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Battelle Contract No. CON00011206

Review of
EPA Hydraulic Fracturing Study Plan
EPA/600/R11/122, November 2011

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June 2012

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EXECUTIVE SUMMARY

In fiscal year 2010, the U.S. House of Representatives Appropriation Conference Committee (Congress) "urged" the United States Environmental Protection Agency (EPA) to "carry out a study on the relationship between hydraulic fracturing and drinking water using a credible approach that relies on the best available science, as well as independent sources of information." The conferees furthermore stated the study was to be conducted through "a transparent, peer-reviewed process that will ensure the validity and accuracy of the data. The Agency shall consult with other federal agencies as well as appropriate state and interstate regulatory agencies in carrying out the study, which should be prepared in accordance with the Agency's quality assurance principles."

The American Petroleum Institute (API) and America's Natural Gas Alliance (ANGA) requested Battelle Memorial Institute (Battelle), an independent non-profit, science and technology research and development organization, to perform a critical review of the EPA *Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources* (study plan). A multidisciplinary Battelle project team with expertise in oil and gas operations, engineering, geosciences, chemistry, modeling, quality assurance/quality control (QA/QC), statistics, toxicology, impact analysis and other relevant disciplines took part in this review. This effort also included reviews of EPA's Quality Management Plan (QMP) and seventeen Quality Assurance Project Plans (QAPPs), as well as an assessment of the responsiveness of EPA's approach to the Congressional request and the advice of the Scientific Advisory Board (SAB).

Battelle's key findings regarding EPA's study plan center on the following major themes:

Purpose—The stated purpose of the study reaches beyond the focused studying of the relationship between the process of hydraulic fracturing and drinking water as articulated in the conferees' request. EPA has interpreted the intent of the congressional statement to require study of more peripheral elements related to generic oil and gas exploration and production, such as various upstream and downstream stages of the water lifecycle as well as standard site development and production activities. This broadening of the scope to "concerns common to all oil and gas production activities" was previously cautioned against by the SAB. EPA also elected to add a study element on Environmental Justice (EJ) that is not central to a scientific study of the drinking water effects of hydraulic fracturing, and by EPA policy required during efforts related to the development of an action. Lastly, given the scientific importance of the study, the effort likely meets the requirements of a "highly influential scientific assessment," yet it is not designated as such. Such designation from the outset would have raised the level of rigor, funding, timing and transparency of all stages of the study.

Scoping—EPA interprets the congressional intent for this study broadly including many activities commonly associated with oil and gas development. While it is in EPA's discretion to do so, the departure from conducting a study focused on the process of hydraulic fracturing, i.e., the vertical and horizontal fracturing of underground geologic formations to stimulate the extraction of gas (or oil) from unconventional reservoirs, adds complexity and risks as well as commitments competing for limited resources and time available for completing the study. This risks weakening and obscuring the significance of the research findings and their relevance with respect to the central question about the relationship between hydraulic fracturing and drinking water. While there can be merit in looking at both the hydraulic fracturing water and production well lifecycles, from a "cradle to grave" perspective, EPA has clearly identified the study boundary as the hydraulic fracturing water life cycle. Therefore, the study should be designed and implemented focusing only on this element of production, appropriately segregating potential environmental impacts associated with other phases. Specific to the hydraulic fracturing water lifecycle, environmental aspects such as upstream stages of water acquisition and downstream stages of production, water treatment and discharge are largely addressed by existing

regulatory and permitting frameworks and established industry standards. The added complexity from including peripheral elements and factors that are well understood considerably raises the level of difficulty of achieving the requisite scientific rigor, considering the large number of interrelated study elements and research questions. Additionally, significant resources and time are being expended without materially advancing the study of the relationship between hydraulic fracturing and drinking water.

Study Design—The study will likely generate influential scientific information, yet EPA has not approached or designated it during the planning process as a "Highly Influential Scientific Assessment." Such designation triggers rigorous standards for peer review, and by implication study design, data quality, transparency and execution. Even in the absence of such formal designation, there is no direct evidence documented in the study plan or in associated documents that EPA followed its quality policy in framing the study objectives and developing the study design, as asked for by Congress for "preparing the study in accordance with EPA quality assurance principles." Additionally, ambitious schedules, driven by various 2012 reporting goals, may undermine the robustness of data collection and analysis as well as the soundness of scientific conclusions. Also, the site data collected from the companies are from 2006-2010, and the final report will be in 2014. The changes occurring at these sites in the intervening years will likely render the data obsolete for purposes of the study.

Case Studies—Congress requested a study "relying on best available science and independent sources of information." It appears questionable, because of its genesis and design, whether the proposed case study element will satisfy this expectation and provide the scientifically defensible data and knowledge required in support of the fundamental research question, "can hydraulic fracturing impact drinking water resources?"The limited and possibly statistically biased pool from which the retrospective sites were drawn, and the lack of baseline information, are likely to limit the scientific validity and usefulness of case study findings and may result in incorrect or flawed conclusions. Two prospective sites cannot deliver the range of data required for scientifically rigorous treatment of all the research questions asked. These limitations need to be acknowledged and made more explicit.

Quality—There is insufficient alignment and nexus between the processes of developing the study and those for the development of the QA program that is to ensure systematic planning for design and implementation. In fact, the QMP does not provide guidance or requirements for the use of systematic planning. It also does not provide sufficient guidance to ensure all projects are: 1) conducted in a comprehensive, consistent, and coordinated manner and 2) linked to the overall program objectives defined in the study plan, even though this is specifically recognized as an essential requirement by EPA in the study plan. There is wide variability among the individual QA documents in terms of level of detail, consistency, guidance for documents and records and data management, as well as approaches for complying with QA and assessment requirements. And, there is no overarching roadmap laying out the interrelationships among the individual studies among QAPPs or how the intramural and extramural teams working on the individual projects will coordinate different elements of the project.

***Collaboration and Transpar*ency**—Congress asked this study to be conducted through "a transparent, peer-reviewed process that will ensure the validity and accuracy of the data. The Agency shall consult with other federal agencies as well as appropriate state and interstate regulatory agencies." EPA's approach, in a number of areas, is not consistent with this congressional request. It is also not responsive to several SAB recommendations, such as "developing a balanced and collaborative advisory group of stakeholders representing a broad range of perspectives, and engaging with this stakeholder group throughout the research process." Transparency is critical to successful EPA and industry collaboration. Specifically, given industry's extensive experience with production of oil and gas from unconventional reservoirs, its unique expertise in the process of hydraulic fracturing and associated technologies, and its wealth of relevant data and information available to inform this effort, it is a weakness of the study plan, and its implementation, that significant industry collaboration is not envisioned.

ACRONYMS AND ABBREVIATIONS

ANGA	America's Natural Gas Alliance
API	American Petroleum Institute
BMP	best management practice
DOE	Department of Energy
DQO	data quality objective
EJ	Environmental Justice
EPA	United States Environmental Protection Agency
LCA	life cycle assessment
OMB	Office of Management and Budget
POTW	publicly owned treatment work
QA/QC	quality assurance/quality control
QAPP	Quality Assurance Project Plan
QMP	Quality Management Plan
QSAR	quantitative structure-activity relationship
SAB	Scientific Advisory Board
USACE	U.S. Army Corps of Engineers
USDW	underground source of drinking water
USGS	U.S. Geological Survey

1.0 Introduction

In fiscal year 2010, the U.S. House of Representatives Appropriation Conference Committee (referred to as "Congress" throughout this report) "urged" the United States Environmental Protection Agency (EPA) to "carry out a study on the relationship between hydraulic fracturing and drinking water using a credible approach that relies on the best available science, as well as independent sources of information."[1] The conferees furthermore stated the study was to be conducted through "a transparent, peer-reviewed process that will ensure the validity and accuracy of the data. EPA shall consult with other federal agencies as well as appropriate state and interstate regulatory agencies in carrying out the study, which should be prepared in accordance with EPA's quality assurance principles."

In March 2010, EPA released a scoping document for evaluating the relationship between hydraulic fracturing and drinking water. The initial study design adopted "a Life Cycle Assessment (LCA) approach to identify potential interrelationships between energy, water, the chemicals used during hydraulic fracturing, the surrounding environment, and safeguards for public health protection." In April 2010, the EPA received advice on the scoping document from the Science Advisory Board (SAB) in an open meeting, followed in June 2010 by written recommendations.[2] Public comments were also submitted. Later in 2010, EPA held sector specific and State and Federal partner consultation meetings, public meetings and other meetings to solicit input to the overall study plan. EPA also requested information from nine hydraulic fracturing service companies on the chemical composition and other information related to fracturing fluids. In February 2011, EPA released a draft study plan, followed in August by the SAB's evaluation of the draft study plan.[3] Finally, in November 2011 EPA released the *Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources*[4] (study plan).

The American Petroleum Institute (API) and America's Natural Gas Alliance (ANGA) requested Battelle Memorial Institute (Battelle), an independent non-profit, science and technology research and development organization, to perform a critical review of the EPA study plan. A multidisciplinary team of Battelle technical staff with expertise in oil and gas operations, engineering, geosciences, chemistry, modeling, quality assurance/quality control (QA/QC), statistics, toxicology, impact analysis and other relevant disciplines took part in this review. In addition to the study plan, this effort included reports that were developed to document reviews of EPA's Quality Management Plan (QMP), seventeen Quality Assurance Project Plans (QAPPs), as well as an assessment of how responsive the EPA's approach was to the Congressional request and the advice of the Scientific Advisory Board (SAB).

The major themes of Battelle's review comments outlined in the Executive Summary of this report are discussed in more detail in this section and supported by specific comments in the subsequent sections of this report. In addition, Battelle prepared five Appendices on the following topics, from which much of the material in this report is derived:

- Appendix A – Specific Comments Related to EPA Hydraulic Fracturing Study Plan
- Appendix B - Events and Timeline Leading up to the Release of EPA Hydraulic Fracturing Study Plan

[1] US House, 2009. Department of the Interior, Environment, and related agencies Appropriations Act, 2010. Washington, DC: Conference of Committee, US House.
[2] http://www.epa.gov/hfstudy/sab-june2010-finalreport.pdf
[3] http://yosemite.epa.gov/sab/sabproduct.nsf/0/2BC3CD632FCC0E99852578E2006DF890/$File/EPA-SAB-11-012-unsigned.pdf
[4] http://www.epa.gov/hfstudy/HF_Study_Plan_110211_FINAL_508.pdf

- Appendix C - Overview of SAB Recommendations on EPA's Draft Hydraulic Fracturing Study Plan
- Appendix D - Detailed Analysis of EPA's Quality Management Plan
- Appendix E - Detailed Analysis of the EPA QAPPs

Because the study plan is an overview document, it was also important to review the QMP and QAPPs which provide the details of study implementation. The more detailed analyses of EPA's specific implementation are provided in these Appendices.

2.0 Purpose

EPA states the purpose of the planned study "is to elucidate the relationship, if any, between hydraulic fracturing and drinking water resources." Furthermore, according to the study, the overarching goal is to answer the following two research questions: 1) can hydraulic fracturing impact drinking water resources? and 2) if so, what conditions are associated with these potential impacts? Lastly, EPA defines hydraulic fracturing as "a well stimulation technique used to maximize production of oil and natural gas in unconventional reservoirs, such as shale gas, coalbeds, and tight sands."

While those stated purposes, goals and definitions are all consistent with the congressional request, the actual scope and design of the study plan do not provide the same consistency. They reach beyond "studying the relationship between hydraulic fracturing and drinking water" encompassing numerous peripheral elements related to the broader enterprise of all oil and gas exploration and production activities, such as various upstream and downstream stages of the water lifecycle, site preparation and development, and standard oil and gas production and other industrial activities.

EPA also elected to add a study element on Environmental Justice (EJ) that is not central to a scientific study of the drinking water effects of hydraulic fracturing. It is neither explicitly nor implicitly included in the congressional request. Rather, it derives from EPA's 2010 Interim Guidance[5] on considering EJ during the development of an action, such as rule making. However, EPA did not declare this study as part of an action, and so there is no policy requirement to incorporate EJ. Instead, although EJ-related research questions were included in EPA's March 2010 scoping document, EPA in the study plan cites stakeholder input as driving this study element assuming communities with EJ concerns, as a result of exploration, development and production of oil and gas from unconventional reservoirs, had inequitable treatment and impaired drinking water as compared to a standard condition. While it is in EPA's discretion to conduct an EJ assessment, it will add little insight to the central study question at issue and may divert important resources at this early stage that could otherwise be focused on hydraulic fracturing effects research. Importantly again, the scope of the EJ study element is not focused on the process of hydraulic fracturing.

There appears to be some general ambiguity concerning EPA's stated versus implied purpose of this study. The study plan[6] appears to imply, yet leaves unclear, the objective to use the study to inform decision making related to an EPA-regulatory framework. While there is no definitive statement to this effect, EPA states "Ultimately, the results of the study will inform the public and provide policymakers at all levels with sound knowledge that can be used in decision-making processes." If indeed EPA intended to use the study to inform rule-making on hydraulic fracturing, such intent and purpose, in the interest of

[5] http://www.epa.gov/environmentaljustice/resources/policy/ej-rulemaking.html
[6] EPA Study Plan, Page 3.

transparency, should be made explicit. It would have implications for the entire framing and conducting of the study. This concern was also raised by the SAB[7] stating that if the objective was to use the study in rule-making "the study plan should include specific research questions aimed at this objective." Critical research questions, perhaps major elements of the study, would have needed to be framed, planned and designed differently, such as the case study element and scenario evaluation and modeling, in order to make the resulting findings and conclusions more broadly applicable and valid to the universe of conditions subject to intended future regulation.

Lastly, given the scientific importance of the study, the effort likely meets the requirements of a "highly influential scientific assessment." However, the study was not designated as such. Such designation from the outset would have raised the level of rigor, funding, timing and transparency of all stages of the study.

3.0 Scoping

EPA interprets the congressional intent for this study broadly. While it is in EPA's discretion to do so, the departure from more narrowly focusing on the process of hydraulic fracturing, i.e., the vertical and horizontal fracturing of underground geologic formations to stimulate the extraction of gas (or oil) from unconventional reservoirs, adds complexity and risks obscuring the significance of the research findings and their relevance with respect to the postulated question as to a relationship between hydraulic fracturing and drinking water.

While there can be merit in looking at both the hydraulic fracturing water and production well lifecycles, and associated issue of each, from "cradle to grave" perspective, EPA has clearly identified the study boundary as the hydraulic fracturing water life cycle, therefore, the study should be designed and implemented focusing only on this element of the production well lifecycle, appropriately segregating potential environmental impacts associated with other phases of this lifecycle. Specific to the hydraulic fracturing water lifecycle, environmental aspects such as upstream stages of water acquisition, downstream stages of production, water treatment and discharge are largely addressed by existing regulatory and permitting frameworks and established industry standards. The added complexity from including elements beyond the hydraulic fracturing water lifecycle and factors are well understood in the study considerably raises the level of difficulty of achieving the requisite scientific rigor, considering the large number of interrelated study elements and research questions.

The study plan does not draw a clear distinction between the broader enterprise of all exploration, development and production of oil and gas and the process of hydraulic fracturing. In fact, even though EPA defines *hydraulic fracturing*[8] as a process used "to stimulate the production of hydrocarbons from unconventional oil and gas reservoirs," in many instances throughout the study plan the term *hydraulic fracturing* is used synonymous with the full range of activities associated with oil and gas exploration, development and production. This gives rise to ambiguity and confusion and dilutes the focus of the study. Case in point is EPA's statement[9] "The hydraulic fracturing process begins with exploring possible well sites, followed by selecting and preparing an appropriate site." Hence, while the title of EPA's study plan refers to *hydraulic fracturing*, the content of the document relates to the broader relationship between water resources and exploration, development and production of all oil and gas employing the process of *hydraulic fracturing*. This blurring of terminology can give rise to stakeholder misconception and confusion.

[7] 2011 SAB Report, Page 4, http://www.epa.gov/hfstudy/sab-june2010-finalreport.pdf
[8] EPA Study Plan, Executive Summary Page iiiv.
[9] EPA Study Plan, Page 12.

When the decision was made, while planning the study, to expand the scope beyond simply hydraulic fracturing to a more expansive study of oil and gas production from unconventional reservoirs, all subsequent study design elections and decisions were accordingly affected, adding considerable complexity to the study because of the myriad interrelationships between the many study elements as well as the compounding effects of uncertainty. For example, EPA selected a lifecycle approach as the framework and scientific methodology to pursue the study goals. While a formal lifecycle assessment is not contemplated given limitations of time and resources, the using a lifecycle framework requires,[10] as does EPA's DQO process, a clear definition of various methodological elements, such as study objectives, functional unit, system boundaries, and data inventory collection. Hence, if the study objective was implicitly established as the "relationship between unconventional oil and gas exploration and production and water use," the corresponding "functional unit" would be consequently, also implicitly, defined as "water use in unconventional oil and gas exploration and production" (Page 2, Figure 1), rather than "water use in hydraulic fracturing." Once the commitment to the lifecycle study objective and functional unit was made, the methodology in turn drove the scope and design of the study, as well as the formulation of many of the associated research questions, in a direction that a more focused interpretation of the Congress' request, as recommended by the SAB, would not have warranted.

A more focused water lifecycle analysis, starting at the point of injecting hydraulic fracturing fluids into the well and extending through characterizing the flowback up the well and including any potential migration of hydraulic fracturing fluid or fracturing-induced materials through unintended pathways to drinking water, would likely be necessary and sufficient to satisfy the Congress' study request. Lifecycle elements farther upstream (water withdrawal from ground or surface waters; onsite water management) and downstream (onsite wastewater management, treatment and disposal) are associated with activities that are largely within the realm of current regulatory and permitting programs. For instance, state-specific permits pursuant to the Clean Water Act address chemical storage best management practices and spill prevention. Other regulatory instruments address spill reporting and response as well as water appropriation. Likewise, more generic activities related to oil and gas exploration, development and production, such as site preparation, pad construction, drilling and on-site product and waste management are well understood and already addressed by industry management practices.

