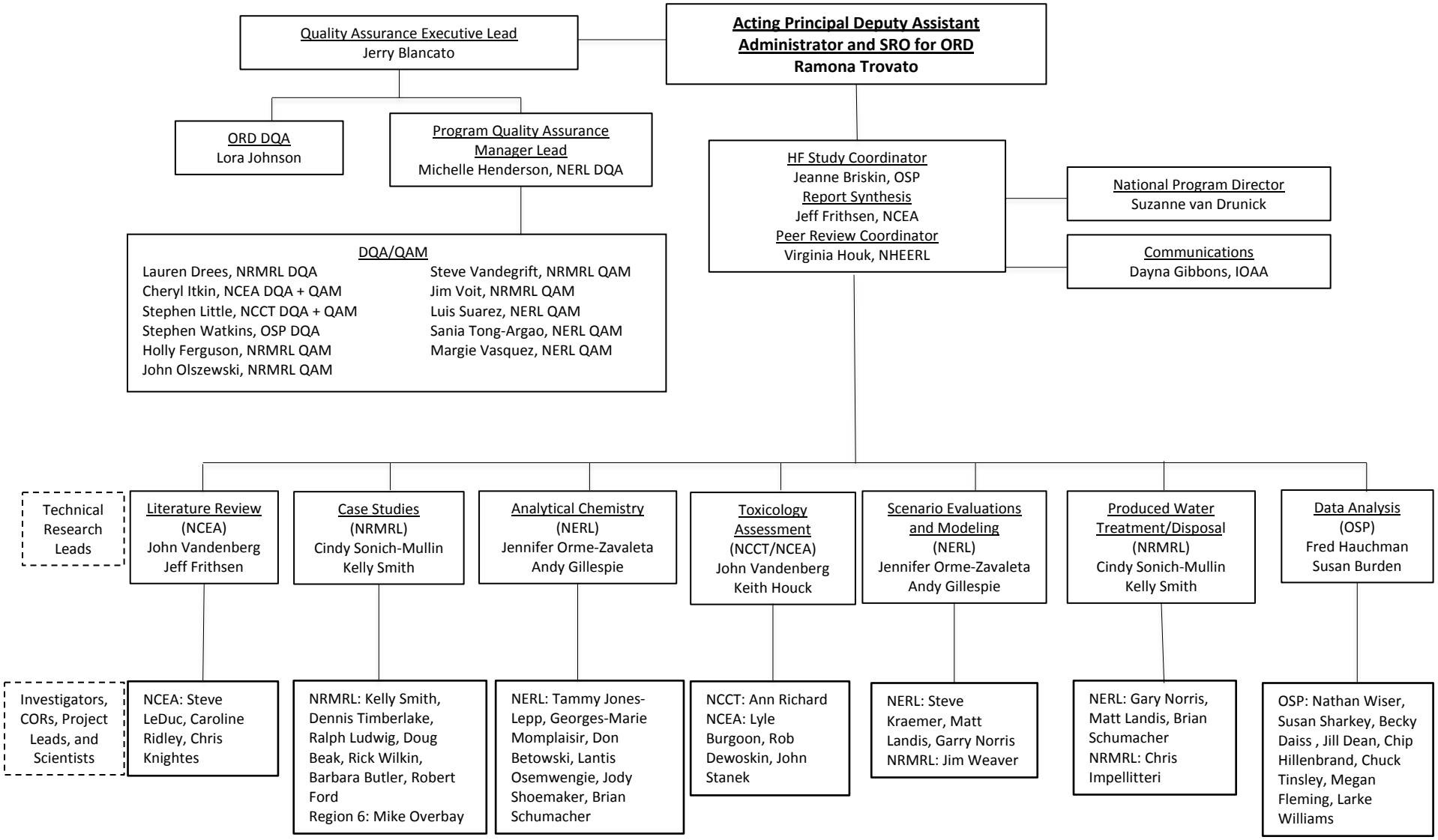
1.7.2. Study Coordinator

- Leads the HF for O&G DW Study Leadership Team
- Coordinates the overall HF for O&G DW Study, operating principles, implementing activities, communications, and annual budgets
- Reviews, approves, and assists in the revision of this HF for O&G DW Study QMP

1.7.3. LCO Directors

- Provide communication avenues to support the activities of the Study Coordinator
- Review, approve, and ensure the implementation of this HF for O&G DW Study QMP
- Review, approve, and ensure the scientific quality of research products for the HF for O&G DW Study
- Implement annual HF for O&G DW Study budgets and resource allocations
- Allocate personnel and other resources to accomplish the HF for O&G DW Study goals
- Perform the responsibilities outlined in their respective LCO QMP
- Oversee and coordinate all research activity within their research area

Figure 3. Hydraulic Fracturing Drinking Water Study Organization Chart.



- Ensure quality of the science in all research products within their research areas
- Provide dispute resolution for QA problems that are elevated above the Investigators and their immediate management
- Responsible for the management of the official record copies of all program documents generated during the HF for O&G DW Study life cycle
- Ensure that a readily identifiable QA section, reviewed and approved by the PQAM, is prepared and included in all HF reports

1.7.4. National Program Director

- Facilitates the development of the ORD Research Action Plan by LCOs that, once finalized, includes the identification of projects, tasks, and resources (including QA) needed to successfully execute the project and deliver the products and outputs

1.7.5. TRLs

- Assist the Investigator or COR in the successful realization of projects, tasks, assignments, and reports in the TRL's area of expertise
- Facilitate in conflict resolution between the QAM and Investigator or COR in their area of expertise

1.7.6. Report Synthesis Lead

- Synthesizes the information and data collected from each research area and writes relevant report sections
- Assures appropriate treatment of QA in the synthesis assessment report

1.7.7. LCO Branch Chief and Division Director

- Perform the responsibilities outlined in their respective LCO QMP
- Ensure the HF for O&G DW Study QMP is implemented
- Allocate appropriate personnel and other necessary resources to support the HF for O&G DW Study requirements
- Approve quality assurance review forms (QARFs) for QAPPs for projects by Investigators that directly report to them
- Ensure that products from this HF for O&G DW Study are reviewed by the QAM and approved prior to publication
- Review products from Investigators that directly report to them

1.7.8. Investigators (includes Project Leads, support personnel for Project Leads, Project Officers (POs), and CORs)

- Implements QMP requirements as they apply to their HF research project
- Leads or assists in the preparation of QAPPs and ensures these plans are approved prior to beginning work
- Ensures that QAPPs are reviewed and revised to reflect changes in the research plan and that these changes are communicated to project staff in a timely manner
- Ensures QARFs are completed for all extramural activities
- Ensures that the approved QAPP is implemented
- Ensures all personnel working on the research are adequately qualified and trained for their assignments
- Ensures that products from this HF for O&G DW Study are reviewed by the QAM and approved prior to publication
- Performs the responsibilities outlined in their respective LCO QMP
- Schedules audits and assessments with their associated QAM
- Manages the official record copies of all project documents generated during the research life cycle

1.7.9. ORD DQA

- Assists in the development of the QMP
- Performs a QSA of the HF for O&G DW Study within 1 year of initial QMP approval and every other year thereafter

1.7.10. PQAM

- Serves as liaison for QA to management, the LCO DQAs and Division QAMs for O&G DW Study QA issues
- Informs HF QA staff regarding developments, accomplishments, and unresolved HF for O&G DW Study QA issues
- Develops, implements, maintains, distributes, and updates the HF for O&G DW Study's QMP
- Provides training concerning the HF for O&G DW Study's QMP to Program Management and QA staff
- Tracks QA activities across the HF for O&G DW Study
- Reports QA activities and problems to the associated LCO DQA, the QAM, and to other appropriate HF for O&G DW Study personnel
- Ensures that all HF for O&G DW Study QA/QC documents (QA Project Plans, Operating Procedures/Standard Operating Procedures (SOPs), QARFs for extramural research, reports, etc.) are prepared and approved according to LCO policies and HF for O&G DW Study QA requirements
- With the assistance of the responsible LCO QA staff, ensures that all HF for O&G DW Study consolidated products are reviewed and approved by LCO QA staff

- Organizes teleconferences for ORD QA staff involved with the HF for O&G DW Study
- Ensures appropriate QAPPs are posted online
- Assists the HF Coordinator in writing the QSA response and tracks QSA corrective actions to closure

1.7.11. LCO DQAs[1]

- Perform the responsibilities outlined in their organization's LCO QMP and this HF QMP
- Review and approve HF for O&G DW Study-related QA/QC documents generated in their LCO if not done at the Division level
- Facilitate problem resolution and tracks corrective action

1.7.12. LCO QAMs [1]

- Perform the responsibilities outlined in their respective LCO QMP and this HF QMP
- Review and approve HF for O&G DW Study -related QA/QC documents generated in their respective LCO or Division
- On receipt of QAPPs for QA review, submit QAPPs to the PQAM for concurrence that the QAPP meets HF for O&G DW Study requirements
- Perform audits (TSAs and ADQs) and performance evaluations [PEs]) of HF for O&G DW Study -related projects performed in their respective LCO or Division
- Provide audit reports and the status of corrective actions identified in audits to the PQAM
- Communicate HF for O&G DW Study -related QA issues to the PQAM
- Facilitate problem resolution and track corrective action
- Provide QA input for Division and or LCO activities into the QA portion of published HF for O&G DW Study reports
- Ensure audits are conducted without conflict of interest by the auditors and assessors
- Review and approve all technical products (e.g., reports, journal articles, models, data summaries, etc.) produced within their organization for this HF for O&G DW Study
- Participate in meetings organized by the PQAM and other HF for O&G DW Study leaders
- Provide HF for O&G DW Study QMP training to HF for O&G DW Study personnel in their respective LCO or Division

1.7.13. Program Records Management Consultant

- Provides related input to QMP
- Assists HF for O&G DW Study personnel in understanding and implementing EPA records management requirements

ORD QA staff (i.e., DQAs, QAMs) whose organizations are involved in the HF for O&G DW Study will support the PQAM's efforts to coordinate QA/QC practices. It is the responsibility of each member of

[1] In NCEA and OSP, the DQA has QAM duties.

the HF for O&G DW Study staff to implement the Quality System requirements defined in the HF for O&G DW Study QMP. This will be accomplished by ensuring that QA/QC requirements are included in QA documentation and by conducting assessments of the appropriate type and frequency to evaluate the implementation of planned QA/QC practices. The DQAs and QAMs are responsible for ensuring the required HF for O&G DW Study QA activities are conducted according to this QMP and their organization's QMP. QAPPs prepared by individuals for specific research areas will be approved by those individuals' respective Division QAMs after consulting with the PQAM to ensure that the QAPP meets the HF for O&G DW Study requirements.