Additionally, by focusing the scope of this study to areas central to the process of hydraulic fracturing, significant resources could be freed up to study the direct relationship between hydraulic fracturing and drinking water in more depth and with greater rigor. Resources and budget constraints appear to limit, in particular, the design and scope of a scientifically defensible case study element, including number of sites and samples at each site. This is important, given the wide range of geologic and man-made conditions that would need to be considered to ensure validity and accuracy as well as statistical significance of data required to inform scenarios, models and research questions in general. This point of budget limitations constraining elements of the study effort was also made by the SAB in its 2010 report.

[10] International Standards Organization, 2006. ISO 14040:2006. Environmental Management – Life Cycle Assessment – Principles and Framework.
International Standards Organization, 1998. ISO 14041:1998. Environmental Management - Life Cycle Assessment - Goal and Scope Definition and Inventory Analysis. October 1998.

4.0 Study Design

The study will likely generate influential scientific information, yet EPA has not approached or designated the effort during the planning process as a "highly influential scientific assessment." Such designation triggers more rigorous standards for peer review, and thus study design, data quality and transparency. Even in the absence of such a formal designation, there is no direct evidence documented in the study plan or in associated documents that EPA followed its quality policy in framing the study objectives and developing the study design, as was requested by Congress in "preparing the study in accordance with EPA quality assurance principles."

For instance, it is not apparent that systematic planning, such as EPA's DQO process,[11] was used in planning the study elements, nor is there mention of systematic planning in the QAPPs. The EPA quality system states that "EPA requires that a systematic planning process be used to plan all environmental data operations" and that the DQO process is the preferred planning method.[12] Use of the DQO Process is important because it "leads to efficient and effective expenditure of resources; consensus on the type, quality, and quantity of data needed to meet the project goal; and the full documentation of actions taken during the development of the project." There is no evidence this approach was used.

It is conceivable, had a systematic planning process been applied from the outset and in more explicit fashion, the study design would have been more appropriately directed and scientifically robust. For example, the study design might contain a different lifecycle approach or scope, a different case study program, a different modeling program, framing of different research questions, etc. Key study concepts would have been established early on, the logic of the study design would have been available for review. Also, study priorities would likely have been rearranged, with priority research activities focusing on relevant work that directly informs an assessment of the potential impact of the process of hydraulic fracturing on drinking water resources.

EPA acknowledges[13] there will be "significant national interest in the results of the study." According to the 2004 Office of Management and Budget (OMB) Memorandum Final Information Quality Bulletin for Peer Review,[14] "A scientific assessment is considered "highly influential" if EPA or the OIRA Administrator determines that the dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest." This designation triggers higher standards for peer review and public participation with regards to all aspects of "scientific assessment." According to the OMB Bulletin[15] "the term *scientific assessment* means an evaluation of a body of scientific or technical knowledge, which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. These assessments include, but are not limited to, state-of-science reports; technology assessments; weight-of-evidence analyses; meta-analyses; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments."

More specifically, it appears the process of scoping and designing of at least some key aspects of the study plan was driven, rather than informed by, stakeholder input. The case study element is one example,

[11] EPA. 2006. Guidance on Systematic Planning Using the Data Quality Objectives Process, EPA QA/G-4.
[12] EPA. 2002. Requirements for Quality Assurance Project Plans, EPA QA/R-5.
[13] EPA Study Plan, Page 8.
[14] 2004 OMB Bulletin, Page 23. http://www.whitehouse.gov/sites/default/files/omb/memoranda/fy2005/m05-03.pdf
[15] See supra footnote 14, Page 36.

the EJ element another. The need for a case study program at all does not appear to have been made based on a rigorous and defensible scoping and planning process. The case study element of the study plan was reportedly framed by inviting stakeholders to nominate potential case studies through "informational public meetings and submitting comments electronically or by email" (Section 9 of the study plan). It is unclear what rationale and process were used to select and invite these stakeholder nominations from the universe of stakeholders and potential site nominations. EPA ended up with seven sites selected from 48 stakeholder nominations rather than derived from a more statistically robust and scientifically-designed case study program that would have taken into consideration the diversity of geological and man-made characteristics of site settings for gas production from unconventional reservoirs. With a well-structured DQO process developed *a priori*, the study plan would have been driven by the rigor of the quality process, and the design of the case study element would have been forced by a credible approach, relying on best available science and independent sources of information, and using a transparent, peer reviewed process. Different and likely a larger number of sites would have been selected.

5.0 Case Studies

Congress requested a study "relying on best available science and independent sources of information." It appears questionable, because of its genesis and design, whether the proposed case study element of the study program will be able meet this expectation and provide the scientifically defensible data and information required to support the fundamental research questions regarding the possibility of impacts of hydraulic fracturing on drinking water resources. Similar concerns were raise by the SAB, and EPA in its response to those concerns confirmed the focus of the study would be on shale gas. However the actual scope appears to be broader, including all three classes of unconventional oil and gas production: shale gas, coalbed methane and tight sand plays. For example one of the five retrospective case studies is the Raton Basin site where gas is being produced from shallow coalbeds.

The limited and possibly statistically biased pool from which the sites were drawn, the small number of sites selected, and the lack of baseline information for all five retrospective sites, are likely to limit the scientific validity and usefulness of case study findings and may result in incorrect or questionable conclusions. The pool of sites for forensic (retrospective) analysis of potential impact of drinking water from hydraulic fracturing, from which five study sites were selected, was established, and thus limited, based on possibly insufficiently substantiated stakeholder reports of drinking water contamination rather than a more scientifically rigorous and hypothesis-driven process. Also, the absence of baseline information for the retrospective studies will limit the scientific validity and utility of resulting findings and may result in flawed conclusions. These limitations need to be acknowledged and made more explicit.

Furthermore, two prospective sites are insufficient to develop meaningful, scientifically significant and defensible data to inform the envisioned scenario evaluations and other research activities, given the wide range of geological and man-made conditions existing across the country where gas production from unconventional reservoirs might be contemplated. Significantly also, it appears EPA plans to address in the study hydraulic fracturing-related issues across all three classes of unconventional oil and gas production: shale gas, coalbed methane and tight sand plays. Two prospective sites cannot deliver the range of data that would be required for scientifically rigorous treatment of all the research questions asked. To this end, SAB[16] had specifically cautioned "with the realm of inference drawn in the report to different activities (i.e., results should not be generalized across all types of HF activity)."

[16] 2011 SAB, Page 3. http://www.epa.gov/hfstudy/peer-review.html

Lastly, much of the data being reviewed for EPA's 2012 study report are being derived from secondary sources including information requests sent in 2010 to nine service provider and in 2011 to nine hydraulic fracturing operators. This represents a small data set of hydraulic fracturing activities. Caution must be taken in generalizing findings. Also, acceptance criteria for secondary data use are not defined in the QAPP, and it is not clear how data obtained from public sources and operator files will be screened for fitness and usability. Significantly also, the data is historic, from 2006-2010, and thus not reflective of current operations and will be significantly out date in 2014 when the final EPA report will be published.

6.0 Quality

There appear to be insufficient alignment and nexus between the processes of developing the study design and individual research activities, and those for the development of the QA program that is to ensure systematic planning for design and implementation of the study and its individual research activities. Importantly, the QMP and QAPPs do not mention use of a systematic planning process or DQOs, and, as mentioned earlier, there is no direct evidence a systematic planning process was used to develop individual study components. The DQO process provides important linkage between the project design and the type, quantity, and quality of data to ensure that the project has a statistically sound basis. DQOs also help explain the rationale for the choice of measurement endpoints, data acquisition and analysis methods, such as analytes, laboratory methods and detection limits.

The data quality objective process is a logical, systematic, planning process that guides development of a study design. It establishes the reason(s) that data are being collected, the type and quality of data needed, and how the data will be used to answer study questions. The DQO process is typically accomplished in seven progressive steps depicted below in Figure 1.

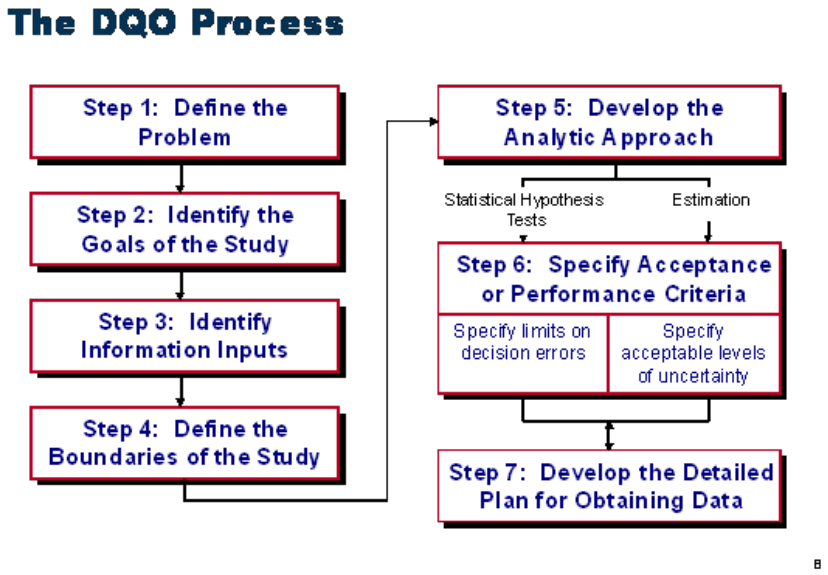

Figure 1. EPA DQO Process

The QA program described in the QMP for the study lacks detail and does not define either requirements or guidance for some of the most important elements of the EPA quality system. For instance, important elements of EPA's Guidance on Systematic Planning Using the DQO Process are not addressed. Use of the DQO Process is important because it "leads to efficient and effective expenditure of resources;

consensus on the type, quality, and quantity of data needed to meet the project goal; and the full documentation of actions taken during the development of the project."

The QMP for this study does not provide guidance or requirements for the use of systematic planning. Furthermore, it does not provide sufficient guidance to ensure that all projects are: 1) conducted in a comprehensive, consistent, and coordinated manner and 2) linked to the overall program objectives defined in the study plan, even though this is specifically recognized as an essential requirement by EPA in the study plan. The QMP does not describe the coordination, roles, and communication paths for extramural participants such as consistent QA procedures and practices, nor does it delineate the communication and accountability between the Writing Theme Leads and the Technical Research Leads (see below schematic from the QMP, Figure 2).

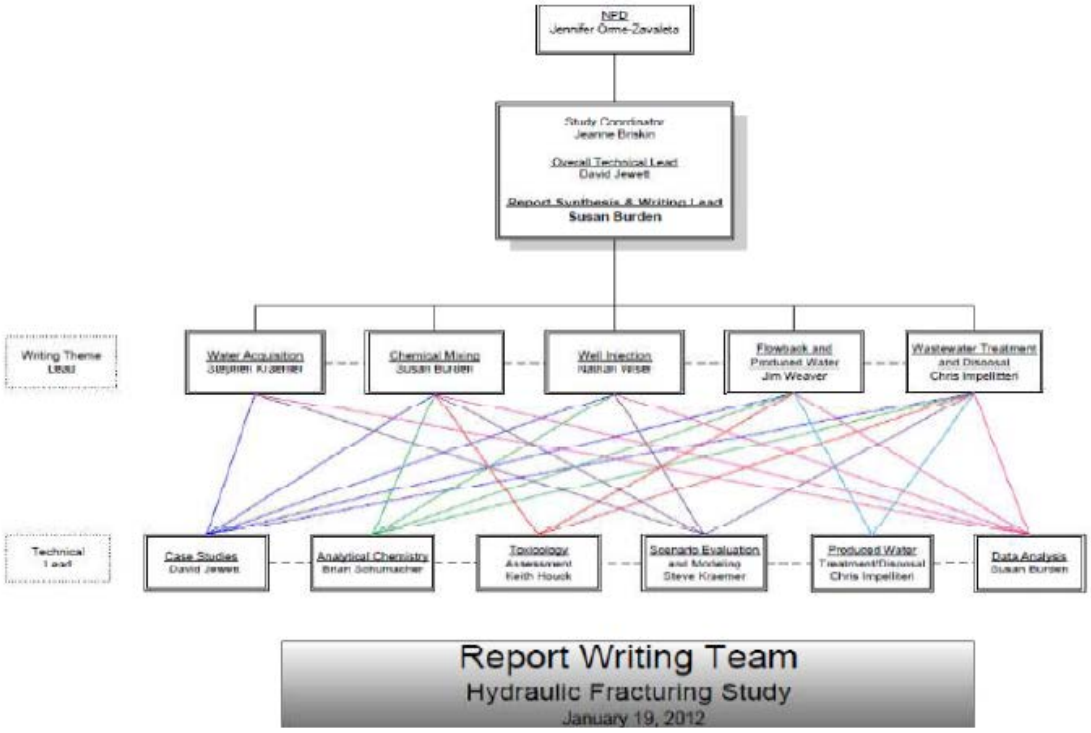

Figure 2. EPA QMP Rev No. 1 Figure 4

Of the 106 quality system items (73 quality system elements using 106 detailed questions) included in the EPA checklist, fewer than half were completely addressed in the QMP. Areas where the QMP is incomplete may lead to confusion, communication gaps, and lack of consistency among study participants. Due to the large number of projects and activities described by the study plan, there is a clear need for defining the interrelationships among the projects and QA documents. The study plan states "The organizational complexity of the hydraulic fracturing research effort also demands that a quality management plan be written to define the QA-related policies, procedures, roles, responsibilities, and authorities for this research. The plan will document consistent QA procedures and practices that may otherwise vary between organizations" (Section 2.6, Page 8). However, the QMP defaults to the quality

systems of the participating intramural and extramural organizations and does not provide programmatic coordination and linkages, or over-arching procedures for data management, data quality, and control.

The QMP was approved December 12, 2011, although it appears it was never published. Revision 1 was approved a month later on January 25, 2012, after the development and implementation of most of the study Quality Assurance Project Plans (QAPPs). It was posted on EPA's webpage on February 9, 2012. The EPA study plan states that "the organizational complexity of the hydraulic fracturing research effort also demands that a quality management plan be written to define the QA-related policies, procedures, roles, responsibilities, and authorities for this research." Because the QMP was developed after most QAPPs were prepared, approved, and implemented, the quality system requirements defined in the QMP are not incorporated into the study QAPPs. This is counter to EPA's quality policy and the ANSI/ASQ E4-2004 principles. Further, although the study plan specifies that "The plan will document consistent QA procedures and practices that may otherwise vary between organizations" the individual QAPPs reference the internal QA/QC procedures of the participating organizations rather than minimum, study-wide requirements which should be, but in fact are not, defined in the QMP.

The QAPPs do not mention that the study design was based on either formal DQOs or another less formal systematic process. It does not establish minimum requirements for systematic planning and the process of developing and documenting project goals, objectives, questions, and issues.

In general, the publically available QAPPs follow EPA guidelines, but there is wide variability among the individual documents in terms of level of detail, consistency, guidance for documents and records and data management, and approaches for complying with QA and assessment requirements. There is no overarching roadmap laying out the interrelationships among the individual studies among QAPPs or how the intramural and extramural teams working on the individual projects will coordinate different elements of the project. The individual documents do not reference each other leading to potential confusion about their scope, interrelationships, relative importance, and application towards meeting the study objectives. The use of consistent approaches across all projects, particularly for QAPP sections common to all activities (e.g., QC requirements, data management, assessments, verification and validation) is important to ensure the quality of the final study results. However, there is little consistency among the individual QAPPs in defining specific procedures.

Studies which collect environmental data must be described by quality assurance documents that establish procedures and requirements to ensure that data of the right type and quality to achieve the study objectives are collected. Once approved, a study QMP and QAPPs must be followed and any deviations documented. It is incumbent upon EPA to ensure during field sampling that improper sample collection procedures are indeed followed. If QAPP requirements are not communicated or the QAPPs did not provide adequate sampling details, data quality assurance cannot be provided.

The purpose of a quality system is to establish processes, procedures, and requirements that will ensure generation of data are "fit for use" - able to answer the study objectives. A weak or ill-defined quality system may result in confusion, inconsistency, and poor quality data that cannot be used to address the study questions. Gaps identified in the EPA study systematic planning process, the QMP, and the QAPP can impact data quality and the scientific rigor required for this important study. The procedures used for sample collection, laboratory analysis, data synthesis and modeling, and the reporting and management are all critical to developing high-quality, accurate data. Quality cannot be built into the back end of a project through rigorous review; it must be built into each step of a scientifically rigorous process to ensure that the end product is high quality data that is defensible and achieves the study goals.

7.0 Collaboration and Transparency

Congress asked this study to be conducted through "a transparent, peer-reviewed process that will ensure the validity and accuracy of the data. EPA shall consult with other federal agencies as well as appropriate state and interstate regulatory agencies." EPA's approach to developing and implementing the study plan is not consistent with this congressional request in regards to the process to be used for the technical direction for the study. Since EPA did not designate it as such, it also does not conform to the more rigorous standard of transparency required for "highly influential scientific assessments."

As mentioned earlier, it is unclear if EPA's intent is for this study to be part of a rule-making effort. The fact that the EJ element is included in the study scope suggests it is. However, there is no such explicit statement. The SAB recommended that if such were the intent, the objective would need to be made explicit because of its implications for designing the research program.

The entirety of the QA program was not commenced, documented and made available for public review in a timely manner. While QAPPs were released before the QMP, the latter was published only in February of 2012. This limited opportunities for stakeholder review and input.

EPA elected not to incorporate the SAB recommendation[17] that an advisory board be established to ensure that a balanced and scientifically sound approach be applied to the EPA study. This type of collaborative approach will result in more scientifically valid and relevant results by providing guidance on research priorities, data acquisition, DQOs and approaches to achieve useful outcomes.

A useful framework for effective collaboration is provided in the National Research Council's (NRC) 2008 assessment[18] of *Public Participation in Environmental Assessments and Decision Making.* The report's following recommendations may be useful to mitigate the challenges inherent with facilitating broad collaboration and participation of key stakeholders and the public:

- Process design should be guided by four principles
    1. Inclusiveness of participation
    2. Collaborative problem formulation and process design
    3. Transparency of the process, and
    4. Good-faith communication.
- In environmental assessments and decision making, special attention must be paid to scientific analysis and the uncertainty in that analysis. Five key principles for effectively melding scientific analysis and public participation:
    1. Ensuring transparency of decision-relevant information and analysis
    2. Paying explicit attention to both facts and values
    3. Promoting explicitness about assumptions and uncertainties
    4. Including independent review of official analysis and/or engaging in a process of collaborative inquiry with interested and affected parties, and
    5. Allowing for iteration to reconsider past conclusion on the basis of new information.

Lastly, given industry's extensive experience with production of oil and gas from unconventional reservoirs, its unique expertise in the process of hydraulic fracturing and associated technologies, and its

[17] 2010 SAB report, Page 2. http://www.epa.gov/hfstudy/peer-review.html

[18] 2008 National Research Council report. http://www.nap.edu/openbook.php?record_id=12434&page=3.

wealth of relevant data and information available to inform this effort, it is a weakness of the study plan, and likely its implementation, that significant industry collaboration is missing. For example, more extensive collaboration with industry for the retrospective case studies would likely strengthen that study element. But more importantly, greater industry involvement beginning with systematic planning and the DQO process through study design and implementation and drafting of the reports would have made the study more robust. EPA has a long history of successfully working with industry on challenging topics and would benefit from doing so here. A collaborative approach will strengthen the study by providing guidance on research prioritization, data acquisition, DQOs, developing meaningful outcomes, and review of study progress and interim results. A similar sentiment was echoed by the SAB in their 2010 report.[19]

[19] 2010 SAB report, Page 20. http://www.epa.gov/hfstudy/peer-review.html

Appendix A

Specific Comments Related to EPA Hydraulic Fracturing Study Plan

Specific comments based on Battelle's review of the study plan are provided below relative to each section of the study plan. The individual comments provided should not be inferred to imply Battelle's endorsement of the EPA subject matter included in the study plan.

1 Introduction and Purpose of Study

Comment 1.1: The scoping of the study plan by EPA went beyond the *prima facie* communication from Congress to include independent sources of information; the extent, to which the scoping of the scientific study was driven, rather than informed by consultations with stakeholders and stakeholder agendas, is not transparent in the study plan. (Section 1, Page 1)

Comment 1.2: The scope of the study was influenced by "public concern" expressed to EPA during formulation of the study plan; to what degree expanding the scope to include issues of public concern biased the scientific study is unclear. (Section 1, Page 1)

Comment 1.3: Congress urged EPA to "carry out a study on the relationship between hydraulic fracturing and drinking water." By interpreting the term "drinking water" to mean "drinking water resources" and defining "drinking water resources" to be any body of water, ground or surface, that could serve as a source of drinking water, EPA extends beyond the central issue of the study which should be the relationship between the injection hydraulic fracturing fluids and underground sources of drinking water (USDW). This broad definition of USDW then becomes the basis for the "cradle to grave" concept of the water lifecycle and the production well lifecycle around which EPA in Section 4 develops the framework and scope for the study. (Section 1, Page 1)

Comment 1.4: The scope of the hydraulic fracturing process considered by EPA appears to be inconsistent, overly broad and encompassing many activities that are commonly associated with oil and gas development activities and other industrial operations and processes. (Section 1, Page 1)

Comment 1.5: The subject of the scientific study communicated by Congress was the relationship between hydraulic fracturing and drinking water; the research activities proposed in the study plan embrace an expansive and programmatic "hydraulic fracturing water lifecycle" for the production of gas from unconventional reservoirs that includes topics such as water acquisition and wastewater treatment and disposal, that are not germane to a scientific study of the EPA-termed "actual fracturing" that is associated with well injection. (Section 1, Page 1 and Figure 1 Page 2)

Comment 1.6: Many of the potential impacts to water resources discussed are related to site management practices rather than the use of hydraulic fracturing technology in the enhanced natural gas extraction process. In contrast, Congress seems to be calling for a scientific endeavor to establish whether a relationship exists between the introduction of hydraulic fracturing fluids in reservoirs and USDW. (Section 1, Page 3)

Comment 1.7: The extent to which scoping was influenced by the intended use of the results of the study to inform the public and provide policy makers with knowledge for use in decision making versus a rigorous scientific study of the relationship between hydraulic fracturing technology and USDW is unclear. (Section 1, Page 3)

2 Process for Study Plan Development

Comment 2.1: The process of scoping and designing some aspects of the study plan appear to have been driven, rather than informed, by stakeholder input; to what extent stakeholder agendas may have biased the scientific integrity of the study plan proposed is a concern. (Section 2.1, Page 3)

Comment 2.2: In developing the study plan, EPA engaged the public to help establish EPA's highest priorities and recommend locations for case studies; the degree to which the scope and relative importance of elements of the study may have been unduly influenced by public concern rather than science-based need is not clear. (Section 2.1, Page 4)

Comment 2.3: Although SAB cautioned EPA against studying all aspects of oil and gas production and emphasized the study of "human health and environmental concerns specific to or significantly influenced by hydraulic fracturing rather than on concerns common to all oil and gas production activities," the study plan still retains many research activities that are ancillary to the subsurface introduction of fluids by hydraulic fracturing. (Section 2.2, Page 5)

Comment 2.4: Taking into account the SAB advice, EPA states that it focused the study plan on features that are particular to or closely associated with hydraulic fracturing; however, the scope of the study plan still includes many research activities that are peripheral to the application of hydraulic fracturing technology underground. (Section 2.2, Page 5)

Comment 2.5: Four of the five fundamental questions that EPA identified in order to frame the scientific research for evaluating the potential for hydraulic fracturing to impact drinking water resources (the top two and bottom two in Figure 1) are extraneous to a scientific study of hydraulic fracturing technology associated with well injection. (Section 2.3, Page 6)

Comment 2.6: The study plan does not contain a detailed discussion of the collection, documentation, information sharing, and QA/QC associated with the data used in the study plan. The QA process could be improved by referencing the quality system that will be implemented for the study and by specifying that all project data are Category I. This will establish the robust level of quality that will be applied to the study. (Section 2.3, Page 6)

Comment 2.7: It is unclear 1) how EPA will document and communicate modifications that EPA may make to the research approach outline "to better answer the research questions," 2) whether an updated study plan will be released documenting how and why changes were made in addition to the Final Study Plan clarification comments posted on the EPA hydraulic fracturing question and answer Web page, and 3) whether the documentation will be peer reviewed. (Section 2.3, Page 7)

Comment 2.8: It is not clear how EPA plans to release the information it collected and used to prioritize its research activities, or how EPA plans to take into account the hydraulic fracturing-related research activities being conducted by Department of Energy (DOE), United States Geological Survey (USGS), United States Army Corps of Engineers (USACE) and others. (Section 2.3, Page 7)

Comment 2.9: The QA discussion in the study plan defines the framework for the study quality system. The study plan states that this system includes a study QMP, QAPPs and systematic planning. The study QMP and several associated QAPPs have been provided on EPA's Web site. These documents lack critical details of how data will be identified, collected and analyzed; how data collection will achieve accuracy, completeness and representativeness; and what data management procedures will be established to ensure traceability and reproducibility. In addition, the QAPPs do not define DQOs that delineate for each objective, the questions being asked, the data needed to address the question, the criteria used to determine data quality and applicability to the study questions, and how data usability will be determined. (Section 2.6, Page 8)

Comment 2.10: Section 2.6 references a "graded approach (to QA for research projects) such that QA requirements are based on the importance of the work to which the program applies." The EPA quality

system guidance[20] states that a graded approach to QA is based on the intended use of the data. This is another detail that should be clearly addressed in the QAPPs: the intended use of data, which data will be used for research to gain further understanding of an issue and which data will be used to draw conclusions and make recommendations. Data collected for the latter use must be collected under a more rigorous QAPP. It is noted that, with the exception of reference to EPA, 2002, the study plan does not contain any references to the EPA documents that define the content and format of a QMP[21]; the development of DQOs and the content of QAPPs. This is the level of detail that is routinely included in a QMP. (Section 2.6, Page 8)

Comment 2.11: The "highest level of quality assurance" (see Executive Summary, Page x) is assumed to be Category I[22] although this level is not stated in Section 2.6 of the study plan. (Section 2.6, Page 8)

3 Overview of Unconventional Oil and Natural Gas Production

Comment 3.1: There is a lack of a discussion of historical hydraulic fracturing operations and practices including mention that hydraulic fracturing has been in existence since the late 1940s. (Section 3, Page 9)

Comment 3.2: A discussion of the natural occurrence, prevalence, properties and potential for migration of methane should be included in this section. (Section 3, Page 9)

Comment 3.3: This section provides contradictory and to the reader confusing definitions of *hydraulic fracturing*; this ambiguity impacts purpose, scope and design of the study plan. First, the section properly defines "hydraulic fracturing" as a discrete step in unconventional gas production. Then, it contradicts this earlier definition stating the hydraulic fracturing process "begins with exploring possible well sites, followed by selecting and preparing an appropriate site." This latter description refers to the entire production well lifecycle encompassing site selection and preparation, well construction and development, and natural gas production that are common to most forms of oil and gas production. (Section 3, Page 12)

Comment 3.4: This section clearly identifies the technological processes that are unique to unconventional natural gas production using hydraulic fracturing namely: 1) water mixed with chemicals and a propping agent are pumped down a well; 2) the fluid containing the proppant is carried into the targeted formation under high pressure to enhance the fractures; and 3) as the injection pressure is reduced, recoverable fluid or "flowback" is returned back up the well to the surface. Research aimed at investigating industrial activities other than these three processes is not fundamental to scientific discovery relative to the use of hydraulic fracturing technology. (Section 3.3, Page 15)

Comment 3.5: There is no mention made here of the composition of the hydraulic fracturing fluid, specifically that the fluid is generally more than 99% water and inert proppant, and less than 1% chemical additives (a fuller discussion is provided in Section 6.2). Also, only brief mention is made of the use of hydraulic fracturing in stages which is commonly done using laterals to optimize the fracture network.

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[20] U.S, EPA. 2002. Overview of the EPA Quality System for Environmental Data and Technology. EPA/240/R-02/003. U.S. Environmental Protection Agency, Office of Environmental Information, Washington, D.C. November 2002. http://www.epa.gov/quality/qs-docs/overview-final.pdf

[21] U.S. EPA, 2001. EPA Requirements for Quality Management Plans. EPA QA/R-2. EPA/240/B-01/002. U.S. Environmental Protection Agency, Office of Environmental Information, Washington, D.C. March 2001.

[22] US EPA, 2012. Quality Management Plan Revision No. 1 Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources. US Environmental Protection Agency. Office of Science Policy. http://www.epa.gov/hfstudy/HF-QMP-1-19-2012.pdf

These and other issues are critical to a full understanding and communication of the hydraulic fracturing technology process. (Section 3.3, Page 15)

Comment 3.6: That hydraulic fracturing requires a large volume of water to be withdrawn from a source is a relative term that is situationally dependent. For example, the volume of water used in hydraulic fracturing may be very small compared with withdrawal rates for other industrial purposes and natural discharge rates in a given watershed. Also, recycling and reuse procedures that reduce the volume of water to be withdrawn from a source are not mentioned here, although briefly referenced in Section 6.1.1. (Section 3.3, Page 15)

Comment 3.7: This section lacks a description of the full extent of existing federal, state, and local regulatory requirements, standards and guidelines, and industry best management practice (BMP) frameworks that already apply to unconventional natural gas production operations relative to permitting and the use, storage, mixing and handling of raw materials, and management of wastewater discharge streams. (Section 3.5, Page 16)

4 The Hydraulic Fracturing Water Lifecycle

Comment 4.1: The underlying issue associated with this section is that the study plan does not differentiate between potential drinking water impacts associated with the implementation of hydraulic fracturing technology underground, and impacts commonly associated with industrial operations such as failure to follow BMPs to prevent incidental surface spills. (Section 4, Page 17)

Comment 4.2: In Table 1 of Section 4, issues related to surface spills and treatment of wastewater are not exclusive to the hydraulic fracturing process; they are common to oil and gas development and many other industrial operations. Drinking water contamination issues that arise from a release of chemicals at the ground surface are not the result of the hydraulic fracturing technology process *per se*, but rather may be the consequence of poor industrial safe management practices. The focus here should be on the potential for interaction and migration of fluids associated with hydraulic fracturing underground. (Section 4, Page 17)

Comment 4.3: Of the 18 secondary research questions identified in Table 1, the following six questions are appropriately relevant to the scientific study of the relationship hydraulic fracturing technology to USDW, the relevance of the remaining 12 questions is incidental:

- What are the identities and volumes of chemicals used in hydraulic fracturing fluids, and how might this composition vary at a given site and across the country?
- What are the chemical, physical, and toxicological properties of hydraulic fracturing chemical additives?
- How effective are current well construction practices at containing gases and fluids before, during, and after fracturing?
- Can subsurface migration of fluids or gases to drinking water resources occur and what local geologic or man-made features may allow this?
- How might hydraulic fracturing fluids change the fate and transport of substances in the subsurface through geochemical interactions?
- What are the chemical, physical, and toxicological properties of substances in the subsurface that may be released by hydraulic fracturing operations?

Additional pertinent research questions may be identified through application of a structured and systematic planning process such as EPA's DQO system. Without having first appropriately and clearly established the extent and boundaries of the questions that the scientific study is tasked to examine, the design of a study plan would be misguided. (Section 4, Table 1, Page 17)

Comment 4.4: When discussing hydraulic fracturing additives, the intent should be to evaluate the properties of the chemicals after a 10-fold dilution with water. (Section 4, Table 1, Page 17)

Comment 4.5: It should be noted that publicly owned treatment works (POTWs) are no longer being used in the majority of the Appalachian Basin (i.e., Pennsylvania) for treatment of wastewater from hydraulic fracturing operations. Accordingly in this case, evaluating the effectiveness of POTWs as a wastewater treatment/disposal option is not generally relevant to current practices. (Section 4, Table 1, Page 18)

Comment 4.6: Of the "Potential Drinking Water Issues" listed in Figure 9, only the following may be considered relevant to the scientific study of the relationship hydraulic fracturing technology to USDW, and these should be more clearly defined:

- Fracturing fluid migration into drinking water aquifers
- Formation fluid displacement into aquifers
- Mobilization of subsurface formation materials into aquifers.

Additional research issues may be identified through application and documentation of an appropriate systematic planning process. (Section 4, Figure 9, Page 19)

5 Research Approach

Comment 5.1: The primary issue associated with this section is a concern that the study plan lacks the detail and specifics necessary to support a scientific and defensible investigation. Also, there is concern regarding the transparency and decision-making criteria associated with the data collection and sharing process. (Section 5, Page 20)

Comment 5.2: The nexus between the fundamental questions stemming from the overarching goal (Page 1), the fundamental research questions (Page 2), the secondary research questions (Table 1), the potential drinking water issues (Figure 9), and the research activities and objectives (Table 2) are not clear. Clarity and continuity of logic in planning the scientific research would be obtained through adherence to a structured and systematic process such as EPA's DQO system.[10] (Section 5, Page 20)

Comment 5.3: Additional information should be provided on the "systematic framework" used in case studies for investigating relationships among relevant factors. (Section 5.2, Page 20)

Comment 5.4: EPA should provide details on the "deductive logic approach" to be used and comment on the likelihood that this approach will lead to an accurate and definitive determination whether or not reported impacts are due to the implementation of hydraulic fracturing given the potential for many confounding issues in retrospective case studies. (Section 5.2, Page 21)

Comment 5.5: The use of numerical modeling simulations should properly focus on the fate and transport of hydraulic fracturing fluids introduced underground for a range of typical regional geologic scenarios. (Section 5.3, Page 21)

Comment 5.6: Laboratory studies to evaluate the fate and transport of chemical contaminants during wastewater treatment are not relevant to investigating the relationship of hydraulic fracturing technology to USDW. (Section 5.4, Page 21)

Comment 5.7: Laboratory study assessment of the potential for "treated flowback and produced water to cause an impact to drinking water" extends beyond the task of studying the relationship between hydraulic fracturing and drinking water. (Section 5.4, Page 21)

Comment 5.8: Consideration of toxicological studies throughout the hydraulic water lifecycle is overly broad. The critical issue is whether the fluid injected under pressure into a targeted hydrocarbon reservoir during hydraulic fracturing results in migration of harmful levels of chemicals into USDW. (Section 5.5, Page 21)

6 Research Activities Associated with the Hydraulic Fracturing Water Lifecycle

Comment 6.1: From a study design standpoint, care needs to be taken when associating hydraulic fracturing operations with compromised water quality. As with other problems of deciding whether a change in Factor "A" causes a change observed in Quantity "B", the power to draw a strong conclusion depends on how variable the underlying quantities are when Factor "A" is constant (i.e., no hydraulic fracturing), and the magnitude of the change when Factor "A" changes (i.e., the effect size) with respect to the magnitude of that variability. For example, with respect to the standard deviation of the measurements made with no hydraulic fracturing taking place (the baseline condition), it is important to anticipate whether hydraulic fracturing will cause the important parameter values to change by a fraction of a standard deviation, by one or two standard deviations, or by many standard deviations. Another important factor is the timing of the observed change with respect to the timing of the factor in question (i.e., the time it takes for the drinking water quality to change after hydraulic fracturing occurs). If the change occurs rapidly and is largely compared to the baseline condition, then it will be straightforward to design a prospective study to draw a strong conclusion. If the change occurs only gradually or is of a subtle magnitude, then it will be much more challenging to design a study that is likely to draw a strong causal conclusion. The observed changes might be attributed to other causes, or a combination of causes. Inclusion of a sensitivity analysis in any evaluation of water quality data will provide valuable input for understanding and validating results. Sampling frequency and the use of replicates need to be tailored to the variability intrinsic in temporal, spatial, and data acquisition conditions. (Section 6.2, Page 28)