2. Quality System Components and Description

This Quality System and QMP apply to all research activities conducted under the HF for O&G DW Study. EPA management will review and approve this QMP and subsequent revisions as QA policy for this HF for O&G DW Study.

2.1. Graded Approach

EPA applies a graded approach to all QA requirements, such that the process of basing the level of application of QA requirements to an item or work is graded according to the intended use of the results and the degree of confidence needed in the quality of the results. In ORD, the application of this graded approach is based on a four-category system, with Category I requiring the most rigorous QA requirements.

Category I: Research that is anticipated to result in high-visibility products. Research of this nature meets one or more of the following criteria.

- Direct regulatory support
- Has a high probability that the results could be used for litigation or enforcement
- Has heightened public or media interest and may be of special interest to the EPA Administrator
- Is a highly influential scientific assessment (HISA) as described in the Office of Management and Budget Final Information Quality Bulletin for Peer Review, December 2004

All projects under this HF for O&G DW Study have been designated as ORD QA Category I efforts because of heightened public and media interest and contribution to a HISA [(15)]. QA categories are described in ORD's Policies and Procedures Manual, Section 13.7, *Use of the Graded Approach* [(12)] (in preparation). Category I projects must comply with Agency requirements and guidance for QAPPs, including systematic planning. QAPPs will be required to adhere to the requirements in *EPA Requirements for Quality Assurance Project Plans.*[(16)] For Category I projects, audits are needed, reports must have a readily identifiable QA section, and products must undergo QA review and approval. EPA Records Schedule 501 applies to this QA category. [(2)]

Investigators with project lead responsibilities will prepare project-specific QAPPs (see Appendix A for research areas and projects) as described in Section 7. Project-specific QA documents, including QAPPs, will be reviewed and approved by the LCO QAMs with concurrence by the PQAM, who is independent of research activities. The review and approval process is equivalent among LCOs.

Organization-specific products from this HF for O&G DW Study also will be reviewed and approved by the LCO QAMs. Consolidated products that encompass information from across ORD will be approved by the PQAM, with assistance from the LCO QAMs. The required documentation for this process is discussed in Section 2.2.5.

Quality, management, and technical assessments will be included throughout the HF for O&G DW Study as described in Section 9.

2.2. Planning Components and Tools

2.2.1. Study Plan

The planning for the HF for O&G DW Study began with the Congressional request and significant stakeholder input that followed. Stakeholder input has been critical in planning the HF for O&G DW Study. Federal, State, and tribal partners, as well as industry, nongovernmental organizations, and the public, were engaged via webinars, sector-specific meetings, and public information meetings. Written and electronically submitted comments also were solicited and incorporated into the planning. This input was reviewed by the SAB and incorporated into the *Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources*[(1)]—the technical basis for this QMP and the HF for O&G DW Study.

2.2.2. Systematic Research Planning and QAPPs

The research performed for this HF for O&G DW Study will use the goals and objectives in the study plan referenced above and, then, develop project-specific objectives. Research will be planned in a systematic manner. In some cases, this may include utilization of EPA's Data Quality Objectives (DQO) process. The DQO process is the Agency's recommendation when data are to be used to make a decision of compliance or noncompliance with a standard or concluding a difference between two conditions. In other cases input from existing data or meetings with EPA HF staff and stakeholders are used to plan appropriate research requirements and activities. The DQO process is described in *Guidance on Systematic Planning Using the Data Quality Objectives Process*, February 2006.[(17)] Project-specific quality documentation also will include QAPPs, SOPs, and similar planning and procedural documents. Appropriate signatures at the beginning of each document verify review and approval responsibilities for each QAPP. Section 7.0 of this QMP provides more specific information.

2.2.3. HF Drinking Water Study QMP and LCO QMPs

Quality requirements for the HF for O&G DW Study are specified in this HF for O&G DW Study QMP. In some instances, the HF QMP refers to the requirements specified in individual LCO QMPs. The requirements of this HF for O&G DW Study QMP, where specified, supersede the requirements of the LCO QMPs. All LCO QMPs have been approved by the EPA Quality Staff and, therefore, meet or exceed EPA QA Program requirements.

The ORD DQA will assess comparability of the quality processes used by the individual LCOs for the HF for O&G DW Study during the QSA and determine if differences in the quality programs have a negative impact on quality. Corrective actions to the findings of the QSA will be tracked by the PQAM and reported during monthly HF QA teleconferences. The PQAM leads the monthly HF QA conference call with the LCO DQAs and QAMs and the QA Executive Lead to discuss best practices in collaboration and

other issues related to the HF for O&G DW Study for O&G DW Study quality program. Action items from these meetings are tracked to resolution.

2.2.4. QARF for Extramural Activities

QA requirements are identified by the COR (with concurrence by the LCO QAM) for each extramural action and incorporated into the extramural documentation. Specific information is provided in Section 4.0.

2.2.5. ORD Product Review Form

QA requirements for products are identified by the Investigators (with concurrence by the LCO QAM) for each product as described in Section 1.5. Products will be reviewed and approved by QA staff as previously identified and documented using a product review/approval form. The QA Product Review and Approval Form is provided in Appendix B. LCOs may use their organizations' internal forms if they are consistent with the form in Appendix B.

2.3. Implementation Components

2.3.1. Routine Communications

The following teleconferences, meetings, and reports are used throughout the HF DW Study to communicate project requirements, status, and activities.

Weekly:

The HF Study Coordinator leads the HF Leadership meetings. The purpose of these meetings is to exchange information among LCO Directors, the PQAM, and others on topics related to the HF for O&G DW Study including research progress and products, Congressional briefings, schedule, budget, coordination within and outside of EPA, communications, QA, and peer review.

Monthly:

The PQAM leads a monthly (actual frequency may vary at the discretion of the PQAM) status communication (teleconference or e-mail) of for O&G DW Study quality and information management with the DQAs, QAMs, and the Executive QA Lead.

The Study Coordinator hosts monthly teleconferences with Investigators to discuss the progress toward milestones, complications, and any other current topic of interest or concern. QA will be a topic on these teleconferences when deemed necessary by the PQAM.

Investigators provide monthly reports to the HF for O&G DW Study. Communication Lead regarding stakeholder outreach activities (e.g., invitations to speak at meetings about HF for O&G DW Study activities).

As Needed:

Extended videoconferences or in person meetings are convened by the Study Coordinator.

2.3.2. Training

Training requirements are described in Section 3.

2.3.3. Chemical Analysis Requirements

2.3.3.1. Elements of a Data Package

Complete data package includes all documentation needed to be able to reconstruct analysis. It is to be provided electronically and include copies of chain-of-custody forms.

- Copy of method or SOP used (or reference if the information is readily available)
- Standards preparation logs and worksheets
- Calibration data
- Raw data (including notebook pages)
- QC data
- Data qualifiers
- Quantitation (reporting) and detection limits
- Deviations from method
- Interpretation of impact on data from deviations from QC or method requirements

2.3.3.2. Analytical Data Review, Data Verification, and Validation Process

- Laboratories verify data prior to reporting them to the Investigators
    - This includes evaluating data with respect to the QC criteria of the method used and flagging data with appropriate qualifiers if needed.

- Data summary reports are reviewed by the Investigators for completeness, correctness, and conformance with QAPP requirements.
    - All sample results are verified by the Investigators to ensure they meet project requirements as defined in the QAPP, and any data not meeting these requirements are appropriately qualified.

- ADQs are conducted on representative data by a party independent of the data collection (performed or overseen by the QAM using a checklist—see example in Appendix E).
    - Typical results may require further qualification of data.
    - A checklist used for these ADQs is provided as Attachment B of the NRMRL SOP for ADQs.

- Investigators use the information from all these data verification and validation activities to assist in making the recommendation of data usability. For example, one outcome may be to discard some data as unusable.

- This information is provided to the appropriate LCO Division Director and the LCO Director for a decision regarding usability of data. This decision may be elevated to the HF Leadership Team, QA Executive Lead, or Acting Principal Deputy AA and SRO for ORD, as needed.

2.3.4. Geospatial Data Policy Procedure

Whenever practical and applicable, this research will adhere to the *EPA National Geospatial Data Policy* (NGDP), which establishes principles, responsibilities, and requirements for collecting and managing geospatial data used by Federal environmental programs and projects within the jurisdiction of EPA. This policy also establishes the requirement of collecting and managing geospatial metadata, describing the Agency's geospatial assets to underscore EPA's commitment to data sharing, promoting existing or secondary data use, and supporting the National Spatial Data Infrastructure. The NGDP, CIO Policy Transmittal 05-022, Classification No. 2121, can be found at http://www.epa.gov/nerlesd1/gqc/pdf/epa_natl_geo_data_policy.pdf.

2.4. Assessment Components

Assessments are an essential part of the HF for O&G DW Study. Details of the assessments that are required are presented in Section 9. Auditors and assessors ensure there is no real or perceived conflict of interest with the project, system, or organization being audited or assessed. It is the responsibility of the QAM to ensure audits are conducted without conflict of interest.

Assessment components discussed in Section 9 are QSAs, TSAs, PEs, ADQs, readiness reviews, and surveillance.

2.5. Reporting Deviations

Deviations from requirements in planning documents (i.e., QMPs, QAPPs) found during technical or data assessments must be documented, as follows.

- Unique project identification
- Unique identifier for assessment deviation
- Deviation found
- Corrective action to be implemented, if any
- Time frame for implementation
- Initial approval by appropriate QA staff
- Closure status
- Closure signature by appropriate QA staff

Appendix F contains the form for the documentation of individual deviations when an LCO does not have a policy for documenting and ensuring closure of deviations.

For deviations found during a project TSA or ADQ, the deviation form is completed and signed by the Investigator or designee in consultation with the QAM. The QAM will review the corrective action within a reasonable time of the date designated for the corrective action to be implemented and, thereafter, as often as needed to document status to the Investigator and PQAM of efforts toward closure of the deviation report. When the deviation report is closed, the QAM then will copy the completed and approved deviation report to the Investigator and the PQAM.

When LCOs have established practices for documenting deviations and corrective actions, they may be used if they are at least equivalent to those found herein. If the LCO uses an internal equivalent established practice, the PQAM will be notified at least monthly of the status and final closure of the assessment.

Deviations found during a program QSA will be tracked by the PQAM to closure. The closed finding report will be submitted to the HF Study Coordinator and the ORD QA Executive Lead for HF.

Monthly, the status of open deviation reports will be discussed during the PQAM's HF QA teleconference, and all deviation reports will be reported to the ORD QA Executive Lead for HF.

3. Personnel Qualification and Training

The HF for O&G DW Study requires that all research and QA staff have appropriate qualifications and training to meet their assigned responsibilities. Line managers are responsible for identifying those key work functions at each organizational level requiring special skills and for establishing procedures to ensure that personnel demonstrate proficiency in performing their assigned work. Individual LCO QA staff will determine the necessary QA training needs via discussions with staff and as a result of findings from audits or assessments.