Comment 6.2: In the retrospective case studies, the monitoring strategy (including spatial locations, frequency and duration) for evaluating short- and long-term impacts associated with hydraulic fracturing activities is poorly characterized, and no specific criteria for identifying sampling locations are identified. Care must be taken in the selection of monitoring locations and understanding the optimal frequency for sample collection. A less frequent sample collection strategy may miss localized or short-term impacts, whereas a more frequent sampling approach may be cost prohibitive. EPA needs to better define the proposed monitoring strategy. (Section 6.2.5, Page 32)

Comment 6.3: Water use for hydraulic fracturing is only one of a number of water uses, including agriculture, industrial and domestic consumption. Water use data from the Susquehanna River Basin Commission and the Colorado Oil and Gas Conservation commission should include data for all domestic and industrial users in addition to water used during hydraulic fracturing operations. EPA's assessment of the impact of water use for hydraulic fracturing must take into account the impact of other uses. (Section 6.1.3, Page 25)

Comment 6.4: It is unclear how the scenario evaluation will define "full exploitation" and "sustainable" given the varying amounts of water necessary for a hydraulic fracturing operation, and potential future efficiencies in water treatment and recycling processes, and reduced process water usage. At a minimum, sensitivity analyses should be performed to account for such changes in water usage associated with hydraulic fracturing operations. (Section 6.1.3, Page 26)

Comment 6.5: When evaluating the impact of the volume of water used during hydraulic fracturing operations, careful assessment of the water cycle in the area of question should be performed. This evaluation should focus on overall water availability, prioritization, and usage in the area in question. (Section 6.1.4, Page 27)

Comment 6.6: Spills and releases of hydraulic fracturing fluid should be addressed through BMPs and existing regulations that address the transportation, disposal, spill reporting and response. EPA should add a discussion of these types of regulations to the plan. (Section 6.2.1, Page 28)

Comment 6.7: The plan contemplates that 10 to 20 different chemical indicators would be used to track the fate and transport of hydraulic fracturing fluids in the environment. One simpler method for evaluating possible flows between or among formations would be to monitor a shortlist of indicators that includes chlorides along with major cations and anions. (Section 6.2.4.1, Page 31)

Comment 6.8: The selection criteria for the 10 to 20 indicator chemicals should include the volume and analytical detection limits of chemicals used during the hydraulic fracturing process in addition to the toxicity. As noted in Table 4 of the study plan, these chemicals make up less than 1% of process water and are often diluted to non-detectable levels during fluid formulation. (Section 6.2.4.1, Page 31)

Comment 6.9: It is likely that the toxicity of most of the candidate compounds will not be known. It is not clear that EPA will be able to perform quantitative structure-activity relationships (QSAR) analyses on hundreds (to potentially thousands) of chemicals. There needs to be additional discussion about alternative selection criteria or ranking schemes, such as presence of certain functional groups that tend to render chemicals toxic that could be employed when narrowing the scope of the work from 1000 chemicals down to six for toxicological testing. (Section 6.2.4.1, Page 31)

Comment 6.10: In its retrospective case studies, EPA intends to identify impacts to drinking water resources from surface spills of hydraulic fracturing fluids. The study plan does not describe how EPA will differentiate between degradation products from hydraulic fracturing fluids and similar products derived from other sources or how EPA will establish background conditions if there is pre-existing contamination from natural or other industrial sources. (Section 6.2.5.1, Page 33)

Comment 6.11: EPA references a number of reports that have indicated faulty well construction or improperly sealed wells may potentially provide pathways that allow migration of contaminants to sources of drinking water. These concerns are not unique to hydraulic fracturing and a thorough investigation of all well integrity issues would require a level of effort beyond the scope of the proposed study. To better focus the efforts of this study, the research into well construction should be focused on evaluating the unique aspects of hydraulic fracturing, including high pressure. This would include the methods that are employed to confirm casings and well cements can contain hydraulic fracturing fluids and pressures. (Section 6.3.2, Page 35)

Comment 6.12: The study plan states that a model will be built to simulate migration of contaminants associated with well integrity failure and local geologic or man-made features. The QAPP describing this modeling, Analysis of Environmental Hazards Related to Hydrofracturing by Lawrence Berkeley National Laboratory, states that data to calibrate the model will not be available. This means that although

the modeling effort could identify scenarios in which contaminants can migrate to ground or surface water resources, the results will not indicate whether those scenarios are plausible. A description of model assumptions and limitations along with a detailed sensitivity analysis of model input parameters and a summary of any model calibration should be included with any modeling analysis. (Sections 6.3.2 and 6.3.3, Pages 36 and 39)

Comment 6.13: In addition to the research activities EPA has identified, additional research areas should include: establishing background levels of methane and all other possible indicator parameters in groundwater and chemical fingerprinting/source tracking through isotopic analysis and other analytical techniques (Section 6.3.3, Page 38)

Comment 6.14: The study plan makes reference to studies that note biogenic methane is prevalent in areas of hydraulic fracturing operations, but makes no reference to how it plans to differentiate between different origins of methane. This type of analysis is essential in understanding background conditions prior to hydraulic fracturing operations. Chemical fingerprinting/source tracking of methane through isotopic analysis and other analytical techniques should be performed as part of the research activities. (Section 6.3.5, Page 41)

Comment 6.15: It is unclear how EPA will move beyond selection of relatively common industrial chemicals for this work (e.g., the chemicals listed in Table E2). Criteria for selection seem to favor compounds that are commonly studied because of existing analytical methods, whether or not these are the most significant ones from a risk perspective. However, the study plan does not describe how the number of chemicals brought forward for ToxCast screening will be determined, nor does it discuss whether the chemicals will be regional- or formation-derived, or randomly selected regardless of formation, manufacturer, or geographic location. (Section 6.4.3, Page 45)

Comment 6.16: EPA may need to consider analytical profiling methods or pattern recognition methods for understanding the relationship between hydraulic fracturing fluids and chemicals in hydraulic fracturing wastewater, so as not to be restricted to only those that are amenable to existing analysis methods. (Section 6.4.3, Page 46)

Comment 6.17: The study plan includes evaluating the effect, if any, that flowback discharge from hydraulic fracturing operations would have on wastewater treatment and disposal. This need for this element of the study should be re-evaluated: (Section 6.5, Page 48)

- The treatment and disposal of flowback are already heavily regulated by state and federal law and there is nothing unique about fracturing operations that demand a study of this type. The Clean Water Act and other state and federal regulations already contain requirements and provisions to establish, enforce, and periodically review pretreatment and effluent standards.
- POTWs are rarely used as a disposal method except in limited circumstances in the Marcellus Shale region. However, recent state regulatory revisions have nearly eliminated the potential for Marcellus Shale operators to discharge the flowback and produced water to POTWs. EPA states that Underground Injection Control (UIC) wells are the primary disposal option and that treatment and recycling are becoming more common.

7 Environmental Justice Assessment[23]

Comment 7.1: Questions over whether gas drilling operations and the water lifecycle disproportionally occur in communities with EJ concerns are not central to a scientific study into the relationship between hydraulic fracturing technology and drinking water. If included as proposed, EJ should be afforded special attention with consideration given to identifying and using a reporting mechanism that feeds appropriately into EPA's decision making so that it is not blurred with the scientific study of hydraulic fracturing and drinking water potentially obfuscating the scientific findings. (Section 7, Page 53)

Comment 7.2: The proposed approach for evaluating EJ concerns needs to be refined; the proposed methodology is not rigorous enough to examine and sufficiently understand the cost benefit of the resource development within an EJ context. Overall, the study considers issues of EJ within a "policy vacuum." The methodology being proposed is not sophisticated enough to examine the actual cost/benefit analysis including alternative land use value, economic impact of value-added activity, etc., weighed against the potential costs. (Section 7, Page 53)

Comment 7.3: The proposed study relies purely on demographic statistics compared against the national average to ascertain whether or not certain sub-segments of the population are being disproportionately impacted by gas drilling operations. It may be anticipated that the EJ assessment will most likely reveal that the majority of the communities where hydraulic fracturing takes place are classified as socio-economically disadvantaged in comparison to the national norm because of the intrinsically rural character of the regions in which these natural resources occur. (Section 7, Page 53)

Comment 7.4: At a minimum, the analysis needs to be controlled for the population demographics of rural America where the natural resources are found, and subsequently the locations of wastewater treatment plants. In other words, the statistical comparison of the population's demographics cannot be compared against the U.S. overall, but needs to be normalized to the demographics of these rural locations to then enable a determination whether certain communities are being targeted and are at a disadvantage. (Section 7, Page 53)

Comment 7.5: EPA could consider running an input/output model to analyze the economic impact (both positive and negative) of unconventional gas production on a region. The information could then be used to develop what/if scenarios and model the potential impact of what is termed "scenario events" (i.e., limiting the economic activity, increasing it, or eliminating it in its entirety, etc.). The analysis could then also be further augmented by analyzing the functional impacts. (Section 7, Page 53)

8 Analysis of Existing Data[24]

Comment 8.1: Data gaps associated with this section involve an absence of a sufficient discussion of QA procedures, and specific information regarding sampling and monitoring strategies. (Section 8, Page 56)

Comment 8.2: The statement that EPA will also "access data from other sources, including peer-reviewed scientific literature, state and federal reports, and other data sources shared with EPA" should be more specific. Sources of all readily available and relevant data should be identified either in the study plan or the QAPPs to ensure unbiased research is conducted. (Section 8.1.1, Page 56)

Comment 8.3: The site data collected from the companies are from 2006-2010, and the final report will be in 2014. The changes occurring at these sites in the intervening years will likely render the data obsolete

[23] Battelle's detailed analysis of EPA's Environmental Justice QAPP can be found in Appendix E.
[24] Battelle's detailed analysis of EPA QAPPs that relate to existing data can be found in Appendix E.

for purposes of the study. Clarification should also be provided on how exactly "randomly selected" wells or locations were selected; based on available information, it is not clear to what extent selection was truly a random or statistically supported process, whether wells were selected to cover a range of geographic and geologic variations, or whether wells were selected on the basis of opportunity and known complaints. (Section 8.1.2, Page 56)

Comment 8.4: The section points to the QAPP for details; however, it does not define the QAPP requirements and format. Activities that will generate data that will be used to draw conclusions or make recommendations should be collected under a QAPP compliant with QA/R-5.[11] It is also noted that the study plan does not discuss study-level standards data management or where data management procedures will be defined in other study documents. (Section 8.2, Page 58)

9 Case Studies[25]

Comment 9.1: Retrospective case studies may yield useful information relative to the planning of prospective studies; however, the number of retrospective cases and level of effort expended should be reduced in favor of increasing the number and level of effort evaluating prospective case studies that rule out potentially confounding issues not necessarily related to hydraulic fracturing such as the inappropriate use, storage, mixing or handling of raw materials, treatment of wastewater discharge streams inconsistent with federal, state or local regulatory requirements, failure to comply with industry BMPs, and naturally-occurring substances. (Section 9.1, Page 58)

Comment 9.2: It is unclear what is meant by the "extent to which conclusions can be generalized" and also as to how this idea will be applied to other sites. (Section 9.1, Page 58)

Comment 9.3: If retrospective case studies are to be conducted, then selection should include instances where hydraulic fracturing has been conducted beneath strata considered to act as barriers to the vertical migration of fracturing fluids, and where drinking water contamination is not potentially attributable to operations other than "actual fracturing," such as those commonly associated with other industrial operations including failure to follow BMPs to prevent leakage of chemicals and incidental surface spills from the ground surface for example. None of the retrospective case study locations selected appears to satisfy these criteria. (Section 9, Table 8, Page 60)

Comment 9.4: Based on the decision criteria that were used, more information should be provided on the specific reasons for selecting the seven sites out of the 48 candidate sites. Specific criteria that resulted in the selection of each of the seven sites should be included here, and would provide information on whether previously designated hydraulic fracturing-impact sites may or may not have been deemed as such during the review process. (Section 9.1, Page 58)

Comment 9.5: The description of the transition between tiers (i.e., Tier 1 to Tier 2, etc.) using the tiered evaluation approach is not well defined. It is not clear: 1) whether there will be some locations where this transition might not apply, 2) if tier-specific results will be available for review during the study, 3) whether uncertainties associated with the transition between tiers will be reported, and 4) if stakeholders will be interviewed during data collection activities. (Section 9.2, Page 63)

Comment 9.6: To provide transparency in the study design, it is essential to know the extent of specific local and federal collaboration for the selected case study and sample locations. (Section 9.3, Page 66)

[25] See supra footnote 24.

Comment 9.7: EPA should provide the timeline for when hydraulic fracturing occurred and when associated complaints were issued within the vicinity of the sample locations at each of the retrospective locations. (Section 9.2, Page 64)

Comment 9.8: It is not apparent how the data will be reconciled with the study objectives and how uncertainties and limitations will be identified and reported. (Section 9.2, Page64)

Comment 9.9: It is unclear what specific field samples will be collected for prospective case study locations after the first year of hydraulic fracturing activity. (Section 9.3, Page 66)

Comment 9.10: It is unclear what, if any, special sampling precautions are to be considered for measuring dissolved gases at depths of hydraulic fracturing; the only approach mentioned is the bomb sampler (Appendix H, Page 164).

10 Scenario Evaluations and Modeling[26]

Comment 10.1: The extent of modeling should be limited to issues concerning the underground injection of fluids and the fate and transport of chemicals in relation to USDW. (Section 10.3, Page 69)

Comment 10.2: Care should be taken when conducting modeling simulations 30 years into the future. Advances in water treatment and well development technologies will likely reduce the volume of water required for hydraulic fracturing operations. It is unclear how the future scenarios will be handled. In any event, a detailed sensitivity analysis of input parameters used in future predictive scenarios should be performed. Although uncertainty is discussed in Section 10.4, methods to address or quantify the uncertainty are not. (Section 10.4, Page 71)

11 Characterization of Toxicity and Human Health Effects[27]

Comment 11.1: The characterization of toxicity and human health effects should be limited to issues concerning the underground injection of fluids and the interaction, fate and transport of chemicals in relation to USDW. (Section 11, Page 71)

Comment 11.2: It is unclear how EPA intends to "develop a prioritized list of chemicals." (Section 11, Page 71)

Comment 11.3: It would be beneficial for EPA to define the procedure for unknown chemicals (e.g., selection of six hydraulic fracturing chemicals for ToxCast screening/ Provisional Peer Reviewed Toxicity Value (PPRTV) database development) as a high concern prior to developing an analytical method. It is unclear whether this approach will be incorporated for both retrospective and prospective case studies. (Section 11, Page 72)

Comment 11.4: It is recommended that consideration be given to using ToxCast testing of mixtures of hydraulic fracturing chemicals, so as to identify and rank formulations rather than individual chemicals that are most toxic. (Section 11, Page 72)

Comment 11.5: The use of the term "risk" in this section implies that a formal risk assessment will be performed. Although EPA may have the information necessary to perform a detailed risk assessment, it has stated that a risk assessment is outside the scope of this investigation. The document should reference

[26] See supra footnote 24.
[27] See supra footnote 24.

relative risks or vulnerabilities instead when the intent is not to produce a detailed ecological or human health risk assessment. (Section 11, Page 72)

12 Summary

Comment 12.1: The text in this section states that "All data, whether generated by the EPA or not, will undergo a comprehensive quality assurance" although the specific procedures for evaluating existing/secondary data are not provided in the study plan, QMP, or QAPPs. (Section 12, Page 73)

Comment 12.2: Regarding the statement "As the research progresses, EPA may learn certain information that suggests that modifying the initial approach or conducting additional research within the overall scope of the study plan is prudent in order to better answer the research questions," it is unclear how these modifications will be managed and how stakeholders will be involved in the process. (Section 12, Page 73)

13 Additional Research Needs

Comment 13.1: The extent of additional research should be limited to issues concerning the underground injection of fluids and the fate and transport of chemicals in relation to USDW. (Section 13, Page 81)

Comment 13.2: Other research areas should include: establishing background levels of methane and all other possible indicator parameters in groundwater and chemical fingerprinting/source tracking through isotopic analysis and other analytical techniques. (Section 13, Page 81)

Comment 13.3: The potential economic costs of hydraulic fracturing (which include the potential costs to the regional water systems) cannot be studied in its entirety unless the economic benefits are also understood. An independent study that examines the entirety of the impact from such operations would be able to analyze the complete situation and could be used to inform more deliberate and complete policy discussions. (Section 13, Page 81)

Comment 13.4: EPA may need to consider analytical profiling methods (e.g., 2D-GC or GC/GC/MS) or pattern recognition methods for understanding the relationship between hydraulic fracturing fluids and chemicals in hydraulic fracturing wastewater, so as not to be confined to only those that are amenable to traditional analytical methods. (Section 13, Page 81)

Comment 13.5: EPA has stated that it may include additional issues in this current study as they apply to potential impacts of hydraulic fracturing on drinking water resources which could expand the scope of the investigation. It is unclear how these modifications will be managed and whether stakeholders will be involved. (Section 13, Page 81)

Appendix B

Events and Timeline Leading up to Release of EPA Hydraulic Fracturing Study Plan

October 2009: The U.S. House of Representatives Appropriation Conference Committee for Fiscal Year 2010 (FY10) tasked the U.S. Environmental Protection Agency (EPA) to:

> "carry out a study on the relationship between hydraulic fracturing and drinking water, using a credible approach that relies on the best available science, as well as independent sources of information. "

Specifically, it was requested that the study applies a

> "transparent, peer-reviewed process that will ensure the validity and accuracy of the data. The Agency shall consult with other federal agencies as well as appropriate state and interstate regulatory agencies in carrying out the study, which should be prepared in accordance with the Agency's quality assurance principles."