HF for O&G DW Study QA training in the requirements of this QMP will be performed by the PQAM via the periodic QA teleconferences and monthly teleconferences led by the Study Coordinator described in Section 2.3. Additionally, HF for O&G DW Study QMP training materials may be prepared by the PQAM and distributed to LCO QAMs. The LCO QAMs will be responsible for training LCO personnel as needed. HF for O&G DW Study QA training records will be maintained by the LCOs. Lists of personnel trained in the requirements of this QMP will be submitted to the PQAM by the LCO QAMs for tracking and reporting purposes.

Any project- or task-specific specialized training or certification requirements will be identified and described in QAPPs. Hazardous Waste Operations and Emergency Response certification is required for all case study field work, including for those conducting QA and safety audits. Anyone working with confidential business information (CBI) must undergo training and be certified to handle this information. Legal access to Toxic Substances Control Act (TSCA) CBI is dependent on meeting the conditions found in Section 14 of the TSCA. The qualifications differ between Federal employees and contractor employees and may require administrative certification. Investigators with project lead responsibilities are responsible for ensuring that personnel working on their projects receive necessary training. Verification of training documentation, other than QMP training noted above, will be the responsibility of the Investigator. This documentation may be verified during project or program assessments.

Specific HF for O&G DW Study training will include training in communications procedures and e-mail record keeping. Training in records management for the HF for O&G DW Study will be provided by the ORD Records Liaison Officer (RLO). The timing of and participants for such training will be determined by the Study Coordinator.

EPA and contracted laboratories and contractors performing field sampling must demonstrate competency in accordance with *Agency Policy Directive FEM-2011-01.*[18] Documentation of competency may include participation in applicable certification and accreditation programs when available for the fields of analysis. Guidance may be found at the EPA Forum on Environmental Measurements site: http://www.epa.gov/fem/accredit.htm.

CORs are responsible for ensuring that contractors have the necessary qualifications for their assigned work.

The need for retraining in any requirement of the project or program may be determined by the supervisor or during an assessment. It is the responsibility of the Investigator to ensure retraining is obtained and documented. The ORD Director of QA may request and review any training or retraining records during the QSA to ensure that qualifications are current.

4. Procurement of Items and Services

All operations performed under extramural agreements must comply with the Agency-wide Quality System requirements as defined by the relevant regulations. Such agreements include contracts, cooperative agreements, grants, and IAs. ORD QA Review Forms[19] for extramural agreements (http://intranet.epa.gov/nrmintra/lsas/eqmp/pdf/qarford071508.pdf) will be prepared by individual CORs and approved by their respective Division QAMs after consulting with the PQAM. Instructions on using this form (ORD-111) are available at http://intranet.epa.gov/nrmintra/lsas/eqmp/pdf/ORDQARFinstructions073008.pdf. Verification that services meet all procurement document requirements is the responsibility of the COR or PO.

Federal procurement and financial assistance regulations provide specific requirements for QA/QC whenever environmental data collection or use is expected as part of a project or activity. Items and services to be procured must be described clearly in the procurement documents by the Investigator. The specific requirements apply to the following.

Any organization or individual under direct contract to EPA to furnish services or items or perform work (i.e., a contractor) under the authority of 48 Code of Federal Regulations (CFR), Chapter 15, Part 46 [10];

Institutions of higher education, hospitals, and other nonprofit recipients of financial assistance (e.g., grants and cooperative agreements) under the authority of 40 CFR Part 30 [11]; and State, local, and tribal governments receiving financial assistance under the authority of 40 CFR Parts 31 and 35 [12].

Non-EPA quality systems that comply with the document *Quality Systems for Environmental Data and Technology Programs*[20] or the *Uniform Federal Policy for Implementing Environmental Quality Systems*[21] (http://www.epa.gov/fedfac/pdf/ufp_v2_final.pdf) are also in compliance with EPA policy.

IAs funded by EPA should include EPA QA/QC requirements in the agreement. Because EPA cannot unilaterally impose such requirements, these requirements must be negotiated into each agreement and include references to the consensus standard ASQ/ANSI E-4[20] or equivalent EPA requirements (QA/R-2, Reference 22, QA-R-5, Reference 16).

The steps and required QA used in the procurement of items and services under this HF for O&G DW Study largely are handled in each LCO QMP. Extramural items or services sponsored by or obtained for the HF for O&G DW Study will be subject to basic QA requirements established by Federal, Agency, and LCO policies and regulations. QA review forms for extramural agreements will be approved by individual CORs and their respective Division QAMs after consulting with the PQAM.

All extramural documents and records that will be transferred to EPA during or at the completion of the project should be specified in the Statement of Work (SOW) or external agreement.

4.1. Contract Support

Considerable laboratory, field work, and other contract support are anticipated during the course of this research. In general, the originating COR, in consultation with the QAM, has the responsibility for QA for the procurement activity. EPA policy requires a completed ORD QA Review Form[19] (http://intranet.epa.gov/nrmintra/lsas/eqmp/pdf/qarford071508.pdf) with each extramural project funding package to document the QA requirements. The COR must then ensure that the requirements are included in the contract language. Contracted laboratories, other facilities, and field personnel have QA responsibilities that are specified in their respective SOW. A SOW must be developed by the COR and provided, along with an ORD QARF, to their QAM for QA review. The QAM must review the SOW and QARF to ensure the QA requirements meet the HF for O&G DW Study's requirements. If needed, the QAM must provide review comments to the COR, who will make the necessary revisions to comply with these requirements. On receipt, the QAM must forward the QARF to the PQAM for review of HF for O&G DW Study consistency.

QA responsibilities and requirements for contractors include, but are not limited to the following.

- Accredited laboratories must be used for critical target analytes. If accreditation is not feasible, then laboratory competency must be demonstrated (documented quality system and methods, instrumentation, and experience; PEs; and independent audits).
- Maintain communication with EPA
- Develop or implement QAPPs as specified in the SOW
- Perform the required QA/QC procedures during technical or analytical activities
- Report technical or analytical results with the associated QA/QC summary and datum-specific information
- Perform corrective actions or other necessary steps when QA issues are identified and report this information to the associated EPA LCO
- EPA will audit contractor activities that perform analysis of critical target analytes (see Section 9).

The contracted laboratory, field, or facility personnel should have a QAM, QA officer, or similar defined position with the responsibility of ensuring these QA requirements are met. The QAM/officer of the contractor must be independent of the data being collected.

4.2. Interagency Agreements

The HF for O&G DW Study will implement IAs to augment capabilities in areas such as laboratory and field support or other research activities. QA requirements, including the identification of a QA lead, will be negotiated between EPA and the other Federal agency and documented in the ORD QARF and the Decision Memorandum. On receipt, the QAM must forward the QARF to the PQAM for review of HF for O&G DW Study consistency. After receiving concurrence from the PQAM, the QARF and Decision

Memorandum must be reviewed and approved by the QAM. Typical requirements may include any of several approaches: The other Federal agency develops and writes a QAPP to be reviewed and approved by EPA; the other agency may implement an EPA-approved QAPP; or it may implement well-documented protocols or methods that are reviewed and approved for use by EPA. The work conducted under an IA must be audited by EPA (Section 9).

When dialogue results in a final determination of these requirements, the final requirements must be documented in the project QAPP.

4.3. Supplies

Each Investigator must establish and appropriately document in the procurement specifications the necessary QA/QC requirements of the needed supplies. The supplies to be procured must be described clearly in the procurement documents by the Investigator. Verification that supplies meet all procurement requirements is the responsibility of the Investigator or designee.

4.4. Regional and ORD Laboratories

EPA Regional and ORD laboratories will provide analytical support for the HF for O&G DW Study. They are subject to the same QA requirements as contracted laboratories. The Investigator, in consultation with the QAM, must clearly transmit requirements to the EPA laboratory and participate in discussions as needed to ensure requirements will be met. The requirements must be documented in the project QAPP.

5. Documents and Records

All research-related documents and records are the property of the Federal government and are subject to the Federal records management policies. Investigators are responsible for the proper handling, storage, and archiving of project documents and records. Each LCO Director is responsible for the proper handling, storage, and archiving of its own program documents and records.

5.1. Quality-Related Documents and Records

Quality-related documents include the HF for O&G DW Study QMP and HF QAPPs.

It is the responsibility of the Investigator to ensure that the EPA QA Level I QAPPs for the HF for O&G DW Study are written according to *EPA Requirements for QA Project Plans (QA/R-5*), or other standard requirements, as appropriate and approved by the PQAM. The QAPPs are reviewed and approved by the Investigator and their supervisor. The QAPP then is reviewed and approved by the Division QAM or LCO DQA, according to LCO and HF program requirements, and reviewed by the PQAM for consistency with the requirements of the current HF QMP.

For the HF QMP and QAPPs, revisions or addenda are reviewed and approved using the same process as the original and will include an updated revision history table and version control block. See the revision history table near the beginning of this HF QMP for an example.

The version control block for the HF QMP and each QAPP will include the following information, at a minimum.

Short Document Title
Revision No. _____
Date _____
Page _____ of _____

All research projects conducted by or for the HF for O&G DW Study must be documented in accordance with ORD's Policy and Procedures Manual, Chapter 13, Section 13.2: *Paper Laboratory Records.*[12] All Federal records will be maintained and stored according to Agency records schedules. As a QA Category I effort, the majority of HF for O&G DW Study records require permanent retention under EPA Records Schedule 501, *Applied and Directed Scientific Research.* [2]

Extramural documents and records will be organized in a contract file or an assistance agreement file by the COR or PO. Scientific records are to be transferred to the EPA Investigator at their request at the end of the project. The Investigator for each project will ensure that the final project, contract, or assistance agreement file is properly assembled for archiving. The scientific records generated as part of extramural actions will be retained in the project file to comply with the records schedule identified above.

5.2. Use of the O:\ Drive

This HF for O&G DW Study will utilize a central information management system as a repository and central location for storing, sharing, and archiving study documents, data, and other record materials. Oversight of the system, including server operations, maintenance, and backups, is the responsibility of the Office of Science Information Management (OSIM). Electronic records (other than e-mail) should be filed on the shared ORD drive, O:\. By selecting the O:\ drive, study participants across all ORD locations may collaborate easily by sharing access to individual files. Collaborators at other EPA locations (i.e., Regional Offices) also can be granted access to the O:\ drive. Access to folders can be controlled using a hierarchical structure that begins with O:\ Priv. Access rights are can granted as "read" or "read, write, and delete."

The Study Coordinator or designee will maintain an Excel spreadsheet of all study participants that require access to the O:\Priv drive and their associated access rights. This spreadsheet will be shared with the OSIM staff responsible for administering access rights on the O:\ drive. Study participants will be granted read and write access to all HF for O&G DW Study folders, with the exception of files that are designated for documents and records for which the technical review process, including QA review, is complete. For these files, only the Study Coordinator and Report Synthesis Lead will have read, write, and delete access; all other users will have read-only privileges.

The EPA ORD shared network group drives are not approved electronic record keeping systems as defined by the National Archives. Therefore, to organize electronic files for proper retention and disposition, they are grouped together by the retention schedule disposition item (e.g., 316-258_501a2). In addition, electronic files are identified by the specific research project for which they were created. All HF for O&G DW Study participants are responsible for proper records retention. An example of the file structure that will be used to accomplish these objectives follows.

O:\Priv\NRP_SSWR_HF\316-258_501a2\20110228_QA_Assessment_ABC.doc

> ***O:*** *= the network common drive accessible to all of ORD*
>
> ***Priv*** *= Private, as opposed to public; access to this directory is controlled.*
>
> ***NRP*** *= National DW Study is a virtual organization identifier because the research is not specific to a particular LCO.*
>
> ***SSWR*** *= Safe and Sustainable Water Resources, the national research program, defined by ORD's Path Forward research portfolio, accountable for the HF project*
>
> ***HF*** *= Hydraulic fracturing (research project name)*

> ***316-258 501a2*** *= EPA file code (316-258 is the functional code for Applied Science; 501 is the EPA record schedule for Applied and Directed Scientific Research; and, a2 is the disposition item for Project Files).*
>
> ***20110228_QA_Assessment_ABC.doc*** *= The file name of a particular document. A standard YYYYMMDD format represents the date the file was created, followed by a subject name, followed by an optional component of the file name indicating the initials of the author ("ABC"). Underscores are used in place of spaces in the file name.*

Investigators and individual researchers may use QAPPs to describe additional standard subfolders within the O:\ drive file structure. When researchers use "My Documents" for storing their electronic files, for example during initial data analyses, no standard file structure is required; however, file names conforming to the conventions described in this section should be considered.

The O:\ drive file structure was constructed according to the following logic.

Some literature will be used for analytical work (i.e., Literature_for_Analysis), other literature will be technical or general reference files that are maintained by individuals or program offices to enable the person or program office to perform its mission and that are kept only for reference and, therefore, placed in Literature_for_Reference.

Documents, data, and other records materials will have life cycles that include initial collection, sharing, and analysis. This information typically is held in electronic files. Prior to technical review and QA review, these types of electronic files will be stored according to the six technical areas described in the HF DW study organization chart (Figure 3) using Project_Files-QA_Incomplete.

When all technical reviews, including QA review, are complete, documents and data will be placed in Final_Project_File-QA_Complete. This folder will be access controlled to ensure that all appropriate QA/QC checks have been completed and, if any changes are required, that their impact can be assessed with respect to other aspects of the study. It is recommended that information in this folder be in portable document format (pdf).

The information that will be used to write the assessment report will be stored in _Report_2014_Assessment using the same themes as used for the HF for O&G DW Study plan reviewed by EPA's SAB. These six themes are depicted in the HF for O&G DW Study organization chart (Figure 3).

The HF for O&G DW Study has an overarching QA program described in this document. Key documents required for the QA program will be stored in Quality_Assurance.

Records schedule 501 includes several retention schedules, ranging from permanent retention (i.e., 316-258_501a2) to retaining files for only 5 years after completion of the project (i.e., 316-258_501c). The majority of HF for O&G DW Study files will be retained permanently; however, any records for maintenance, calibration, or inspection of equipment will be placed in Equipment_Files, which has the shorter retention requirement. Additional folders have been provided for Non-Record materials (008a) and Contract Management records (504 202c).

A shortcut to the subfolders for the HF for O&G DW Study has been created and may be copied to the desktop to avoid the need to drill down through the top level folders. It is located at O/PRIV/NRP_SSWR_HF and is labeled “HF Files on O Drive”.

5.3. File-Naming Conventions

General

The following conventions should be considered for naming files that are created as part of the HF for O&G DW Study

Avoid use of special characters in naming, such as \ / : * ? < > | [ ] & $,

These characters have different effects in various operating systems (e.g., Apple, Microsoft, Linux), and their use could lead to loss of files or errors.

Avoid spaces in naming; use underscores instead.

Spaces are translated in a Web environment as ”%20”, and, in word processing, spaces signal a possible break for a new line.

Consider that the file or folder will move from its original location.

Files are frequently moved (e-mailed, copied, etc.) from the original location that may have given context (e.g., genomic_lab\photos\microscope\00001.gif).

Although this method is efficient when the files stay in this directory structure, it could lose context if the files alone or just one level of the folder were moved. An alternative would be genomic_lab_photos_microscope_0001.gif.

Consider using a date in your file- and directory-naming scheme.

As files are copied, their date of creation is overridden to the date of copy in some operating systems such as Microsoft XP.

If you do choose to use a date, follow the International Organization for Standardization document 8601.[23] Numeric representation of dates is YYYYMMDD.

Examples:

January 5, 2011	20110105
February 13, 1966	19660213
December 20, 1989	19891220

Manage versions.

To manage versions, consider adding a "v" to the file name followed by a two digit number (e.g., v02) to ensure the capture of changes from the original. Once the action is completed and the final version released, change the "v" notation to "FINAL".

Examples:

virtualLiver_tox_study_v01.doc

virtualLiver_tox_study_v02.doc

virtualLiver_tox_study_FINAL.doc

Indicate who created the file.

Include the researcher's name or initials in the file name

Consistency.

Are versions important to your group, or is it more important to include a date? What is most important is that, as a whole, there is consistency in naming practices, particularly within projects.

There will be exceptions.

One exception is batch processing by third-party software. There are times when it is not possible to rename files that are automatically generated. In these cases, apply standardization to the directories in which they reside.

Literature Files

Journal Articles

AuthorLastName_etal_YYYY_JournalAbbreviation_ShortIdentifyingText.xyz
(The "etal" is necessary only if there are multiple authors on the document.)

Another option would be to use the following if there are two authors and the above, "etal" version if there are more than two authors.

AuthorLastName1_AuthorLastName2_YYYY_JournalAbbreviation+ShortidentifyingText.xyz

Report

ReportPublisher_YYYY_ReportNumber_ShortIdentifyingText.xyz

Presentation

PresenterLastName_YYYYMMDD_MeetingAbbreviation_ShortIdentifyingText.xyz

Specific Conventions for Naming Quality Documents: QAPPs, Audit Reports, etc.

A systematic approach to labeling QA documents and files is taken from Chapter 5 of the ORD Quality Management Plan for Scientific Research, Revision 1, June 2012.

> ORD requires each laboratory/center QMP to describe a system for issuing document control numbers (DCNs) for quality records (e.g., QMPs, QAPPs, SOPs, and audit reports). The DCNs should be unique and intuitive to use. To this end, the DCN must indicate the following:
>
> > The acronym for the organization that is accountable for preparing and maintaining the document
> >
> > The acronym for the document type (i.e., QMP, QAPP, SOP, or audit report)
> >
> > A number, typically assigned sequentially, when combined with the acronyms creates a unique DCN
> >
> > The version/revision number (e.g., version 0 is the original; version 1 is the second version; version 1.1 is the second version with minor changes)

For example, the DCN for the ORD QMP is “ORDQMP-01-01”.

This approach needs only a minor modification to indicate the documents and files are tied to the HF for O&G DW Study by adding “HF” to the requirements listed above. For ease in quickly identifying the contents of the document or file, an additional term may be beneficial. For example, the case study QAPPs may include the location (i.e., Kildeer). For audits, including a date may be helpful.

Examples:

For the QAPP for the Kildeer case study, the DCN for the original QAPP will be as follows.

HF_NRMRL_Kildeer_QAPP-01-00

The DCN should be included on the title page, and it should be used to label the file in which it is located on the O:\ drive.

For the first field TSA of the Kildeer case study, the DCN will be as follows.

HF_NRMRL_Field_TSA_Kildeer-01-00-yyyymmdd

5.4. E-mail Management

Since the beginning of the HF for O&G DW Study, the Agency has migrated its e-mail services from Lotus Notes to Microsoft Outlook; consequently, study record e-mails will have been created in both e-mail applications and, at this time, will be managed differently. EPA has established the enterprise content management system (ECMS) as the certified record keeping system for Agency e-mail, and it should be utilized when available. Guidance on e-mail as records [24] can be found at (http://www.epa.gov/records/faqs/email.htm).

For Lotus Notes e-mails:

Record e-mails associated with the HF for O&G DW Study should be kept as part of the research project file or part of the project administrative correspondence in ECMS. Study participants are responsible for ensuring that e-mail records are filed appropriately at the end of the study or when the participant leaves the team for any reason.

So that HF for O&G DW Study e-mails can be compiled, accessed, and stored in a central information system, an "organization" has been established in the ECMS database for the HF for O&G DW Study (e.g., ORD/NRP/SSWR/HF). Collaborators may register in ECMS for access to the HF for O&G DW Study file plan, as a secondary organization, by "Requesting a group membership change" (http://intranet.epa.gov/ecms/start/register.htm). On obtaining access, users must file all project e-mail in custom HF for O&G DW Study folders already established in the file plan.

As ECMS "organization" folders, the contents of these folders are accessible to all members of the HF for O&G DW Study, unless otherwise restricted by the e-mail filer. Additional customized subfolders may be requested by contacting the ORD RLO.

For Outlook e-mails:

At this time, Outlook has yet to be configured to transfer record e-mails to the ECMS application. Until Outlook is integrated fully with ECMS, Outlook e-mails for the HF for O&G DW Study should be retained in a user-designated HF for O&G DW Study folder within the Outlook application. When ECMS has been enabled to accept these e-mails, users will be informed of how to move their records from their Outlook folder into ECMS for long-term retention.

5.5. Alternatives to Sharing Data on the O:\ Drive

Guidance for alternatives for sharing data is provided in this section.

Small files (≤10 MB): E-mail is a quick and convenient option.

Medium files (10 MB to 100 GB): Using EPA's Science FTP Server is an option. FTP stands for "File Transfer Protocol," a network protocol for copying files over a network such as the Internet. This service, run by the Office of Environmental Information (OEI), has been in operation since 2004 and is designed for both inbound and outbound file sharing. It is available to both EPA staff and external collaborators. Click on the link above to set up an account and create accounts for external collaborators. Generally, collaborator accounts are good for 1 to 4 weeks, but requests for an extension for up to 1 year can be made by e-mailing Ravi Nair (at nair.ravi@epa.gov). Note: Files on the Science FTP Server are deleted after 28 days without prior notice. Science FTP Server is a place to transfer files to other collaborators. It is not a place to store files, such as the O:\ drive, which is backed up.