March 2010: EPA released a scoping document for evaluating the relationship between hydraulic fracturing and drinking water. The initial study design adopted, "a Life Cycle Assessment (LCA) approach to identify potential interrelationships between energy, water, the chemicals used during hydraulic fracturing, the surrounding environment, and safeguards for public health protection".

April 2010: The Agency received advice on the scoping document from the Science Advisory Board (SAB) in an open meeting. The review was conducted by the SAB Environmental Engineering Committee and selected additional members of the SAB.

June 2010: The SAB provided written recommendations.[28] Public comments were also submitted. In general, the SAB endorsed a lifecycle approach for the study plan, and recommended that:

1) Initial research be focused on potential impacts to drinking water resources, with later research investigating more general impacts on water resources
2) Five to ten in-depth case studies be conducted at "locations selected to represent the full range of regional variability of hydraulic fracturing across the nation"
3) Engagement with stakeholders occurs throughout the research process.

The SAB recommended using a lifecycle framework, without actually performing a formal lifecycle assessment, as an organizing tool to identify the most important research questions. The Board also suggested using a risk-based research prioritization approach to characterize the risk of human and ecological exposure to hydraulic fracturing fluids and products. They suggested that EPA direct the study towards:

- identifying the conditions most likely to lead to impacts on drinking water resources;
- evaluating potential pathways to human and ecosystem exposure under a range of hydraulic fracturing process conditions relative to different geological formations and conditions;
- evaluating the existence and formation of hydraulic fracturing injection and product fluid transport pathways as a result of hydraulic fracturing;
- assessing the effect of hydraulic fracturing processes on water quantity;
- characterizing the composition and variability of the source fluids, flowback water and produced water that is co-mingled with the flowback water;

[28] http://www.epa.gov/hfstudy/sab-june2010-finalreport.pdf

- assessing possible synergistic effects of mixtures of chemicals in fracturing fluids and due to interactions with materials in the fractured injection zone;
- identifying potential secondary effects associated with hydraulic fracturing such as enhanced methane transport , changes in redox conditions, mobilization of arsenic and naturally occurring radioactive materials (NORM); and
- focusing health effects research towards chemicals of potential concern that are likely to pose the greatest human health risk and have the greatest potential for possible exposure to humans and ecological receptors.

The SAB recommended that the EPA apply an in-depth case study approach using five to ten different locations that represent the full range of regional variability. The Board suggested partnering with industries during the case studies to leverage expertise and resources. Potential outcomes from in-depth case studies that the SAB highlighted include:

- knowledge about best management practices (BMPs) that favorably affect quality and quantity of source fluids, flowback water and produced water that is co-mingled with the flowback water;
- data on the impacts of the composition and variability of source fluids on flowback/produced water; and
- increased understanding of human and ecological exposure in relation to hydraulic fracturing activities.

The SAB also suggested that the Agency develop a balanced, collaborative advisory group of stakeholders that could be engaged throughout the research process. The Board also recommended that EPA engage with other federal agencies to share data, collaborate, leverage expertise, and align research priorities for optimal use of limited resources.

Summer 2010[29]**:** The EPA held sector specific and State and Federal partner consultation meetings, public meetings, and tribal government consultation meetings to solicit input on the overall study plan and nominations for potential case-study sites. Total attendance for all of the information public meetings exceeded 3,500 and more than 700 verbal comments were heard. EPA also conducted webinars on their Hydraulic Fracturing Study Plan, and began packaging the information differently for different audiences: “stakeholders” and “public”.

September 2010: EPA requested information from nine hydraulic fracturing service companies[30] on the chemical composition of fluids used in the hydraulic fracturing process, data on the impacts of the chemicals on human health and the environment, standard operating procedures at hydraulic fracturing sites and the locations of sites where fracturing has been conducted. There appear to be no scientific basis for limiting the request for information to nine companies. The Agency restricted the request to nine companies so they would not have to fulfill additional requirements in accordance with the Paperwork Reduction Act of 1995[31] if they had obtaining information from 10 or more entities. The 2010 survey identified these nine service companies had, collectively, fractured about 25,000 wells, for 1,150 operators, between 2009 and 2010. It should be noted that this data collection activity was conducted prior to the approval of a Quality Assurance Project Plan.

[29] http://www.epa.gov/hfstudy/publicoutreach.html
[30] BJ Services, Complete Well Services, Halliburton, Key Energy Services, Patterson-UTI, RPC, Schlumberger, Superior Well Services, and Weatherford
[31] http://www.archives.gov/federal-register/laws/paperwork-reduction/

February 2011: The EPA released a Draft Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources and requested that the SAB form a committee to review and provide comments and advice. The draft study plan incorporated input from the 2010 SAB consultation, stakeholder meetings, and public comments. In addition to SAB comments, over 5,500 stakeholder comments were received, including over 2,000 electronic submissions of a form letter written by Energycitizens.org (sponsored by API).

The draft study plan defined a "hydraulic fracturing water lifecycle" that includes five stages:

- Water acquisition
- Chemical mixing
- Well injection
- Flowback and produced water
- Wastewater treatment and waste disposal

The research approach was built around case studies, scenario evaluation, toxicity screening of chemicals, and environmental justice. The case studies are subdivided into retrospective investigations of reported instances of drinking water contamination and prospective shadowing of hydraulic fracturing before, during, and after water acquisition, drilling, hydraulic fracturing fluid injection, flowback, and gas production. The pool of potential case study sites was developed from nominations submitted to the Agency during the development of the plan.

June 2011: Case study locations are announced by EPA.

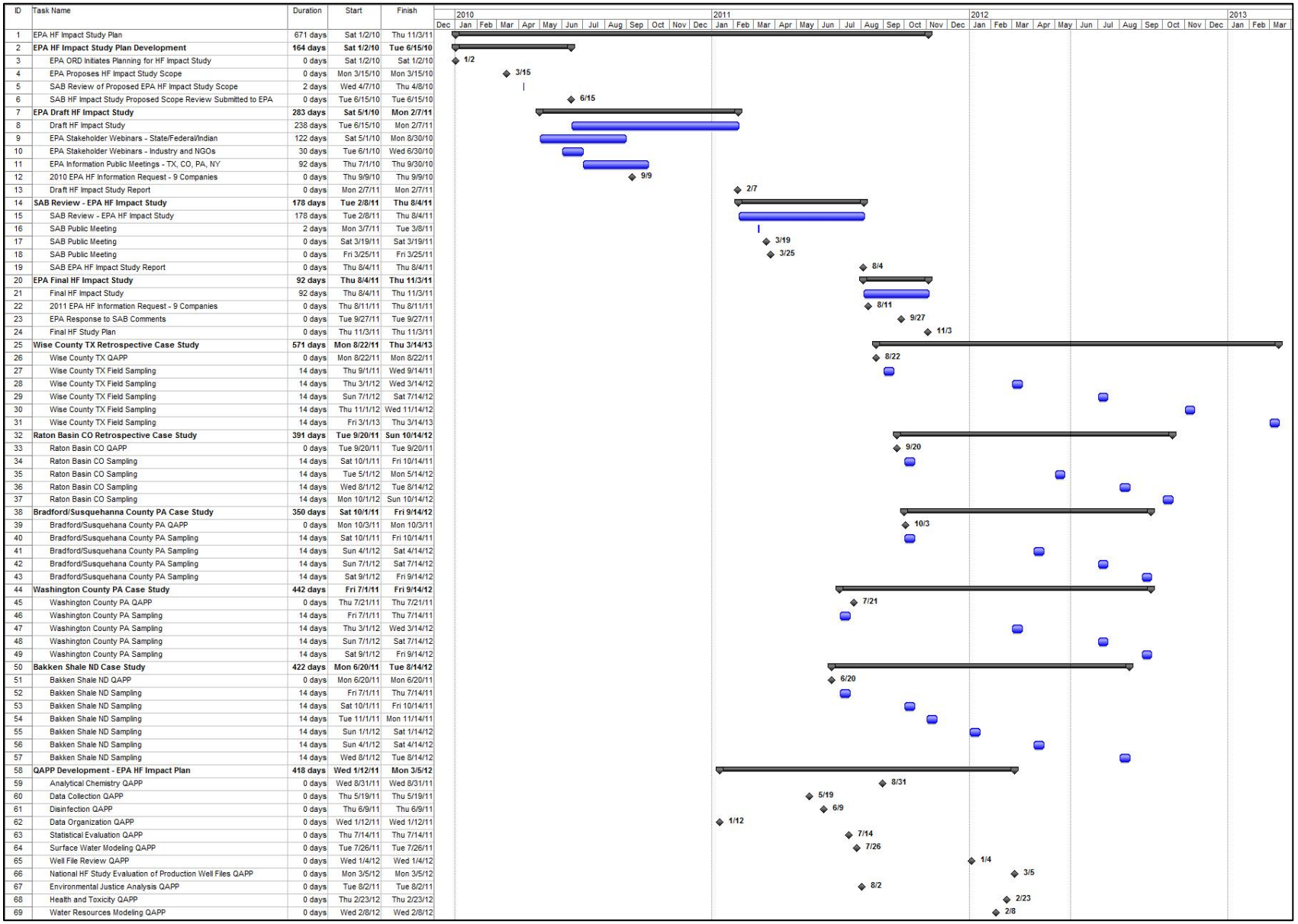
August 2011: SAB provided an evaluation of the draft study plan[32]. The SAB submitted an 89 page report (including appendices) to the Agency with responses to charge questions and over 130 detailed recommendations. The recommendations addressed the general scope and format of the study, the water lifecycle, the case studies, scenario evaluation, chemical toxicity assessment, and environmental justice. The EPA formally responded to about 25% of recommendations in September 2011[33,34]. Excerpts of the SAB recommendations are summarized in a separate Battelle Project Memorandum.

August 2011: Nine[35] of the 1,150 operators (0.8%) surveyed in September 2010 were randomly selected for a follow-up information request (a "large" operator from each of the four EPA regions where hydraulic fracturing is active: R2, R3, R6, and R8; two "medium" and three "small" operators). Each of the nine companies was asked to provide data on well construction, design, and well operation practices for oil and gas wells that were hydraulically fractured from 2009 to 2010. In total, the well data request was targeted at 350 wells (less than 2% of the total number of fractured wells) that were geographically dispersed among the nine operators. (Note that percentages listed are limited to the dataset EPA collected, and not representative of the total wells per year that are hydraulically fractured.)

November 2011: The EPA released a study plan entitled: Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources[36].

[32] http://yosemite.epa.gov/sab/sabproduct.nsf/0/2BC3CD632FCC0E99852578E2006DF890/$File/EPA-SAB-11-012-unsigned.pdf
[33] http://yosemite.epa.gov/sab/sabproduct.nsf/c91996cd39a82f6485257424006901 27/2BC3CD632FCC0E99852578E2006DF890/$File/EPA-SAB-11-012_Response_09-27-2011.pdf
[34] http://www.epa.gov/hfstudy/final_epa_response_to_sab_review_table_091511.pdf
[35] Clayton Williams Energy, Conoco Phillips, EQT Production, Hogback Exploration, Laramie Energy II, MDS Energy, Noble Energy, Sand Ridge Operating, and Williams Production
[36] http://www.epa.gov/hfstudy/HF_Study__Plan_110211_FINAL_508.pdf

2011-2012: Figure B-1 provides a Gantt chart summarizing the timeline for activities leading up to the release of the EPA Study Plan and Quality Assurance Project Plan (QAPP) development. EPA began finalizing QAPPs for this study in January 2011 and is currently still posting new QAPPs as of the writing of this document.



ID	Task Name	Duration	Start	Finish
1	EPA HF Impact Study Plan	671 days	Sat 1/2/10	Thu 11/3/11
2	**EPA HF Impact Study Plan Development**	**164 days**	**Sat 1/2/10**	**Tue 6/15/10**
3	EPA ORD Initiates Planning for HF Impact Study	0 days	Sat 1/2/10	Sat 1/2/10
4	EPA Proposes HF Impact Study Scope	0 days	Mon 3/15/10	Mon 3/15/10
5	SAB Review of Proposed EPA HF Impact Study Scope	2 days	Wed 4/7/10	Thu 4/8/10
6	SAB HF Impact Study Proposed Scope Review Submitted to EPA	0 days	Tue 6/15/10	Tue 6/15/10
7	**EPA Draft HF Impact Study**	**283 days**	**Sat 5/1/10**	**Mon 2/7/11**
8	Draft HF Impact Study	238 days	Tue 6/15/10	Mon 2/7/11
9	EPA Stakeholder Webinars - State/Federal/Indian	122 days	Sat 5/1/10	Mon 8/30/10
10	EPA Stakeholder Webinars - Industry and NGOs	30 days	Tue 6/1/10	Wed 6/30/10
11	EPA Information Public Meetings - TX, CO, PA, NY	92 days	Thu 7/1/10	Thu 9/30/10
12	2010 EPA HF Information Request - 9 Companies	0 days	Thu 9/9/10	Thu 9/9/10
13	Draft HF Impact Study Report	0 days	Mon 2/7/11	Mon 2/7/11
14	**SAB Review - EPA HF Impact Study**	**178 days**	**Tue 2/8/11**	**Thu 8/4/11**
15	SAB Review - EPA HF Impact Study	178 days	Tue 2/8/11	Thu 8/4/11
16	SAB Public Meeting	2 days	Mon 3/7/11	Tue 3/8/11
17	SAB Public Meeting	0 days	Sat 3/19/11	Sat 3/19/11
18	SAB Public Meeting	0 days	Fri 3/25/11	Fri 3/25/11
19	SAB EPA HF Impact Study Report	0 days	Thu 8/4/11	Thu 8/4/11
20	**EPA Final HF Impact Study**	**92 days**	**Thu 8/4/11**	**Thu 11/3/11**
21	Final HF Impact Study	92 days	Thu 8/4/11	Thu 11/3/11
22	2011 EPA HF Information Request - 9 Companies	0 days	Thu 8/11/11	Thu 8/11/11
23	EPA Response to SAB Comments	0 days	Tue 9/27/11	Tue 9/27/11
24	Final HF Study Plan	0 days	Thu 11/3/11	Thu 11/3/11
25	**Wise County TX Retrospective Case Study**	**571 days**	**Mon 8/22/11**	**Thu 3/14/13**
26	Wise County TX QAPP	0 days	Mon 8/22/11	Mon 8/22/11
27	Wise County TX Field Sampling	14 days	Thu 9/1/11	Wed 9/14/11
28	Wise County TX Field Sampling	14 days	Thu 3/1/12	Wed 3/14/12
29	Wise County TX Field Sampling	14 days	Sun 7/1/12	Sat 7/14/12
30	Wise County TX Field Sampling	14 days	Thu 11/1/12	Wed 11/14/12
31	Wise County TX Field Sampling	14 days	Fri 3/1/13	Thu 3/14/13
32	**Raton Basin CO Retrospective Case Study**	**391 days**	**Tue 9/20/11**	**Sun 10/14/12**
33	Raton Basin CO QAPP	0 days	Tue 9/20/11	Tue 9/20/11
34	Raton Basin CO Sampling	14 days	Sat 10/1/11	Fri 10/14/11
35	Raton Basin CO Sampling	14 days	Tue 5/1/12	Mon 5/14/12
36	Raton Basin CO Sampling	14 days	Wed 8/1/12	Tue 8/14/12
37	Raton Basin CO Sampling	14 days	Mon 10/1/12	Sun 10/14/12
38	**Bradford/Susquehanna County PA Case Study**	**350 days**	**Sat 10/1/11**	**Fri 9/14/12**
39	Bradford/Susquehana County PA QAPP	0 days	Mon 10/3/11	Mon 10/3/11
40	Bradford/Susquehana County PA Sampling	14 days	Sat 10/1/11	Fri 10/14/11
41	Bradford/Susquehana County PA Sampling	14 days	Sun 4/1/12	Sat 4/14/12
42	Bradford/Susquehana County PA Sampling	14 days	Sun 7/1/12	Sat 7/14/12
43	Bradford/Susquehana County PA Sampling	14 days	Sat 9/1/12	Fri 9/14/12
44	**Washington County PA Case Study**	**442 days**	**Fri 7/1/11**	**Fri 9/14/12**
45	Washington County PA QAPP	0 days	Thu 7/21/11	Thu 7/21/11
46	Washington County PA Sampling	14 days	Fri 7/1/11	Thu 7/14/11
47	Washington County PA Sampling	14 days	Thu 3/1/12	Wed 3/14/12
48	Washington County PA Sampling	14 days	Sun 7/1/12	Sat 7/14/12
49	Washington County PA Sampling	14 days	Sat 9/1/12	Fri 9/14/12
50	**Bakken Shale ND Case Study**	**422 days**	**Mon 6/20/11**	**Tue 8/14/12**
51	Bakken Shale ND QAPP	0 days	Mon 6/20/11	Mon 6/20/11
52	Bakken Shale ND Sampling	14 days	Fri 7/1/11	Thu 7/14/11
53	Bakken Shale ND Sampling	14 days	Sat 10/1/11	Fri 10/14/11
54	Bakken Shale ND Sampling	14 days	Tue 11/1/11	Mon 11/14/11
55	Bakken Shale ND Sampling	14 days	Sun 1/1/12	Sat 1/14/12
56	Bakken Shale ND Sampling	14 days	Sun 4/1/12	Sat 4/14/12
57	Bakken Shale ND Sampling	14 days	Wed 8/1/12	Tue 8/14/12
58	**QAPP Development - EPA HF Impact Plan**	**418 days**	**Wed 1/12/11**	**Mon 3/5/12**
59	Analytical Chemistry QAPP	0 days	Wed 8/31/11	Wed 8/31/11
60	Data Collection QAPP	0 days	Thu 5/19/11	Thu 5/19/11
61	Disinfection QAPP	0 days	Thu 6/9/11	Thu 6/9/11
62	Data Organization QAPP	0 days	Wed 1/12/11	Wed 1/12/11
63	Statistical Evaluation QAPP	0 days	Thu 7/14/11	Thu 7/14/11
64	Surface Water Modeling QAPP	0 days	Tue 7/26/11	Tue 7/26/11
65	Well File Review QAPP	0 days	Wed 1/4/12	Wed 1/4/12
66	National HF Study Evaluation of Production Well Files QAPP	0 days	Mon 3/5/12	Mon 3/5/12
67	Environmental Justice Analysis QAPP	0 days	Tue 8/2/11	Tue 8/2/11
68	Health and Toxicity QAPP	0 days	Thu 2/23/12	Thu 2/23/12
69	Water Resources Modeling QAPP	0 days	Wed 2/8/12	Wed 2/8/12

Figure B-1. Timeline for Activities Leading up to the Release of the EPA Study Plan and QAPP Development

Appendix C

Overview of Science Advisory Board (SAB) Recommendations on EPA's Hydraulic Fracturing Study

The Science Advisory Board (SAB) suggested that EPA direct the study towards:

- identifying the conditions most likely to lead to impacts on drinking water resources;
- evaluating potential pathways to human and ecosystem exposure under a range of hydraulic fracturing process conditions relative to different geological formations and conditions;
- evaluating the existence and formation of hydraulic fracturing injection and product fluid transport pathways as a result of hydraulic fracturing;
- assessing the effect of hydraulic fracturing processes on water quantity;
- characterizing the composition and variability of the source fluids, flowback water and produced water that is co-mingled with the flowback water;
- assessing possible synergistic effects of mixtures of chemicals in fracturing fluids and due to interactions with materials in the fractured injection zone;
- identifying potential secondary effects associated with hydraulic fracturing such as enhanced methane transport , changes in redox conditions, mobilization of arsenic and naturally occurring radioactive materials (NORM); and
- focusing health effects research towards chemicals of potential concern that are likely to pose the greatest human health risk and have the greatest potential for possible exposure to humans and ecological receptors.