Large files (≥100 GB): Use a CD, removable hard drive, or other similar device and overnight delivery service if needed

5.6. CBI

In some instances, work may entail use of documents or data that describe or involve CBI. This includes any information in any form received from any person, firm, partnership, corporation, association, or local, State, or Federal agency that contains trade secrets or commercial or financial information; that has been claimed as confidential by the person submitting it; and that, legally, has not been determined to be nonconfidential by the EPA General Counsel. TSCA CBI procedures will be used to maintain CBI collected under the HF for O&G DW Study.[22] HF for O&G DW Study managers and staff must ensure that this information is protected from general release and is kept in a secure system, as required by the above reference.

5.7. Chain of Custody Procedures

HF for O&G DW Study QAPPs will describe specific procedures and forms required to provide for a program of strict chain of custody for each sampling event. All samples will be uniquely identified so that records of a sample can be followed from the time and location of sampling to the table of analytical results in the final report.

6. Computer Hardware and Software

Procedures to ensure the accuracy and integrity of computer-resident data are of critical importance to the overall quality and credibility of the HF for O&G DW Study. EPA's OEI publishes guidance that generally will be followed throughout the EPA ORD LCOs participating. This guidance includes EPA Directive 2100B8, *Information Resources Management Policy*[26] and EPA CIO 2104.0, *Software Management and Piracy Policy.*[27] These comprehensive guidance documents address many issues regarding the use of computer systems, including purchase of computers, purchase or development of software, design of databases, records management, security, and data standards. Network- and PC-based databases and the networks themselves will adhere to Agency information management standards developed by the Office of Information Resources Management and to other standards and guidelines as applicable for the development of software and specialized computer hardware. Specification for computer hardware and software will be described in the individual LCO QMPs. It is the responsibility of each Investigator to interpret and adhere to the applicable standards of their respective LCO for each intramural or extramural project or study.

Projects that entail modeling, existing data, and require significant databases should specify computer hardware and software requirements in the associated QAPPs. Should there be a need for project-level software to be developed, this will be described in individual planning documents and conducted according to the OEI guidance and requirements for installing, using, maintaining, controlling, and documenting hardware and software. Procedures for assessing and documenting the impact of changes to the system and for ensuring that items meet necessary quality requirements prior to purchasing are included. These QAPPs also must follow EPA software-, modeling-, and database-specific guidance, including EPA G-5M, Section 7.0[28] if applicable.

If HF for O&G DW Study-wide hardware or software is required (e.g., database), OSIM is responsible for ensuring these systems adhere to the Agency information management standards.

7. Planning

EPA requires that all research conducted must follow a systematic planning process. EPA staff from LCOs, national research programs, and Regions contributed to the initial planning of the HF for O&G DW Study as defined in the *Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources*.[(1)] These representatives sought input from a broad range of stakeholders, including other Federal agencies, States, tribes, local government representatives, industry, nongovernmental organizations, academia, and private citizens. EPA staff participated in a series of meetings that established the water cycle as the parameter for the design and developed the research questions and contributed to the development of research approaches. The study plan was finalized after input from the public and peer review by the SAB.

This HF for O&G DW Study has been designated as a QA Category 1 effort. All work conducted specifically for this HF for O&G DW Study must follow the minimum QAPP requirements as described in EPA/QA R-5 *EPA Requirements for QAPPs.*[(16)] The guidance used to develop the project planning documents should be tailored to the project. Quality Management Tools for developing QAPPs are available at http://www.epa.gov/quality/qapps.html.

The planning and implementation of EPAs HF for O&G DW Study projects involving multiple LCOs in a balanced matrix organization require the use of collaborative leadership within each of the LCOs during the weekly HF Leadership team meetings. Given that Investigators communicate with and take instruction from both LCO Directors and the Study Coordinator on research progress and products, weekly HF Leadership meetings are an opportunity for the Study Coordinator to speak directly with LCO Directors, as well as QA Leadership, to ensure consistency with respect to project guidance and QA.

EPA guidance is available for projects that expand beyond typical measurement projects. Research projects that entail modeling should utilize the *Guidance for QAPPs for Modeling*, EPA QA/G-5M.[(28)] When existing data are used, the QAPP should indicate how "good" the data or information must be to meet the objectives of the project. During the planning process, acceptance or performance criteria should be determined for the data and documented in the QAPP. Research projects that entail the use of existing (secondary) data should utilize the EPA Guidance QA/G-5: *Guidance for QAPPs*, Chapter 3.[(29)]

Other agencies (e.g., DOE) may follow the *Uniform Federal Policy for Implementing Environmental Quality Systems*[(21)] (http://www.epa.gov/fedfac/pdf/ufp_v2_final.pdf). This policy is equivalent to the EPA guidance for planning.

Regardless of the type, each QAPP will include boilerplate information, specific to the HF for O&G DW Study. This boilerplate language is included in Appendix G.

QAPPs will be reviewed internally by Division QAMs according to LCO requirements. The QAM will forward the QAPP to the HF for O&G DW Study PQAM for concurrence with the requirements of this QMP. QA staff are independent of the work being reviewed.

For each project, project objectives need to be clearly identified and designated as primary or secondary. Primary objectives are those that are critical to meeting the goals of the research activity. Secondary objectives are ancillary to the primary objectives and often provide additional information to supports the primary objectives. Associated measurements then must be classified as either critical for primary objectives or noncritical for secondary objectives. This enables a better focus for the planned QA activities (e.g., audits).

In instances where routine steps are used for sampling, analysis, data searching, or other activities, the preparation and use of an SOP is of significant value. In these instances, an SOP should be written, especially if the procedure is to be followed by more than one person. SOPs are descriptions of repetitive functions written to a level of detail that enables the function to be performed in the same way among personnel and over time. SOPs may describe, for example, fundamental, programmatic actions and technical actions, such as analytical processes and processes for maintaining, calibrating, and using equipment. SOPs are intended to be specific to the organization or facility whose activities are described and assist that organization in maintaining their QC and QA processes and ensuring compliance with governmental regulations. If a new procedure needs to be developed under this HF for O&G DW Study, LCO QMPs should be consulted. The need for an SOP is determined by the Investigator, QAM, or line management. SOPs will be reviewed and approved according to procedures found in LCO QMPs.

8. Implementation of Work Processes

Proper implementation of a project requires the following facets.

1. Adherence to all planning and procedural documents (QAPPs, written operating procedures), with documentation of any significant deviations or amendments

2. Routine QC checks and periodic self-assessments to provide regular, ongoing quantitative and qualitative evaluation of project performance. Where measurement quality objectives have been established, the Investigator is responsible for ensuring that all resulting project design constraints are adhered to and that all associated data quality requirements for specific measurement methods are met routinely.

3. Timely reporting and documentation of significant problems, corrective actions taken, and potential impact on task or project results

4. Complete, accurate, verifiable documentation of all aspects of the task or project implementation that may affect the quality of the results and the overall credibility and defensibility of the work. This includes documentation of experimental objectives, approach, sample chain of custody, methods, and materials.

5. QA review of all products produced in this HF for O&G DW Study

All members of ORD's research staff are required to comply with ORD Policies 13.2, *Paper Laboratory Records*[12], and 13.4 *Quality Assurance/Quality Control Practices for ORD Laboratories Conducting Research.*[12] It is the responsibility of the Investigator or COR for each project of the HF for O&G DW Study to ensure that a project is implemented properly so that the results are scientifically defensible and of the type and quality required.

The LCO Directors, Division Directors, and Branch Chiefs are directly responsible for ensuring that all personnel involved in the conduct of the project are appropriately qualified, trained, and supervised. The Investigator or COR is responsible for ensuring that all project personnel fully understand the research objectives, the technical and QA or QC requirements of all of the project's research plans and procedures, and their roles and responsibilities in implementing these plans and procedures and in the overall conduct of the project.

The current versions of QAPPs and associated SOPs are to be available to all project workers. Work must be implemented according to those planning documents. SOPs that are written for projects should follow LCO guidance.

QAPP and SOP revisions are required whenever significant changes to a plan or procedure are implemented. QAPPs and project-related SOPs must be reviewed within 18 months for long-term projects. Reviews should be documented and tracked for all QAPPs and SOPs.

National Institute of Standards and Technology-traceable standards will be used, as available, for calibration of equipment and to confirm the quality of generated data. Secondary source standards must be included in the calibration for analytical systems. Where no such standards exist, other means will be used to establish the quality of the data, including agreement with established scientific knowledge and historical data, reproducibility and internal consistency, comparability between different measurement techniques, and conformity with approved technical plans and directives.

9. Assessment and Response

Regular assessments of project operation, systems, and data (including existing or secondary data) will be conducted under this HF for O&G DW Study. In most cases, the assessments are described in the QAPPs and scheduled by the Investigator in coordination with the associated LCO QA staff who will perform the assessment. Final audit reports will be added to the HF for O&G DW Study O:\ drive by the LCO QAM.

As defined in the EPA QA/G-7, *Guidance on Technical Audits and Related Assessments for Environmental Data Operations*, [29] a technical assessment is "a systematic, objective, and independent examination of a project during its implementation phase to determine whether environmental data collection activities and related results comply with the project's QAPP and other planning documents, are implemented effectively, and are suitable to achieve its data quality goals." Types of assessments that will be performed to support the HF for O&G DW Study are described below, and, along with their frequency and responsibilities, are identified in Table 2.

QSAs are management-independent, qualitative evaluations of a quality management system. They review the management structure, policies, and procedures of an operation. For this HF for O&G DW Study, a QSA will be conducted to ensure the HF for O&G DW Study is being conducted according to the requirements of this QMP and to the applicable requirements of the individual LCO QMPs, where applicable to the HF for O&G DW Study. A QSA will be performed by the ORD DQA within 1 year of approval of the HF for O&G DW Study QMP. The QSA report will be sent to the Study Coordinator, Investigators, their supervisors, LCO Directors, the QA Executive Lead, and the PQAM. The Investigator's supervisors will have the ultimate responsibility for ensuring corrective actions have been completed for any QSA findings. The PQAM will track corrective actions to closure.

TSAs qualitatively document the degree to which the procedures and processes specified in the approved QAPP are being implemented. TSAs will be performed by LCO QAMs for all for O&G DW Study projects early in the project or when the QAM and Investigator determine it is most appropriate. TSA requirements will be included in each QAPP and will cover IA, extramural, and contracted requirements. Where applicable, TSAs will focus on critical target analytes. TSA reports are to include who and what was assessed, any problems (e.g., findings) and noteworthy practices identified, and recommended corrective actions. TSA reports are submitted, at a minimum, to the Investigator, the appropriate supervisor, the COR for extramural audits, and the PQAM.

PEs quantitatively test the ability of an analytical system to obtain acceptable results. PEs need to be conducted on all critical measurements (where available). If a contract or Regional laboratory is not currently participating in a PE program, it will be provided with PEs by the Investigator in consultation with the QAM.

Verification of Data is the process of evaluating the completeness, correctness, and conformance or compliance of a specific data set against the method, procedural, or contractual requirements. Data collected during this HF for O&G DW Study are to undergo verification against the generic requirements, such as the analytical method or contract. Data that do not meet requirements will be qualified. QAPPs will include a table of data qualifiers to be used during data verification. An example table of data qualifiers is included in Appendix D. Verification is performed by the data generators (laboratories) and the Investigator or TRL, as identified in the associated QAPP [(30)].

ADQs are conducted by QA staff on verified data to document the capability of a project's data management system (hardcopy and electronic) to collect, analyze, interpret, and report data as specified in the QAPP. ADQs assess the effectiveness of the "big picture," as opposed to data verification, which concern individual data points. ADQs will be conducted on a representative sample of critical data generated early in the project. For example, a representative sample may be the first complete data package for the critical target analytes from the first sampling event. An example of a checklist for an ADQ is included in Appendix E. The components of a complete data package are included in Section 2.3.3.1 of this QMP. The NRMRL SOP *Performing Audits of Data Quality (ADQ)*[(31)] (http://intranet.epa.gov/nrmintra/lsas/eqmp/pdf/SOPLSASQA020.pdf) can be consulted for example guidance regarding ADQs. QA staff also may decide that additional ADQs be performed based on the quantity of data and issues observed.

Data Usability Assessment entails using the information collected during data verification and ADQs to assess whether the data can be used for the intended purposes. In some cases, data may have been collected but not all quality objectives were met, or sampling and handling may have impacted the analytes. Under these conditions, the data may be rejected or used with certain conditions or qualifications attached to the results. These assessments are performed by the Investigator or TRL, as identified in the associated QAPP.

Other assessments that may be useful (but are optional) are the following types.

Readiness Reviews are conducted before specific technical activities (e.g., laboratory analysis) are initiated to assess whether procedures, personnel, equipment, and facilities are ready for environmental data to be collected according to the QAPP. QA staff, in consultation with investigators, will determine the need for readiness reviews for any aspect of the HF for O&G DW Study.

Surveillance is used to continuously or periodically assess the implementation of an activity or activities to determine conformance to established procedures and protocols. QA staff, in consultation with investigators, will determine the need for surveillances for any aspect of a specific project.

Table 2 Assessment Frequency and Responsibilities

Assessment Type	Frequency	Responsibility To Plan	Responsibility To Implement	Reports Are Provided To
QSA	Within 2 years of QMP approval	ORD Director of QA	ORD Director of QA	PQAM, Study Coordinator, Overall TRL, QA Executive Lead
TSA	At least once for each project	Investigator, COR, LCO QAMs	LCO QAMs	PQAM, Investigators, CORs, TRLs associated with the project
PE (second source)	For each critical measurement if an applicable PE is available	Investigator and QAM	Investigator and QAM	Investigator, QAM, PQAM
Data Verification	Each data set associated with a project	Investigator	Data generator and Investigator and supporting personnel	In project report
ADQ	Sample of each critical measurement associated with a project	Investigator, LCO QAMs	LCO QAMs	PQAM, Investigators, TRLs associated with the project
Data Usability Assessment	Each data set associated with a project	Investigator	Investigator and supporting personnel	In project report
Readiness Reviews	Prior to start of new procedures, as needed	Investigator	Investigator and supporting personnel	PQAM
Surveillances	As needed	Investigator, LCO QAMs	LCO QAMs	PQAM

When significant quality issues are encountered, the Investigator should be contacted as soon as possible. Assessors do not have stop-work authority; however, they can advise the Investigator if a stop-work order is advisable, such as in situations where data quality may be impacted significantly. The Investigator makes the final determination as to whether or not to issue a stop-work order.

Corrective Action includes the tasks that are to be enacted because of findings identified during audits. Corrective actions are to be tracked by the LCO QA staff or the PQAM, as determined by the level of the assessment. The Investigators are responsible for ensuring corrective actions are implemented. The LCO QAMs will ensure corrective actions for audits within their LCO have been completed. QAMs may

document corrective action closure using the Deviation Report located in Appendix F. LCO QAMs will provide quarterly status updates of assessments and corrective actions to the PQAM.

10. Quality Improvement

Quality improvement is the responsibility of every staff person involved with this HF for O&G DW Study. The policies and procedures described in this QMP document the QA planning and implementation steps for this HF for O&G DW Study with the procedures in place for assessment described in Section 9. It is the responsibility of each person in the program, especially QAMs and the PQAM, to monitor these quality procedures throughout the data life cycle.

The primary means for discovering opportunities for continuous quality improvement will be the systematic technical assessments in use within the entire HF for O&G DW Study's Quality Management System. These assessments, as discussed in Sections 2 and 9, will provide information from which the HF for O&G DW Study can learn and improve on. Participants are encouraged to immediately report to Investigators any QA concerns and to communicate regularly with their colleagues on project progress and potential issues or steps for improvement.

11. Terms and Definitions

Assessment. The evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: QSA, TSA, and ADQ.

ADQ. An examination of a set of data after it has been collected and verified by project personnel, consisting of tracing representative test data from original recording through transferring, calculating, summarizing, and reporting. It is documented in a data audit report.

DQA. A DQA has lead responsibility for the mandatory Agency-wide QA program for each of the ORD Laboratories and Centers.

DQO. The qualitative and quantitative statements derived from the DQO process that clarify a study's technical and quality objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions

DQO Process. A systematic planning process that clarifies research objectives and establishes a basis for the types, quality, and quantity of data required. It provides a method for establishing DQOs for a research project.

Lead Organization. The organizational home of the Investigator with project lead responsibilities is by definition the Lead Organization (i.e., LCO, Division, or Immediate Office).

ORD Audit Finding Definitions:

> **Noteworthy Best Practice.** A best practice is noteworthy because it benefits the organization by increasing the efficiency and credibility of project operations. The exemplary nature of a best practice makes it a model for other organizations.
>
> **Observation with Recommendation.** An observation is a deficiency that may impact operational efficiency but will not have a significant adverse effect on quality. Although a change in procedure may result from an observation, corrective action is not required officially or tracked.
>
> **Finding Requiring Corrective Action.** A finding is a deficiency to implement or meet a requirement specified in QA documentation that may or will have a significant adverse effect on quality. A finding requires corrective action and is tracked until corrected. Examples of QA documentation that have requirements specified at the project level are QAPPs and SOPs.

PE. PEs are a type of audit in which the quantitative data generated in an analytical system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

PQAM. The PQAM is the person who serves in the lead QA role for a research effort. Their role is typically described in a QMP. This individual is typically a QAM for an ORD Division or is a Director of QA for an ORD Laboratory or Center.

QAPP. A document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

Second Source Standard. Second source standards are purchased from a manufacturer other than the standards used for calibration. At a minimum, the second source standard must be of a different lot number. The second source standard is used as a quality control check of the calibration standards and the QC criteria will be stated in the QAPP.

TSA. TSAs are thorough, systematic, onsite, qualitative audits of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system.

12. References

1. U.S. Environmental Protection Agency, *Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources,* EPA/600/R-11/122, Office of Research and Development, Washington, DC 20460. November 2011.

2. U.S. Environmental Protection Agency, EPA Records Schedule 501, Applied and Directed Scientific Research, http://www.epa.gov/records/policy/schedule/sched/501.htm.

3. U.S. Environmental Protection Agency, *EPA Quality Program Policy, EPA CIO 2106.0,* Office of Environmental Information, Quality Staff, Washington, DC 20460, October 2008, http://www.epa.gov/irmpoli8/policies/21060.pdf.

4. U.S. Environmental Protection Agency, *EPA Procedure for Quality Policy, EPA CIO 2106-P-01.0,* Office of Environmental Information, Quality Staff, Washington, DC 20460, October 2008, http://www.epa.gov/irmpoli8/policies/2106p01.pdf.

5. U.S. Environmental Protection Agency, *Policy and Program Requirements for the Mandatory Agency-Wide Quality System, EPA CIO 2105.0*, Office of Environmental Information, Quality Staff, Washington, DC 20460, May 2000, http://www.epa.gov/irmpoli8/policies/21050.pdf.

6. U.S. Environmental Protection Agency, *EPA Quality Manual for Environmental Programs, EPA CIO 2105-P-01-0*, Office of Environmental Information, Quality Staff, Washington, DC 20460, May 2000, http://www.epa.gov/irmpoli8/policies/2105P010.pdf.

7. U.S. Environmental Protection Agency, *Information Quality Guidelines,* Office of Environmental Information, Washington, DC 20460, http://intranet.epa.gov/quality/informationguidelines.

8. U.S. Environmental Protection Agency, *Assuring the Competency of Environmental Protection Agency Laboratories*, Agency Science Policy Council. Washington, DC 20460, February 2004, http://epa.gov/osa/fem/pdfs/labdirective.pdf.

9. U.S. Environmental Protection Agency , *EPA Quality Standard for Environmental Data Collection, Production, and Use, EPA CIO 2106-S-01.0,* Office of Environmental Information, Quality Staff, Washington, DC 20460, Draft Final.

10. U.S. Environmental Protection Agency, *EPA Guidance on Quality Management Plans, EPA CIO 2106-G-02,* Office of Environmental Information, Quality Staff, Washington, DC 20460, Draft Final.

11. U.S. Environmental Protection Agency, *EPA Guidance on Quality Assurance Project Plans, EPA CIO 2106-G-05,* Office of Environmental Information, Quality Staff, Washington, DC 20460, Draft Final.

12. U.S. Environmental Protection Agency, ORD Policies and Procedures Manual, Washington, DC, April 2006, http://dcordhqapps1.epa.gov:9876/orma/policies.nsf/webPolicy.

13. U.S. Environmental Protection Agency, Standard Operating Procedure: *Quality Assurance (QA) Review and Approval of Products for NRMRL Clearance*, LSAS-QA-01-0, National Risk Management Research Laboratory, Effective Date May 4, 2011, http://intranet.epa.gov/nrmintra/lsas/eqmp/pdf/SOPLSASQA010.pdf.

14. U.S. Environmental Protection Agency Peer Review Handbook, 3rd Edition, 2006 (EPA Number EPA/100/B-06/002).

15. U.S. Environmental Protection Agency, ORD QMP-01-00, Revision 0, Office of Research and Development *Quality Management Plan for Scientific Research,* Draft, April 2011.