The SAB also suggested that the Agency develop a balanced, collaborative advisory group of stakeholders that could be engaged throughout the research process. The Board also recommended that EPA engage with other federal agencies to share data, collaborate, leverage expertise, and align research priorities for optimal use of limited resources. Table C-1 is summary of SAB recommendations to the draft EPA study plan, which is excerpted and paraphrased from SAB Report[37].

[37] http://yosemite.epa.gov/sab/sabproduct.nsf/c91996cd39a82f6485257424006901 27/2BC3CD632FCC0E99852578E2006DF890/$File/EPA-SAB-11-012-unsigned.pdf

Table C-1. Summary of SAB Recommendations related to EPA's Draft Study Plan

Study Component	Focus area	Summary of SAB Recommendation
Study Design	Prioritize research activities	• Use a risk assessment framework analysis (i.e., hazard identification, exposure assessment, dose-response assessment, and risk characterization) to assess and prioritize research activities for the lifecycle stages associated with hydraulic fracturing.
	Chemical contaminants	• Identify contaminants of primary concern based on an initial investigation of their usage rates, physical/chemical properties, and potential routes of human exposure. • Gather currently available information on the composition of post-fracturing produced water from the hydraulic fracturing process, and proprietary information on all additives included in any injected water. • Assess the potential of constituents in hydraulic fracturing-impacted waters to form disinfection byproducts during drinking water treatment.
	Fate and transport	• Carry out transport-and-fate studies by a combination of laboratory, field, and computer modeling experiments on contaminants of primary concern. • Assess the potential release of volatile contaminants to the air, and their potential for subsequent deposition to surface water resources. • Soil geochemistry studies may shed light on the question of vapor transport associated with the hydraulic fracturing process.
	Analytical methods	• Give a low priority to development of analytical methods for specific components for which there are no existing EPA-approved methods.
General Guidance	Data sources and use	• Set a standard for use of data and prior research information. • Use a wide variety of available data sources. • Analyze data from hydraulic fracturing service companies and states.
	Generalizing results	• Exercise caution in generalizing results across all types of hydraulic fracturing activity. • Identify or estimate the uncertainty or confidence in all research conclusions, and in the assessment of cause and effect associated with potential hydraulic fracturing impacts to drinking water supplies. • Be aware of difficulties of infer impacts of hydraulic fracturing activities based on water quality changes. • Because of the limited number of retrospective and prospective case studies, it is not likely that the data gathered can be generalized. • Impact analysis for individual chemicals should consider complete mass balances (i.e., summations of transfers to air, water, soil, and other media). • Reliance on inorganic salts as hydraulic fracturing fluid tracers will raise the question of whether hydraulic fracturing was truly the cause of any observed change in chemical composition. • The absence of a strong contaminant signal could be misinterpreted as support for the null hypothesis (i.e., that the contaminants cannot migrate to the water body), because the observation period may not be long enough to capture the time lag between the initiation of hydraulic fracturing activities and the appearance of hydraulic fracturing fluids in the water source.
	Monitoring	• Water quality evaluations might need to extend beyond the initial research period before the outcome can be established with reasonable confidence. • Long term monitoring is preferred over short term monitoring with respect to monitoring of hydraulic fracturing impacts on water resources. • Water quality data should be collected from carefully selected locations, including the ongoing studies of quality of surface waters in the regions with significant hydraulic fracturing activity.

Table C-1. Summary of SAB Recommendations related to EPA's Draft Study Plan

Study Component	Focus area	Summary of SAB Recommendation
Water	General	• Develop a "vulnerability index" or a list of criteria that could be used to indicate situations where a water supply is vulnerable to adverse impacts on water quality or quantity, and identify where further evaluation may be warranted. • Potential impacts to drinking water resources that are the result of particular management practices should be identified. • Spatial (e.g., geographic locations of wells and their proximity to nearby drinking water resources) and temporal (e.g., length of time associated with operation of hydraulic fracturing wells within a watershed) issues should be considered in assessing cumulative water quality impacts. • The Study Plan should address the cumulative consequences of multiple hydraulic fracturing operations in a single watershed or region. For example, considering the role of disturbing and revegetating many acres of land, the presence of multiple well pads on the landscape, and how these changes to the landscape in turn affect the water budget and downstream water quality. • Since groundwater can potentially be contaminated by hydraulic fracturing during well injection (including leakage from the injection wells, leak off during hydraulic fracturing along faults or up abandoned wells), the possibility of exposures through potential groundwater contamination should be assessed.
	Acquisition	• Assess the volume of water in context with the needs and availability of water to the surrounding community. • Inventory types of water being used in hydraulic fracturing to answer questions regarding how much high quality water is being used (e.g., water less than 10,000 mg/L TDS) vs. lower quality waters. • Include environmental flow requirements based on hydrological processes in the region where hydraulic fracturing is being practiced.
	Chemical mixing	• It should be noted that chemical storage and mixing in hydraulic fracturing are not obviously and fundamentally different from the corresponding activities in many other industrial settings.
	Well injection	• Identify and characterize common and best practices for well construction (e.g., casing design, construction under different scenarios, settings, failure rates, life expectancies, and performance of cements under a variety of hydraulic fracturing conditions) and monitoring, and determine whether such practices meet minimum standards from a public water supply perspective.
	Flowback and produced water	• Coal bed methane hydraulic fracturing facilities have documented best management approaches for produced waters and boundaries for use of and expectations associated with produced water quality and hazard scenarios and spills. • Use documented events to identify the potential for leaks and spills during storage and transport and to assess the probability for contaminant release during different stages of flowback and produced water management provided that trends in management practices are taken into consideration.

Table C-1. Summary of SAB Recommendations related to EPA's Draft Study Plan

Study Component	Focus area	Summary of SAB Recommendation
	Wastewater treatment	• The form and potential impacts of wastewater treatment and disposal vary significantly with local conditions and practices. EPA should explicitly identify these variations across the country to determine how the potential for reinjection varies across the country and across geological formations where hydraulic fracturing is practiced. • Use literature searches for treatment of post-fracturing produced water constituents on literature searches of municipal and industrial wastewater management practices with similar waters. • Assess whether land application of hydraulic-fracturing associated wastewaters or residuals from treatment of these waters has the potential to affect drinking water resources.
Case studies		• Use scenario modeling, in concert with both retrospective and prospective case studies, 'to define the boundaries' for activities. Narrow the scope of activities associated with specific case studies and site investigations. • Case study locations must be chosen based on reasonable, mechanistically possible contamination scenarios, incorporating uncertainty. • Case studies alone will not provide sufficient information regarding effectiveness of mitigation approaches in reducing impacts to drinking water resources.
	Retrospective studies	• In retrospective case studies there is concern that it may not be possible to obtain sufficient data to separate risks that may be associated with the various management practices employed. • The EPA retrospective studies need to assess the need for any special storage, handling, management, or disposal controls if hydraulic fracturing wastewater contaminants are collected in the POTW residuals stream. • Review the documented data to assess the efficacy and success of industrial wastewater treatment operations and pre-treatment operations for hydraulic fracturing return flows.
	Prospective studies	• The prospective case studies need clearly defined boundaries. For example, it is unclear if waste disposal will be incorporated in the case studies. • A full life cycle approach should be applied to the prospective case studies, where life cycle includes the acquisition of water through to disposal of wastewater across multiple potential options. • Develop a recommended protocol for collecting baseline hydrogeologic and water quality data in each prospective study area before hydraulic fracturing activity begins, so that significant changes in water availability or water quality caused by hydraulic fracturing activity can be more readily documented. • EPA should identify a shallow site known to have faults as one of the prospective case studies. • The partners involved in the prospective case studies will likely follow best management practices and take extra precautions, the impact of which will be difficult to assess.

Table C-1. Summary of SAB Recommendations related to EPA's Draft Study Plan

Study Component	Focus area	Summary of SAB Recommendation
Scenario Evaluation		• The scenario evaluation component of the research plan should clarify how "typical management and engineering practices in representative geological settings" will be selected for scenario generation and how system vulnerability will be incorporated into models. • Scenario modeling may be useful in developing the list of priorities for future toxicity testing. • Assess the capacity of microseismic data to provide detailed information about the extent of fracturing and to assist in the hydraulic fracturing modeling.
Toxicity studies		• The SAB strongly discourages using any of EPA's limited resources for toxicity studies of chemical constituents. • The SAB does not agree that it will be possible for EPA to collect and evaluate new data on human toxicity of hydraulic fracturing chemical additives given the cost and time constraints of the current project. • Literature sources and available databases should be used to evaluate the toxicity of selected constituents determined to have a high potential for exposure for which toxicity is unknown. • The review of existing toxicity data and of the QSARs should be used to identify chemicals for further assessment. • Low priority should be given to toxicity testing or developing Provisional Peer-Reviewed Toxicity Values (PPRTVs) if exposure to a substance is not likely and/or levels of exposure are minimal (e.g., parts per trillion).
Environmental Justice		• For the case studies, EPA should also assess demographic information, such as race, color, national origin, and income, to screen whether hydraulic fracturing disproportionately impacts some citizens near sites used for the case studies (e.g., identify whether more hydraulic fracturing wells are near communities with lower incomes). • Develop one or more focused research outcomes related to the planned research pertaining to environmental justice issues.

Appendix D

Detailed Analysis of the Quality Management Plan Prepared to Support the EPA Hydraulic Fracturing Study

Detailed Analysis of the Quality Management Plan Prepared to Support the EPA Hydraulic Fracturing Study

1.0 SUMMARY

The U.S. Environmental Protection Agency (EPA) hydraulic fractioning study plan states that "the organizational complexity of the hydraulic fracturing research effort also demands that a Quality Management Plan (QMP) be written to define the quality assurance (QA)-related policies, procedures, roles, responsibilities, and authorities for this research. The plan will document consistent QA procedures and practices that may otherwise vary between organizations" (EPA, 2011). EPA prepared a QMP "Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources" as required by EPA's quality system; Revision 1 was approved in January 2012 (EPA, 2012).

According to EPA, the hydraulic fracturing program QMP was prepared to describe the "necessary elements to plan, implement, document, and assess the effectiveness of QA and quality control (QC) under the Hydraulic Fracturing Research Program." The QMP follows a standard format which includes the 10 elements specified in EPA/QA R-2 (EPA, 2001), and is typically reviewed using the EPA checklist for QMPs. This checklist was used to conduct the QMP review presented in this section. Based on Battelle's review of the document, the QMP contains both general and specific data gaps. This appendix summarizes the positives attributes, major gaps, and recommendations for improvements identified during the review.

2.0 CONFORMANCE WITH REQUIREMENTS

- The QMP provides a good description of the roles and responsibilities of QA and technical personnel for implementing the QMP.
- The description of communication paths and meeting schedules between the Contracting Officer Representative (COR) and the Project QA Manager (PQAM) and between the PQAM and Office of Research and Development (ORD) Laboratories, Centers, and Offices (L/C/O) QAMs is detailed. However, a description of communication paths among technical participants is incomplete; this is discussed further in Section 3.0.
- The procurement and review process for interagency and extramural agreements is complete and well organized.
- The QMP clearly defines requirements for the storage of documents and records on a public drive which can be accessed by all approved participants, regardless of location. The QMP establishes permissions for documents, naming conventions, e-mail management, and file sharing. Guidance is provided on folder naming conventions and file naming conventions.
- The assessment section is detailed and provides good descriptions of assessment roles and responsibilities.

3.0 BIG-PICTURE DATA GAPS

The QMP Revision 1 was approved and posted on the EPA Web site in January 2012. This posting was made after development of most of the Quality Assurance Project Plans (QAPPs), although it is recognized that the original document (Revision 0) may have been completed, but not posted, by December 2011. The significance of this gap is that the QMP defines the quality system requirements for the program and each QAPP relies on the QMP to describe how the quality system will be implemented for specific projects in the program.

Overall, the QMP for the hydraulic fracturing research program does not provide sufficient guidance to ensure that all projects conducted for the hydraulic fracturing program are conducted in a comprehensive, consistent, and coordinated manner which supports the study objectives, although this is specifically recognized as an essential requirement by the EPA hydraulic fracturing study plan. The EPA QMP checklist identifies 73 quality system elements to be addressed by each QMP. The checklist examines these elements using 106 detailed questions to determine if the QMP meets the requirements of EPA/QA R-2 (EPA, 2001). Based on this checklist, approximately 40% of the quality system elements were completely addressed in the QMP, 40% were partially addressed, and 20% were not addressed. Areas where the QMP is incomplete may lead to confusion, communication gaps, and lack of consistency among study participants.

The following issues specific to the hydraulic fracturing program QMP are identified:

- The QMP does not describe the coordination, roles, and communication paths for extramural participants such as Department of Energy (DOE), U.S. Geological Survey (USGS), state regulators, EPA labs, EPA Regions and does not clearly delineate the communication and accountability between the Writing Theme Leads and the Technical Research Leads. The organization charts presented in Figures 3 and 4 are complex and it appears that there is no direct relationship between the principle investigators and the Writing Theme Leads. The QMP specifies, however, that the Technical Research Leads will review products within their research areas (Figure D-1).
- The intended use of data and products generated for the hydraulic fracturing program is not described consistently in the QMP. The QMP states that EPA does not consider the 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. However, the QMP later states that all hydraulic fracturing projects are classified as Category I, indicating research that directly or immediately supports specific Agency rule-making, enforcement, regulatory, or policy decisions or research of significant national interest, such as tasks that might be monitored by the Administrator (Table D-1). Although neither the EPA Study Plan nor Science Advisory Board specifically mentions the Office of Management and Budget "Data Quality Act" (OMB, 2002), it appears that the EPA hydraulic fracturing program will result in reports that could disseminate influential scientific information. The QMP does not provide guidance on how study transparency will be achieved and indicates that only the 2012 and 2014 reports will receive external peer review. All other reports will receive at least an internal peer review. The internal review process and independence of reviewers is not defined.
- The QMP does not serve as the overarching quality system document that establishes policies and minimum requirements for all project activities.

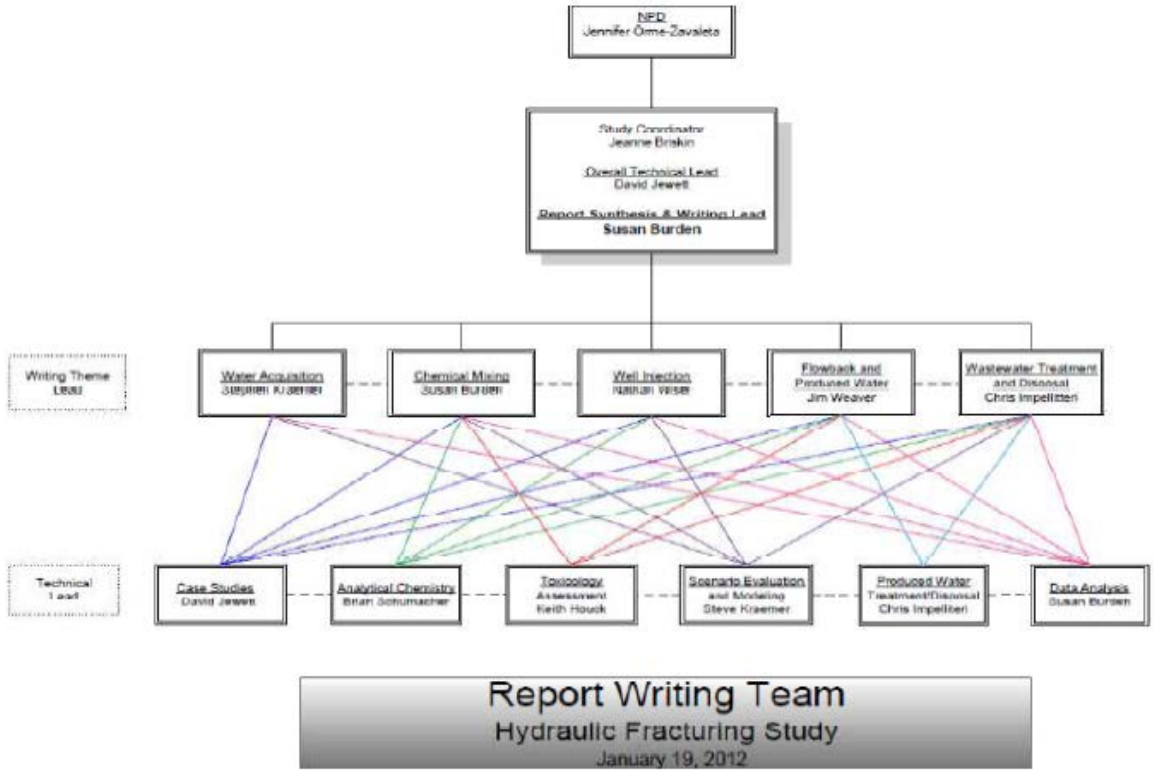


Figure D-1. Depiction of the Hydraulic Fracturing Study Report Writing Team and Chain of Command (from Figure 4 in EPA QMP)

Table D-1. Overview of EPA Quality Categories (adapted from EPA Web site[38, 39])

Category	QAPP Preparation Requirements	Technical Systems Audit	Data Quality Audits	Records Retention
I	EPA QA/R-5[40]	Required for every project	50% of data sets	Permanent
II	EPA QA/R-5	Required for every project	25% of data sets	Permanent
III	Laboratory Specific	Required for two projects per year	Not required	20 years
IV	Laboratory Specific	Required for two projects per year	Not required	20 years

- The QMP should establish the QA document hierarchy by defining the inter-relationships of QAPPs (e.g., a QAPP describing analytical chemistry procedures and QA/QC requirements has been developed, as have QAPPs for the retrospective case studies). It is

[38] http://www.epa.gov/quality/
[39] http://www.epa.gov/nrmrl/qa/chapter2.html#2_1
[40] http://www.epa.gov/quality/qs-docs/r5-final.pdf

not clear if the analytical chemistry QAPP requirements are applicable to the case study QAPP activities.