16. U.S. Environmental Protection Agency, *EPA Requirements for Quality Assurance Project Plans,* EPA QA/R-5, Office of Environmental Information, EPA/240/B-01/003, March 2001, http://www.epa.gov/quality/qs-docs/r5-final.pdf.

17. U.S. Environmental Protection Agency, *Guidance on Systematic Planning Using the Data Quality Objectives Process*, EPA/240/B-06/001, Office of Environmental Information, Quality Staff, Washington, DC 20460, February 2006, http://www.epa.gov/quality/qa_docs.html.

18. U.S. Environmental Protection Agency, Office of Science Advisor, Agency Policy Directive FEM-2011-01, March 28, 2011, http://www.epa.gov/fem/pdfs/fem-lab-competency-policy.pdf.

19. U.S. Environmental Protection Agency, Office of Research and Development, ORD QA Review Form, July 2008, http://intranet.epa.gov/nrmintra/lsas/eqmp/pdf/qarford071508.pdf.

20. ANSI/ASQC E4-2004, *Quality Systems for Environmental Data and Technology Programs*.

21. U.S. Environmental Protection Agency, *Uniform Federal Policy for Implementing Environmental Quality Systems,* EPA-505-F-03-001, Version 2, March 2005, http://www.epa.gov/fedfac/pdf/ufp_v2_final.pdf.

22. U.S. Environmental Protection Agency, *EPA Requirements for Quality Management Plans,* EPA/240/B-01/002, EPA QA/R-2, Office of Environmental Information, Quality Staff, Washington, DC 20460, March 2002, http://www.epa.gov/quality/qs-docs/r2-final.pdf.

23. International Standards Organization, Document ISO 8601, *Data Elements and Interchange Formats-Information Interchange-Representation of Dates and Times*, Third Edition, December 2004, http://www.iso.org/iso/support/faqs/faqs_widely_used_standards/widely_used_standards_other/date_and_time_format.htm.

24. U.S. Environmental Protection Agency, Frequent Questions about E-Mail and Records, http://www.epa.gov/records/faqs/email.htm.

25. U.S. Environmental Protection Agency, TSCA CBI Protection Manual, October 20, 2003.

26. U.S. Environmental Protection Agency, Directive 2100B8, Information Resources Management Policy Manual, Located at http://www.epa.gov/irmpoli8/policies/index.html.

27. U.S. Environmental Protection Agency (2010), *CIO 2104.0 (formerly 2165.1), Software Management and Piracy Policy*, Retrieved from http://www.epa.gov/irmpoli8/policies/CIO2104.1.pdf.

28. U.S. Environmental Protection Agency, *Guidance on developing Quality Assurance Project Plans for modeling projects,* EPA QA.G-5M, EPA/240/R-02/009, Office of Environmental Information, Quality Staff, Washington, DC 20460, December 2002, http://www.epa.gov/quality/qa_docs.html.

29. U.S. Environmental Protection Agency, *Guidance on Technical Audits and Related Assessments for Environmental Data Operations,* EPA QA/G-7, EPA/600/R-99/080, Office of Environmental Information, Quality Staff, Washington, DC 20460, January 2000, http://www.epa.gov/quality/qa_docs.html.

30. U.S. Environmental Protection Agency, *Guidance on Environmental Data Verification and Data Validation,* EPA QA/G-8, EPA/240/R-02/004, Office of Environmental Information, Quality Staff, Washington, DC 20460, November 2002, http://www.epa.gov/quality/qa_docs.html.

31. U.S. Environmental Protection Agency, Standard Operating Procedure: *Performing Audits of Data Quality (ADQ)*, LSAS-QA-02-0, National Risk Management Research Laboratory, Effective Date May 4, 2011, http://intranet.epa.gov/nrmintra/lsas/eqmp/pdf/SOPLSASQA020.pdf.

APPENDIX A

QUALITY ASSURANCE PROJECT PLAN RELATIONSHIP TO THE HYDRAULIC FRACTURING PRIMARY AND SECONDARY RESEARCH STUDY QUESTIONS

Table A-1. Research Tasks Identified for Water Acquisition

Water Acquisition: ***What are the potential impacts of large-volume water withdrawals from ground and surface waters on drinking water resources?***		
Secondary Question	**Applicable Research Projects**	**QAPPs [1]**
How much water is used in hydraulic fracturing operations, and what are the sources of this water?	Literature Review	1, 3, 4, 5, 8
	Service Company Analysis	
	Well File Review	
	FracFocus Analysis	
	Water Availability Modeling	
How might water withdrawals affect short- and long-term water availability in an area with hydraulic fracturing activity?	Literature Review	1, 8
	Water Availability Modeling	
What are the possible impacts of water withdrawals for hydraulic fracturing operations on local water quality?	Literature Review	1

Table A-2. Research Tasks Identified for Chemical Mixing

Chemical Mixing: ***What are the possible impacts of surface spills on or near well pads of hydraulic fracturing fluids on drinking water resources?***

[1] See Table A-6 for the list of related QAPPs.

Secondary Question	Applicable Research Projects	QAPPs[1]
What currently is known about the frequency, severity, and causes of spills of hydraulic fracturing fluids and additives?	Literature Review	1, 2, 3, 4
	Spills Database Analysis	
	Service Company Analysis	
	Well File Review	
What are the identities and volumes of chemicals used in hydraulic fracturing fluids, and how might their composition vary at a given site and across the country?	Literature Review	1, 3, 5, 12
	Service Company Analysis	
	FracFocus Analysis	
	Analytical Method Development	
What are the chemical, physical, and toxicological properties of hydraulic fracturing chemical additives?	Toxicity Assessment	13
If spills occur, how might hydraulic fracturing chemical additives contaminate drinking water resources?	Literature Review	1, 14-18
	Retrospective Case Studies	

Table A-3. Research Tasks Identified for Well Injection

Well Injection: ***What are the possible impacts of the injection and fracturing process on drinking water resources?***		
Secondary Question	**Applicable Research Projects**	**QAPPs**[1]
How effective are current well construction practices at containing gases and fluids before, during, and after hydraulic fracturing?	Literature Review	1, 3, 4, 6, 14-18
	Service Company Analysis	
	Well File Review	
	Subsurface Migration Modeling	
	Retrospective Case Studies	
Can subsurface migration of fluids or gases to drinking water resources occur, and what local geologic or man-made features may enable this?	Literature Review	1, 3, 4, 6, 14-18
	Service Company Analysis	
	Well File Review	
	Subsurface Migration Modeling	
	Retrospective Case Studies	

TABLE A-4. Research Tasks Identified for Flowback and Produced Water

Flowback and Produced Water: ***What are the possible impacts of surface spills on or near well pads of flowback and produced water on drinking water resources?***		
Secondary Question	**Applicable Research Projects**	**QAPPs**[1]
What currently is known about the frequency, severity, and causes of spills of flowback and produced water?	Literature Review	1-4
	Spills Database Analysis	
	Service Company Analysis	
	Well File Review	
What is the composition of hydraulic fracturing wastewaters, and what factors might influence their composition?	Literature Review	1-4
	Spills Database Analysis	
	Service Company Analysis	
	Well File Review	
What are the chemical, physical, and toxicological properties of hydraulic fracturing wastewater constituents?	Toxicity Assessment	13
If spills occur, how might hydraulic fracturing wastewaters contaminate drinking water resources?	Literature Review	1, 14-18
	Retrospective Case Studies	

Table A-5. Research Tasks Identified for Wastewater Treatment and Waste Disposal

Wastewater Treatment and Waste Disposal: ***What are the possible impacts of inadequate treatment of hydraulic fracturing wastewaters on drinking water resources?***		
Secondary Question	**Applicable Research Projects**	**QAPPs**[1]
What are the common treatment and disposal methods for hydraulic fracturing wastewaters, and where are these methods practiced?	Literature Review	1, 4, 5
	Well File Review	
	FracFocus Analysis	
How effective are conventional publically owned and commercial treatment systems in removing organic and inorganic contaminants of concern in hydraulic fracturing wastewaters?	Literature Review	1, 10
	Wastewater Treatability Studies	
What are the potential impacts from surface water disposal of treated hydraulic fracturing wastewater on drinking water treatment facilities?	Literature Review	1, 6, 9, 11
	Surface Water Modeling	
	Source Apportionment Studies	
	Brominated Disinfection By-Products (Br-DBP) Precursor Studies	

Table A-6. HF Program Research QAPPs

QAPP Reference Number [2]	Research Project	QAPP Title [3]
1	Literature Review	QAPP for Hydraulic Fracturing Data and Literature Evaluation for EPA's *Study of the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources*
2	Spills Database Analysis	QAPP for Hydraulic Fracturing Surface Spills Data Analysis
3	Service Company Analysis	Final QAPP for the Evaluation of Information on Hydraulic Fracturing
		QAPP for Analysis of Data Received from Nine Hydraulic Fracturing Service Companies
4	Well File Review	QAPP for Hydraulic Fracturing
		National Hydraulic Fracturing Study Evaluation of Existing Production Well File Contents: QAPP
		Supplemental Programmatic QAPP for Work Assignment 4-58: National Hydraulic Fracturing Study Evaluation of Existing Production Well File Contents
5	FracFocus Analysis	Supplemental Programmatic QAPP for Work Assignment 4-58: National Hydraulic Fracturing Study Evaluation of Existing Production Well File Contents
		QAPP for Analysis of Data Extracted from FracFocus
6	Subsurface Migration Modeling	Analysis of Environmental Hazards Related to Hydrofracturing
7	Surface Water Modeling	QAPP for Surface Water Transport of Hydraulic Fracturing-Derived Waste Water

[2] These numbers are used to link the Research Projects and QAPPs listed in Table A-7 to the Primary and Secondary Research Questions, Research Projects, and Potential Products from the *Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources*, November 2011, as listed in Tables A-1 through A-6.

[3] Current HF Drinking Water Study QAPPs are located at http://www.epa.gov/hfstudy.