  - The hydraulic fracturing program relies heavily on ORD L/C/Os and extramural organizations for technical support. The QMP frequently states that work within these organizations will follow their internal QMPs. Since the requirements of these documents may vary, depending on the type of work and intended use of data, the QMP should establish minimum requirements. The QMP does not indicate that L/C/O QMPs will be reviewed to determine adequacy for the hydraulic fracturing program and whether the internal procedures for these organizations will support Category 1 data.

- The QMP states that systematic planning should be used in project development but does not describe the systematic planning process to be implemented for environmental data operations. Although the QMP references EPA QA/R-5 for development of QAPPs and EPA QA/G-4 for systematic planning, it does not provide guidance for use of the data quality objective (DQO) process, which is EPA's recommended planning approach for many EPA data collection activities. It does not describe how the need for, type of, and quantity and quality of data will be determined nor state that QAPPs will be developed as an outcome of the systematic planning process.
- The QMP does not discuss the hydraulic fracturing program technical activities (e.g., case studies, modeling, sampling, data management) and does not define the technical activities that require quality management. While a well-developed QAPP will include the quality management requirements for specific project activities, the QMP should define the application of the quality system to the anticipated technical activities.
- The QMP does not provide guidance for determining the usability of existing (i.e., secondary) data. Because existing data will be used for most hydraulic fracturing projects, a consistent process should be established to ensure that data are of known and documented quality.
- The QMP states that objectives for each project must be clearly identified as primary (critical to meeting the goals of the research activity) or secondary (ancillary to the primary objectives) but does not discuss the process of developing and documenting project goals, objectives, questions, and issues. It also does not describe how individual project objectives must be tied to the overall hydraulic fracturing program objectives defined in the EPA study plan.
- The QMP assigns significant responsibility to the PQAM to coordinate QA activities, train program participants in QMP requirements, and act as a liaison with L/C/Os QAMs and Division QA Managers. However, the QMP does not define any PQAM authority.
- The QMP does not conform to the requirements for a controlled document (EPA QA/R-5). The first eight pages of the document are not paginated, there is no control header block identifying the document version number, and the total number of pages is not defined.
- Several standard quality system elements are not addressed in the QMP. Among them, the QMP does not:
  - describe requirements for controlled document review and approval;
  - state that training and qualifications must be documented and where the records will be maintained; and
  - define minimum chain of custody requirements.
- The QMP relies heavily on the EPA QA Review Form (QARF) to ensure that the appropriate level of quality is incorporated into interagency and extramural agreements. However, the

QARF is a general form. The QMP should define the minimum QA elements that must be incorporated into each statement of work (SOW).

- The QMP does not identify the process for identifying quality-related documents and records; preparing, reviewing, approving, issuing, using, authenticating, and revising documents and records; or ensuring that records and documents accurately reflect completed work. Further, the QMP does not define who is responsible for maintenance of project records.
- The QMP states that audits of data quality (ADQs) will be conducted on a representative sample of each critical measurement. However, the ORD QMP specifies that ADQs should be conducted on 50% of Category 1 data.
- The QMP cites and provides links to numerous EPA guidance documents and standards. The links may not be usable for extramural organization and stakeholders. Further, the QMP does not state that all project personnel should be familiar with and trained in these procedures.

Table D-2 contains detailed QMP-specific comments.

4.0: RECOMMENDATIONS FOR IMPROVEMENT

The QMP should establish minimum requirements for each element of the quality system to ensure that the data generated for the program are comparable and of adequate quality to achieve the objectives. In addition, the QMP should describe the process that should be used to implement the quality system elements. The hydraulic fracturing program will be implemented by several interagency and extramural agreements. Independent technical systems audits of each organization should be conducted by the PQAM and/or by the ORG Director of QA.

Table D-2 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

5.0: REFERENCES

U.S. EPA, 2001. EPA Requirements for Quality Management Plans. EPA QA/R-2. EPA/240/B-01/002. U.S. Environmental Protection Agency, Office of Environmental Information, Washington, D.C. March 2001.

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

U.S. EPA, 2012. Quality Management Plan Revision No. 1 Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources. US Environmental Protection Agency. Office of Science Policy.

U.S. OMB, 2002. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies. Part IX. Office of Management and Budget. February 22, 2002.

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources[41]

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
MANAGEMENT AND ORGANIZATION	1-14	1			
1. Signed and dated by senior manager?	Cover Page	N/A	Y	The QMP has been signed by the hydraulic fracturing program Study Coordinator and Overall Technical Research Lead; Director, Office of Science Policy/Study Coordinator Supervisor; and the National Program Director.	Note that Revision 1 was approved in January 2012, after the majority of QAPPs had been developed and approved.
2. Signed and dated by senior line management?	Cover Page	N/A	Y	The QMP has been signed by the Overall Technical Research Lead Supervisor; Director, Office of Science Policy/Study Coordinator Supervisor; and National Program Director.	
3. Signed and dated QA manager?	Cover Page	N/A	P	The QMP is signed and dated by the PQAM.	EPA QA/R-2 Section 3.2 states that the "QA Manager" and "Director of Quality Staff" should sign the QMP. The QMP is signed by the PQAM but not the Director of Quality Staff.
4. Includes signature lines for Quality Staff approval?	Cover Page	N/A	N		With the exception of the PQAM, no Quality Staff have signed the document. It would be appropriate for the ORD DQA to sign the document.
5. Includes signature lines for OEI approval?	Cover Page	N/A	N		No signature line is included for OEI approval. EPA QA/R-2 requires OEI approval on all QAPPs.

[41] This checklist is based on EPAQA/R-2 (2001). Final Checklist: QMP Reviews Revision No.: 2. September 28, 2001. EPA Checklist for Reviewing Quality Management Plans

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
5. Includes signature lines for OEI approval? (Continued)					
6. Includes statement of the organization's QA policy?	3	1.2	Y	Defines five overarching policies that require all EPA L/C/O to develop QA procedures.	
6a. QA policy statement includes general objectives/goals?	3	1.2	P	EPA has provided the overarching EPA objectives and goals through reference to four EPA headquarter-level documents.	Hydraulic fracturing study specific quality objectives and goals are not defined and may result in inconsistent products given the broadness of the statements. The QMP does not discuss the process of developing and documenting project goals, objectives, questions, and issues. It also does not describe how individual QAPP objectives must be tied to the overall hydraulic fracturing program objectives defined in the EPA study plan.
6b. QA policy statement includes allocation of intramural, extramural, and travel funds and personnel?	3	1.2	N		The text of the QMP identifies intramural and extramural organization but does not address the allocation of intramural, extramural, and travel funds.

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
7. Includes organizational chart?	9-10	1.7	Y	The QMP provides two organizational charts, one for the hydraulic fracturing Study Research Team and one for the Report Writing Team.	The parallel structures of the two organization charts create confusion. Due to the number and relationship of technical areas used to develop each of the report themes, the chart lattice is difficult to follow. In addition, figures do not identify the role and communication paths for extramural participants such as DOE, USGS, state regulators, EPA labs, EPA Regions, etc.
7a. Organizational chart identifies all components of organization?	9-10	1.7	P	The organizational chart appears to identify key technical and QA staff for all aspects of the project and their inter-relationships.	The organizational charts do not list personnel affiliations. As currently written, is it is not possible to determine which L/C/Os are involved in which aspects of the study.
7b. Organizational Chart identifies position of QA manager?	9-10	1.7	Y	The QMP shows the PQAM as independent of technical activities, reporting to the ORD DQA with direct access to the Study Coordinator.	
7c. Organizational Chart identifies lines of reporting of the QA manager?	9-10	1.7	Y	The organizational chart shows the PQAM reporting to both the research team (Study Coordinator and Overall Technical Research Lead) and the ORD Director of QA.	
7d. Organization Chart identifies any other QA staff?	9-10	1.7	Y	The organizational chart identifies several QAM/DQA personnel.	Note that because organizational affiliations are not defined, it is hard to determine if all L/C/Os are represented in the organizational chart.
8. Includes discussion of authorities of the QA manager and staff?	8-14	1.7	N	QMP Table 1 defines responsibilities but not authorities for the QA manager and staff.	QA manager and staff authorities are not defined.
9. Documents the independence of QA manager?	1-14	1	Y	The QMP organizational chart illustrates the independent reporting of the PQAM and states that assessments are independent.	Although illustrated in the organizational chart, the QMP does not specifically state that the PQAM is independent of the technical work.

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
10. Describes procedures to ensure QA staff has access to appropriate levels of management?	1-14	1	Y	L/C/O QAMs report assessment activities to the PQAM and management within their respective organizations (Section 1.7 and Table 2).	
11. Discusses technical activities or programs that require quality management?	4-5	1.4	N	The QMP defines programmatic requirements for quality management, review of products, and assessments.	The QMP does not discuss technical activities specific to the hydraulic fracturing study (e.g., case studies, modeling, sampling, data management) that require quality management. A well-developed QAPP will include the quality management requirements for specific project activities. However, the QMP does not establish linkage between the hydraulic fracturing program QAPPs (e.g., the QMP does not state that all analytical chemistry will follow the chemistry QAPP requirements and that QAPP is not cited in any of the case study QAPPs). Therefore, it does not appear that the hydraulic fracturing program has a cohesive quality system that is applied to all aspects of the program, particularly because the requirements and procedures in L/C/O QMPs may differ.
12. Discusses where oversight of delegated or extramural programs is needed?	4	1.3	Y	The PQAM reviews QARFs for extramural and contracted activities. EPA will audit contractors performing analysis of critical target analytes. L/C/O QAMs will audit their own organizations and report results to the PQAM.	The QMP does not define specific assignments for extramural and contracted activities. It does not define standards that will ensure that QA and QC procedures will be coordinated for data consistency.

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
13. Identifies where internal coordination of QA and QC activities among organizations is needed?	4-5	1.4	P	The QMP defines the reporting relationship between the PQAM and L/C/O QAMs.	The internal review process and independence of reviewers is not defined.
14. Discusses how management assures understanding and implementation in all programs?	8-14	1.7	P	The Program QA Manager is responsible for distribution of the QMP. The PQAM and L/C/O QA staff assists implementation within their organizations. Implementation of the hydraulic fracturing QMP is specifically identified as a responsibility for most technical management and staff positions listed in Section 1.7 of the QMP.	The QMP does not describe assessment of the hydraulic fracturing QMP requirements vs. the L/C/O QMP requirements to ensure that technical staff is aware of hydraulic fracturing QMP requirements 'over and above' or different than their standard practice.
15. Describes process for resolving disputes?	6	1.6	Y	The QMP defines the hierarchy for dispute resolution and presents a good philosophy that disputes are resolved at the lowest possible management level before being elevated. There are seven different dispute levels noted.	
QUALITY SYSTEM COMPONENTS	15-17	2			
16. Includes description of quality system?	15	2.1	Y	The QMP identifies the hydraulic fracturing program as an ORD Category 1 Program and describes the quality system.	
17. Describes principal quality system components (e.g., quality system documentation, annual reviews and planning, project- specific quality documentation?	15-16	2.1-2.2	Y	The quality system components are defined as the hydraulic fracturing study plan, QMP, QAPPs, systematic planning QA reviews of extramural activities, communication and training, and assessments. The responsibilities of the key investigators for development of the QAPP are specified. The PQAM is responsible for reviewing consolidated products with assistance from the L/C/O QAMs, who review products produced within their organizations.	There is no distinction between quality system components and tools. An internal standard operating procedure (SOP) is referenced as an example of the QA review process for technical products. The QMP should state that all L/C/O QAMs will use equivalent review procedures.

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
18. Description of components includes how they are implemented?	16	2.3	Y	The QMP references Sections 3, 4, 7, and 9 for details on implementation of quality system components. Section 2.3.1 provides a list of routine communications that will occur on a bi-weekly, monthly, quarterly, and "as needed" basis.	
19. Description of components includes responsibilities of management and staff?	16	2.3	P	Responsibilities for management are defined in Section 2.0 and referenced in Sections 3, 4, 7, and 9.	The QMP should specifically state the responsibility of technical staff to implement the quality system requirements defined in the hydraulic fracturing program QMP.
20. Lists tools for implementing each component (e.g., QMPs, Quality Systems Audits, Training Plans, and QA Project Plans?	17	2.4	Y	The QMP tools include training by the PQAM, QA and peer assessments, references to quality system components are defined as the hydraulic fracturing study plan, QMP, QAPPs, systematic planning QA reviews of extramural activities, communication and training, and assessments.	
21. Identifies internal organizations that develop QMPs?	15-17	2	Y	Throughout the QMP, EPA notes that L/C/Os have and must follow their own QMPs.	The individual L/C/O QMPs are not referenced or linked within the document.
22. Identifies review and approval procedures for these internal QMPs?	15-17	2	N		The QMP does not include information on the review and approval procedures for the internal QMPs.
23. Includes assurance that QA responsibility is incorporated into performance standards (consistent with Agency personnel policy)?	15-17	2	N		The QMP does not specify how roles and responsibilities for the principal components of the quality system are incorporated into performance standards.
QUALIFICATIONS AND TRAINING	17-18	3			
24. States policy regarding QA training for management and staff?	17-18	3	Y	The QMP states that all research and QA staff have appropriate qualifications and training to meet their assigned responsibilities.	

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
25. Describes process for identifying, ensuring, and documenting that personnel have necessary quality-related qualifications?			P	Line managers within each organization are responsible to identify key work functions that require special skills and establish procedures to ensure demonstrated proficiency. QAPPs identify specialized training requirements. Key investigators identify the need for CBI training. L/C/O QA staff identifies the need for QA-related training.	The QMP does not specify that training and qualifications be documented and does not identify where such records should be stored. Without documentation, ensuring qualifications cannot be traced.
26. Describes process for ensuring personnel maintain quality-related qualifications?	17-18	3	N		The QMP does not describe a process to ensure that qualifications are maintained (i.e., current).
27. Describes process for identifying the need for quality-related retraining based on changing requirements?	17-18	3	P	Personnel retraining in QA-related requirements is accomplished through periodic QA teleconferences and the distribution of QA-related material.	The QMP does not define the participants of the teleconferences; the effectiveness of QA training is directly related to the communication of information to all study participants. It also does not describe a process to ensure that personnel are retraining in technical procedures as requirements change (e.g., QAPPs are updated).
28. Includes roles, responsibilities, and authorities in description of above processes?	17-18	3	Y	The PQAM, L/C/O QAMs, Line Managers, and Study Coordinator are responsible for ensuring staff qualifications and training. The QMP defines the authority of Line Management to appoint key staff.	
PROCUREMENT OF ITEMS AND SERVICES	19-21	4			
29. Describes process for reviewing and approving all extramural agreements (grants, cooperative agreements and contracts)?	19-21	4	Y	QA requirements and responsibilities for extramural and interagency agreement are defined by the COR in SOWs and ORD QARF and approved by Division QAMs. The PQAM reviews QARFs for consistency with the hydraulic fracturing program requirements.	

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
29a. Review process ensures documents are complete and accurate?	19-21	4	Y	The review process for procurement documents is complete and includes QA review by both the COR QAM and the PQAM.	The QARF is a general document. The QMP should define minimum QA elements that should be defined in Interagency Agreement (IA) and extramural requirements to ensure consistency.
29b. Review process ensures agreement clearly describes the item or service needed?	19-21	4	P	The QMP states that QA requirements; documents and records that must be submitted to EPA; and QA responsibilities must be in the QARF and/or SOW. The QMP states that the COR will prepare contracts, SOWs and IAs and that the QAMs and PQAM will review them.	The QMP does not specify whether the review verifies that items and services are clearly described. Rather, the QA review appears geared more toward addressing QA requirements.
29c. Review process ensures agreement describes the associated technical and quality requirements?	19-21	4	N		The elements included in the review of extramural, IAs, and contracts are not defined.
29d. Review process ensures agreement describes the quality system elements for which the supplier is responsible?	19-21	4	Y	The QARF defines required quality elements. QARFs are reviewed by a QAM and/or PQAM.	
29e. Review process ensures that the supplier's conformance to the customer's requirements will be verified?	19-21	4	Y	The QMP states that work conducted under an IA will be audited by EPA and that contractors must have independent QA personnel to verify compliance with the QAPP. QA staff at EPA L/C/Os will conduct internal audits for conformance to QAPP requirements. An annual quality system audit will assess compliance with the hydraulic fracturing program QMP.	