QAPP Reference Number [2]	Research Project	QAPP Title [3]
8	Water Availability Modeling	Data Collection/Mining for Hydraulic Fracturing Case Studies
		Modeling on the Impact of Hydraulic Fracturing on Water Resources Based on Water Acquisition Scenarios
9	Source Apportionment Studies	QAPP for Hydraulic Fracturing Waste Water Source Apportionment Study
10	Wastewater Treatability Studies	QAPP for Assessment of the Fate of Contaminants in Hydraulic Fracturing Wastewater Treatment Process and Characterization of Wastewater Residuals
11	Br-DBP Precursor Studies	Formation of Disinfection By-Products from Hydraulic Fracturing Fluid Constituents: QAPP
12	Analytical Method Development	QAPP for the Chemical Characterization of Select Constituents Relevant to Hydraulic Fracturing
		QAPP for the Interlaboratory Verification and Validation of Diethylene Glycol, Triethylene Glycol, Tetraethylene Glycol, 2-Butoxyethanol and 2-Methoxyethanol in Ground and Surface Waters by Liquid Chromatography/Tandem Mass Spectrometry
		Validation of Rapid Radiochemical Methods for Radionuclides Listed in EPA's Standardized Analytical Methods (SAM) for Use During Homeland Security Events
13	Toxicity Assessment	QAPP: Health and Toxicity Theme, Hydraulic Fracturing Study
		NCCT Health and Toxicity Theme, Hydraulic Fracturing Study
14	Las Animas and Huerfano Counties, CO	Hydraulic Fracturing Retrospective Case Study, Raton Basin, CO
15	Dunn County, ND	Hydraulic Fracturing Retrospective Case Study, Bakken Shale, Killdeer and Dunn County, ND
16	Bradford County, PA	Hydraulic Fracturing Retrospective Case Study, Bradford-Susquehanna Counties, PA
17	Washington County, PA	Hydraulic Fracturing Retrospective Case Study, Marcellus Shale, Washington County, PA
18	Wise County, TX	Hydraulic Fracturing Retrospective Case Study, Wise and Denton Counties, TX
19	Prospective Case Study	These studies have not been initiated as of January 2014.

APPENDIX B

OFFICE OF RESEARCH AND DEVELOPMENT QUALITY ASSURANCE PRODUCT REVIEW AND APPROVAL FORM

ORD QA PRODUCT REVIEW AND APPROVAL FORM

ORD National Program: SSWR
Project ID: 2.4: Mitigating environmental impacts of subsurface land use practices
Task ID: 2.4 A1 EPA Hydraulic Fracturing Study

L/C/O:
Technical Lead Person (e.g., Investigator/PO):
Division/Branch:
QA Manager:
Product Type/Title:

Date Received by QAM:
L/C/O Tracking Number:

QA Manager's Recommendation

☐ **Approved—**No deficiencies were identified.

☐ **Approved with minor revisions—**Observations were identified that should be addressed but no additional QA review is required.

☐ **Not approved—**Findings were identified that require corrective action. A response to each finding, along with corrected text, must be provided for additional QA review.

☐ **QA requirements are not applicable.**

Definitions:

Observation: An identified deficiency that does not have a significant impact on the ability to attain the project's/program's objectives.

Finding: An identified deficiency that has a significant impact on the ability to attain the project's/program's objectives.

Comments/Attachments:

QA Manager Signature/Date

APPENDIX C

COMPONENTS OF A QUALITY ASSURANCE SUMMARY FOR REPORTS

What should be included in a project QA summary?

The quality assurance (QA) summary for a project is a narrative that provides a subjective evaluation of both the quality and the appropriate use of project data. The QA summary should be based on specific QA activities, and the details of those activities should be provided. The length of the QA summary will depend on the type of project it supports and ranges from a paragraph to multiple pages. Details on which the QA summary is based may be best presented in an appendix.

The QA summary should provide specific references to the following items.

Preparation of a QAPP, to include

- Title with version(s) (see ORD Quality Management Plan [QMP], p. 35, for naming convention)
- Approval date
- Description of any revisions

Conducting audits, (e.g., Technical Systems Audits) to include

- Subject of audit
- Date of audit
- General conclusions
- Any required corrective action
- Summary statement tying audit conclusions to impact on data (positive, negative, or neutral)

Description of deviations from planning documentation

- Describe deviations from QA documentation (i.e., QMP, Quality Assurance Project Plan [QAPP], Standard Operating Procedure)
- Explain why the deviation occurred
- Explain any impact on data quality

For projects involving measurement data (use tables as appropriate)

- Describe Audits of Data Quality (who, what, and when)
- Summarize QC sample results, noting exceptions from QC criteria. If the number of QC samples is very large, refer to requirements in the QAPP and discuss what criteria were not met for each analyte and the impact(s) to the reported results (e.g., flagging).
- Note deviations to methods
- Describe any general limitations on the use of the results
- Describe any specific limitations on the use of the results

QA review of project reports, to include

- Describe review of report focusing on accurate incorporation of data, the conclusions made, and any limitations
- A statement that the QA Manager reviewed and approved the project report

APPENDIX D

DATA QUALIFIERS FOR CHEMICAL ANALYTES

Notes for next page:

The result is an estimated quantity, but the result may be biased high.

For both detected and nondetected results, the result is estimated but may be biased low.

The analyte is found in a blank sample above the QL, and the concentration found in the sample is less than 10 times the concentration found in the blank.

The sample was prepared or analyzed beyond the specified holding time. Sample results may be biased low.

If both an analyte and an associated blank concentration are between the method detection limit (MDL) and QL, then the sample results are reported as <QL and qualified with U.

For samples associated with high Matrix Spike recoveries, the J+ qualifier was not applied if the analyte was less than the QL.

Data Qualifiers

Qualifier	Definition
U	The analyte was analyzed for, but was not detected above the reported quantitation limit (QL).
J	The analyte was positively identified. The associated numerical value is the approximate concentration of the analyte in the sample (due either to the quality of the data generated because certain quality control criteria were not met, or the concentration of the analyte was below the QL).
J+	The result is an estimated quantity, but the result may be biased high.
J-	For both detected and non-detected results, the result is estimated but may be biased low.
B	The analyte is found in a blank sample above the QL and the concentration found in the sample is less than 10 times the concentration found in the blank.
H	The sample was prepared or analyzed beyond the specified holding time. Sample results may be biased low.
*	Relative percent difference of a field or lab duplicate is outside acceptance criteria.
R	The data are unusable. The sample results are rejected due to serious deficiencies in the ability to analyze the sample and/or meet quality control criteria. Sample results are not reported. The analyte may or may not be present in the sample.

Data Descriptors

Descriptor	Definition
NA	Not Applicable (See QAPP)
NR	Not Reported by Laboratory or Field Sampling Team
ND	Not Detected
NS	Not Sampled

Note:

If the analyte concentration was less than the Quantitation Limit (<QL), then the B qualifier was not applied.

If both an analyte and an associated blank concentration are between the MDL and QL, then the sample results are reported as <QL and qualified with U.

For samples associated with high Matrix Spike recoveries, the J+ qualifier was not applied if the analyte was less than the Quantitation Limit (<QL).

For samples associated with low Matrix Spike recoveries, the J- qualifier was applied to the analyte with low recovery regardless of analyte concentration (< or > QL).

APPENDIX E

AUDIT OF DATA QUALITY CHECKLIST

AUDIT OF DATA QUALITY CHECKLIST

	Yes	No	NA	Comments
Sample Information				
Are samples uniquely identified and correctly transcribed throughout the data package to the summary of results?				
Does sample collection documentation indicate that samples were collected as described in the QAPP?				
If calculations were used for sample collection information (e.g., air volumes), are these calculations correct?				
Does sample collection documentation indicate appropriate preservation?				
If applicable, is chain-of-custody documentation complete?				

Sampling and Analysis Method Information				
Were methods specified in QAPP used?				
If method modifications were used, are these modifications appropriate and well documented?				
Were sample preparation and analytical method holding times met?				
Summary of Results				
Are the correct units reported?				
Are reported results correct (verify any calculations performed[1])?				
Were QC samples (blanks, second source checks, surrogates, spikes, replicates) analyzed at the frequency specified in the QAPP?				
Did QC results meet the requirements specified in the QAPP?				
Raw Data				
Were instruments calibrated as described in the QAPP?				
Were calibration criteria met for initial and continuing checks?				
Were reported results analyzed within calibration range?				
Were instrument outputs correctly transcribed to data summary?				
Data Qualifiers				
If QC requirements were not met, were corrective actions performed?				
If necessary, were data qualified appropriately?				

APPENDIX F

DEVIATION REPORT

HF Quality Assurance Deviation Report

DATE OF DEVIATION:

REFERENCE DOCUMENT:

_____

DESCRIPTION OF DEVIATION:

CAUSE OF DEVIATION:

IMPACT OF DEVIATION ON PROJECT:

CORRECTIVE ACTION (if any) with TIMELINE FOR IMPLEMENTATION:

_____
REPORTED BY/DATE

_____
CORRECTIVE ACTION APPROVAL TO IMPLEMENT (KI)/DATE

_____
CORRECTIVE ACTION VERIFIED (QAM)/DATE

1. Investigator to e-mail approved copy to QAM and PQAM
2. QAM to e-mail verified final report to Investigator and PQAM

APPENDIX G

QUALITY ASSURANCE PROJECT PLAN BOILERPLATE LANGUAGE FOR HYDRAULIC FRACTURING PROJECTS

U.S. Environmental Protection Agency Study of the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources
Required Front Matter for Quality Assurance Project Plans

Instructions: Insert the single page of text containing the "Disclaimer" and "The U.S. Environmental Protection Agency Quality System and the Hydraulic Fracturing Research Study" located on the next page into the Hydraulic Fracturing Quality Assurance Project Plan (QAPP) between the signature page and the table of contents. The QAPPs are listed below in relation to each phase of the Water Cycle. Some QAPPs are listed in more than one phase.

Water Acquisition Stage Projects
Literature Review
Service Company Analysis
Well File Review
FracFocus Analysis
Water Availability Modeling

Chemical Mixing Stage Projects
Literature Review
Spills Database Analysis
Service Company Analysis
Well File Review
FracFocus Analysis
Analytical Method Development
Toxicity Assessment
Dunn County, ND
Bradford County, PA
Wise County, TX

Well Injection Stage Projects
Literature Review
Service Company Analysis
Well File Review
Subsurface Migration Modeling
Las Animas and Huerfano Counties, CO
Dunn County, ND
Bradford County, PA

Flowback and Produced Water Stage Projects
Literature Review
Spills Database Analysis
Service Company Analysis
Well File Review
Analytical Method Development
Toxicity Assessment
Bradford County, PA, Case Study
Washington County, PA, Case Study
Wise County, TX, Case Study

Wastewater Treatment and Waste Disposal Stage Projects
Literature Review
Well File Review
FracFocus Analysis
Surface Water Modeling
Source Apportionment Studies
Wastewater Treatability Studies
Bromide—Disinfection By-Product Precursor Studies

Disclaimer

The U.S. Environmental Protection Agency 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 U.S. Environmental Protection Agency Quality System and the Hydraulic Fracturing Research Study

The U.S. Environmental Protection Agency (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 also are 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 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. The HF QMP then is 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 the [Insert the stage(s) of the water cycle from the list on the previous page.] of the HF water cycle as found in Figure 1 of the HF QMP and as described in the HF Study Plan. Appendix A of the HF QMP includes the links between the HF Study Plan questions and those QAPPs available at the time the HF QMP was published.