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
30. Describes process for reviewing and approving applicable responses to solicitations to ensure that they satisfy all technical and quality requirements?	19-21	4	N		The QMP does not describe a process to review and approve responses to solicitations.
30a. Review process ensures the review of evidence of the supplier's capability to satisfy EPA quality requirements?	19-21	4	P	The QARF defines supplier quality requirements via submission of quality documents (QMPs, QAPPs).	The QMP does not indicate that QMPs for participating organizations, whether through internal standards, extramural agreement, or contract, will be reviewed to ensure they are adequate and consistent with hydraulic fracturing program QA requirements.
30b. Review process ensures procured items and services are acceptable?	19-21	4	P	The key investigator is responsible to verify that supply meet requirements. The QMP states that procurement of items and services are described in each L/C/O QMP.	The QMP does not specifically state that supplies should be inspected to ensure that they meet quality requirements, are in good condition, and operate as intended. It does not provide overall guidance for the review process to ensure consistency.
31. Describes process for review and approval of suppliers' quality-related documentation (e.g., QAPPs and QMPs)?	19-21	4	P	The PQAM reviews and approves all QAPPs developed for the hydraulic fracturing program.	The QMP does not describe a process for reviewing and approving the QMP to ensure consistency with the hydraulic fracturing program.
32. Includes discussion of any policy and criteria for delegations of review of QAPPs and QMPs?	19-21	4	P	Under the roles and responsibilities section of the QMP, EPA has listed responsibilities for QAPP review (e.g., PQAM and Technical Research Leads).	The QMP does not discuss delegation of review for QAPPs and QMPs.
33. Describes process to ensure EPA extramural agreement policies satisfied?	19-21	4	Y	The QAM reviews the SOW and QARF for extramural agreements to ensure the QA requirements meet these hydraulic fracturing research program's requirements.	The QARF is a general document. The adequacy of this process is dependent on the level of detail included in the SOW.

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
34. Includes roles, responsibilities, and authorities in description of above processes?	19-21	4	Y	The COR, key investigators, L/C/O QAMs and PQAMs are responsible for implementing the procurement process. The PQAM provides SOW and QARF review comments which must be addressed by the COR.	
DOCUMENTS AND RECORDS	22-28	5			
35. Describes process for identifying quality-related documents and records (including electronic) requiring control?	22-28	5	N		The QMP is not formatted as a controlled document with version number and effective date. The document is not continuously paginated and does not include the total number of pages. The first eight (8) pages of the document are not paginated or dated at all, thus not tied to the main text. The QMP does not currently identify the process for identifying quality-related documents and records; preparing, reviewing, approving, issuing, using, authenticating, and revising documents and records; or ensuring that records and documents accurately reflect completed work.
36. Describes process for preparing, reviewing, approving, issuing, using, authenticating, and revising documents and records?	22-28	5	P	The QMP describes the requirements for review and revision of one type of document - SOP.	The QMP does not define the review and revision process for the QMP or QAPPs.

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
37. Describes process for ensuring that records and documents accurately reflect completed work?	22-28	5	P	Self, QA and peer reviews are defined for QA documents and products/reports.	The QMP does not define a process for technical or one-over-one review of raw data, laboratory record books, bench sheets, etc.
38. Describes process for maintaining documents and records including transmittal, distribution, retention, access, preservation, traceability, retrieval, removal of obsolete documentation, and disposition?	22-28	5	P	The section provides good guidance for the storage of documents and records on the O drive, establishing permissions for documents, naming conventions, e-mail and management, and file sharing. Guidance is provided on folder naming conventions and file naming conventions.	The documents and records section of the QMP uses words like "suggest" and "example" indicating guidance rather than requirements. In addition, the QMP talks about researchers using their "My Documents" for storing electronic files (e.g., during initial data analyses) which could result in misplaced and lost files if not transferred to the specified O Drive; the QMP does not establish when in the analysis life cycle files should be transferred or how frequently.
39. Describes process for establishing and implementing appropriate chain of custody and confidentiality procedures for evidentiary records?	22-28	5	P	The QMP specifies that staff will receive training in, and implement TSCA CBI procedures (Sections 3.0 and 5.5, respectively).	The QMP does not describe the process for establishing and implementing appropriate chain of custody and confidentiality procedures for evidentiary records.
40. Above processes comply with EPA Order 2160 and EPA Directive 2100, Chapter 10?	22-28	5	Y	(These references appear to be obsolete). However, the document cites the guidance of EPA Directive 2100B8 (Information Resources Management Policy) and EPA CIO 2104.0 (Software Management and Piracy Policy).	Training in the requirements of these methods should be specifically required.
41. Includes roles, responsibilities, and authorities in description of above processes?	22-28	5	N	The Study Coordinator maintains a record of O drive permissions.	The QMP does not describe the roles, responsibilities and authorities to ensure the proper handling of documents and records.

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
COMPUTER HARDWARE AND SOFTWARE	29	6			
42. Describes process for developing, installing, testing, using, maintaining, controlling, and documenting computer hardware and software? 43. Describes process for assessing and documenting the impact of changes to user requirements and/or the hardware and software on performance? 44. Describes process for evaluating purchased hardware and software?	29	6	P	The QMP states that EPA OEI published guidance, including EPA Directive 2100B8 (Information Resources Management Policy) and EPA CIO 2104.0 (Software Management and Piracy Policy) will be generally followed by the EPA ORD participating L/C/Os. The key investigators are assigned the responsibility of interpreting and adhering to these standards for the work conducted by their L/C/O.	The QMP does not discuss a process for developing, installing, testing, using, maintaining, controlling, and documenting computer hardware and software; assessing and documenting the impact of changes to user requirements and/or the hardware and software on performance; or evaluating purchased hardware and software. In addition, the QMP does not discuss requirements for model calibration or verification testing. Because the QMP does not describe how EPA requirements will be implemented, training in the requirements should be included in Section 3.0.

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
45. Describes process for ensuring that data and information produced from or collected by computers meet applicable requirements and standards?	29	6	P	The QMP states "Projects that entail modeling, existing data, and require significant databases should specify computer hardware and software requirements in the associated QAPP."	The QMP does not describe how computer output, including model output, will be assessed to ensure that requirements and standards are met. Use of standard software versions should be identified to ensure that information from various reports can be merged into the final reports. The QMP does not define any hydraulic fracturing research program wide hardware or software. It is not clear who would determine the need and how the need would be established and communicated. The QMP should specify that QAPP define specific hardware and software need to avoid inconsistent and incompatible uses of software by L/C/O staff or subcontractors.
46. Includes roles, responsibilities, and authorities in description of above processes?			Y	The QMP states that the Study Coordinator (or designee) is responsible for ensuring that any hydraulic fracturing research program wide hardware or software adheres to Agency information management standards.	
47. Are the requirements of EPA Directive 2100 are addressed in the above processes?	29	6	P	The QMP references EPA Directive 2100B8 Information Resources Management Policy; however, no other "requirements" or processes are discussed.	The QMP does not describe how the requirements of EPA Directive 2100 will be implemented for the program.

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
PLANNING	30	7			
48. Includes a description of the systematic planning process for environmental data operations?	30	7	N	States that all hydraulic fracturing program work must follow the minimum QAPP requirements of EPA QA/R-5.	The QMP does not describe the systematic planning process to be implemented for environmental data operations. Although it references EPA QA/R-5, it does not reference the DQO process, which is EPA's recommended planning approach for many EPA data collection activities. A discrepancy is also noted between Section 7.0, which states that EPA G-5M "must" be followed for modeling QAPPs, and Section 8.0k, which states that EPA G-5M "should" be followed.
48a. Does process include identification and involvement of all customers and suppliers?	30	7	N		The involvement of stakeholders in the planning process is not mentioned.
48b. Does process include description of the project goal, objectives, and questions and issues to be addressed?	1	1.1	P	The QMP identifies the overall study purpose and the questions and issues to be addressed. The planning section (7.0) states that objectives for each project must be clearly identified as primary or secondary.	The QMP does not discuss the process of developing and documenting project goals, objectives, questions, and issues. It also does not describe how individual project objectives should be tied to the overall hydraulic fracturing program objectives. The QMP quality objectives should be tied to the study plan objectives. Individual QAPP objectives should be tied to the overall study objectives. .
48c. Does process include identification of project schedule, resources, milestones, and any applicable requirements?	30	7	N		The QMP planning process does not mention the inclusion of schedules, resources, milestones or requirements.

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
48d. Does process include identification of the type and quantity of data needed and how the data will be used to support the project's objectives?	30	7	N	The QMP specifies that measurements to support primary and secondary objectives must be classified as critical or non-critical, respectively: 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 that supports the primary objective. Data to support primary objectives are classified as critical; data to support secondary objectives are classified as non-critical.	The QMP does not describe how the need for, type, and quantity of data will be determined.
48e. Does process include specification of performance criteria for measuring quality?	30	7	Y	The QMP states that acceptance or performance criteria for data should be determined and documented in the QAPP.	
48f. Does process include specification of needed QA and QC activities to assess the quality performance criteria?	30	7	N	The QMP states that the hydraulic fracturing research program is a Category 1 effort.	The QMP does not mention how the need for QA/QC activities will be determined during the planning process.
48g. Does process include description of how, when, and where the data will be obtained (including existing data) and identification of any constraints on data collection?	30	7	P	Constraints of existing data are insinuated through application of acceptance or performance criteria defined in QAPPs.	The planning process does not discuss data acquisition procedures.
48h. Does process include description of how the acquired data will be analyzed, evaluated, and assessed against its intended use and the quality performance criteria?	30	7	P	The QMP planning process requires that data acceptance criteria be defined in QAPPs.	The QMP planning process does not discuss how data will be assessed for usability based on the criteria.

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
49. Describes process for developing, reviewing, approving, implementing, and revising QA Project Plans?	30	7	P	The QMP references EPA guidance documents (QA/R-5, QA/G-5M, etc) for developing QAPPs. The review, approval, implementation, and revision process is discussed in Section 2.1.	The QMP does not present a process by which QAPPs are developed as an outcome of a systematic planning process (i.e., DQO process).
50. Describes process for evaluating and qualifying data collected for other purposes or from other sources?	30	7	P	The QMP states that individual QAPPs should define required data quality for existing data and the acceptance criteria.	The process for evaluating and qualifying existing data is not described.
51. Includes roles, responsibilities, and authorities in description of above processes?	30	7	P	The QMP provides information on the roles and responsibilities for SOP development in cases where SOPs do not already exist.	The QMP does not define who is responsible for implementing the systematic planning process and guiding QAPP development.
IMPLEMENTATION OF WORK PROCESSES	31-32	8			
52. Describes process for ensuring that work is performed according to planning and technical documents?	31-32	8	Y	Project work requirements are established to implement the QMP. Defining requirements establishes the process.	
53. Describes process for identifying operations needing procedures?	31-32	8	Y	Section 7 defines the process for determining when a SOP is required.	
54. Describes process for preparation, review, approval, revision, and withdrawal of these procedures?	31-32	8	P	Section 7 defines the process for SOP preparation, review, and approval. Section 8 describes when a revision is required and specifies that a documented SOP review should be conducted annually.	The QMP does not describe the process for withdrawing SOPs and for ensuring that staff has the most current SOP version. However, this process may be described in the L/C/O QMPs.
55. Describes policy for use of these procedures?	31-32	8	Y	The QMP requires adherence to all planning and procedural documents, including SOPs.	

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
56. Describes process for controlling and documenting the release, change, and use of planned procedures?	31-32	8	P	Section 7 states that SOPs will be developed and reviewed according to L/C/O QMPs.	The QMP does not discuss document control procedures for SOPs, including the importance of ensuring that staff has the current version of approved SOPs.
56a. Process includes description of necessary approvals?	31-32	8	N	Section 7 states that SOPs will be developed and reviewed according to L/C/O QMPs.	The QMP does not define a SOP review and approval process.
56b. Process includes removal of obsolete documentation from work areas?	31-32	8	N		The QMP does not discuss document control procedures, including the removal of obsolete documents from work areas.
56c. Process includes verification that the changes are made as prescribed?	31-32	8	N		The QMP does not discuss procedures for ensuring that changes in revised SOPs are implemented as described.
57. Includes roles, responsibilities, and authorities in description of above process?	31-32	8	P	The key investigator or COR is responsible for ensuring that projects are implemented according to hydraulic fracturing program requirements, that QC checks are conducted and are acceptable, and that staff are qualified for and informed about their assignments.	The QMP states that ORD staff is responsible for complying with ORD policies for paper records (13.2) and QA/QC practices (13.4). However, it does not specify that non-ORD organizations must establish and implement procedures consistent with ORD requirements.
ASSESSMENT AND RESPONSE	33-36	9			
58. Describes the process for assessing the adequacy of the quality system at least annually?	33-36	9	P	The QMP specifies that an independent quality system audit will be conducted by the ORD Director of QA within one year of QMP approval.	The QMP does not specify whether the Quality System Audit (QSA) will extend to IA, extramural, and contract organizations.

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
59. Describes the process for planning, implementing and documenting assessments and reporting results to management?	33-36	9	Y	The QMP defines the types of independent assessments to be conducted, responsibility, frequency, and who will receive the assessment reports.	The results of assessments are reported to hydraulic fracturing program managers but not to the organization line manager. The QMP states that ADQs will be conducted on a representative sample of each critical measurement. However, the ORD QMP specifies that ADQs should be conducted on 50% of Category 1 data.
59a. Process includes selecting an assessment tool, the expected frequency, and the roles and responsibilities of assessors?	33-36	9	Y	Table 2 defines assessment tools, frequencies, roles and responsibilities.	
59b. Process includes determining the level of competence, experience and training needed for assessment personnel?	33-36	9	N		The QMP does not define the qualifications of QA staff and assessment personnel.
59c. Process includes ensuring that personnel have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed?	33-36	9	Y	Sections 1.7 and 2.4 of the QMP state that L/C/O QAMs will ensure that audits are conducted by people that do not have a conflict of interest, and have no direct involvement or responsibility for the work being assessed	

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
59d. Process includes ensuring that personnel conducting assessments have sufficient authority, access to programs and managers, access to documents and records, and organizational freedom?	33-36	9	N	The QMP defines auditor access to management (Table 2).	The QMP does not outline the authorities of the auditors. Auditors are to contact the key investigators when a problem is identified and the key investigators will determine whether work is stopped.
60. Describes process for management's review of, and response to, findings?	33-36	9	P	A footnote to Table 2 states that supervisors will receive a copy of the reports.	The QMP does not outline a process for management's review of, and response to, findings.
61. Describes process for identifying how and when corrective actions are to be taken in response to the findings of the assessment?	33-36	9	P	The QMP describes responsibilities for corrective action in response to QSAs and technical systems audits but not for other assessments.	The QMP does not describe a corrective action process in response to assessment findings.
61a. Process includes ensuring corrective actions are made promptly?	33-36	9	N		The QMP does not define a time line for identifying and implementing corrective actions.
61b. Process includes confirming the implementation and effectiveness of any corrective action?	33-36	9	P	The PQAM is responsible for tracking corrective actions for TSA findings across the program.	The QMP does not discuss verification that corrective actions have been implemented effectively.
61c. Process includes documenting actions?	33-36	9	P	The PQAM is responsible for tracking corrective actions for TSA findings across the program as reported by L/C/O/ QAMs.	The QMP does not discuss documentation of corrective actions.
62. Describes process for addressing disputes encountered as a result of assessments?	6	1.6	P	The QMP outlines the process for addressing disputes in Section 1.6.	The QMP does not describe the process for resolving disputes stemming from assessments.

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
63. Includes roles, responsibilities, and authorities in description of above processes?	33-36	9	Y	The QMP identifies roles and responsibilities for each type of assessment. The QMP states that key investigators determine whether a stop work order will be issued when problems arise.	
QUALITY IMPROVEMENT	36	10			
64. Describes process for ensuring that conditions adverse to quality are prevented, identified promptly, corrected promptly and that actions are taken toward prevention, documented and actions tracked to closure?	36	10	P	The QMP quality improvement process consists of the staff communication to management and assessments.	The QMP does not discuss preventive action and how opportunities for improvement are investigated, implemented or tracked.
65. Describes process for encouraging staff to establish communications between customers and suppliers, identify process improvement opportunities, and identify and propose solutions for problems?	36	10	P	The QMP states that staff is encouraged to report concerns to key investigators and colleagues.	The QMP does not discuss a process for communicating with customers and suppliers, identify process improvement opportunities, and identify and propose solutions for problems.
66. Includes roles, responsibilities, and authorities in description of above processes?	36	10	P	The role of staff, the QAMs, PQAM, and key investigators is defined.	The QMP does not define who is authorized to implement improvements for the program.
OTHER REVIEW CRITERIA					
67. Are regulatory or other citations accurate?			Y	Most appear accurate, but some could not be verified or accessed.	

Table D-2. Quality Management Plan (Revision 1): Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources (Continued)

U.S. EPA QA/R-2 QMP Element	Page	Section	Completeness vs. EPA Process (Yes/No/Partial)	Conformance with Requirements	Data Gaps/Comments
68. Are there any inconsistencies in the text?			Y	The QMP states that all hydraulic fracturing projects are classified as Category 1 but the disclaimer indicates that the document will not be used for decision making. The QMP references L/C/O QMPs; it is unclear if these documents have consistent requirements and procedures.	
69. Is the writing clear?			Y		
70. Are organizational units identified consistent with the most recent reorganization?			Y		
71. Are past Quality System management assessment findings resolved?			Unknown		
72. Are activities described in the QMP consistent with QA Annual Report and Work Plans?			Unknown		
73. Are tasks proposed for other organizations not covered solely by this QMP documented elsewhere (e.g., in another organization's QMP)?			Y	The QMP references L/C/O QMPs.	

Appendix E

Detailed Analysis of Quality Assurance Project Plans Prepared to Support the EPA Hydraulic Fracturing Study

Detailed Analysis of Quality Assurance Project Plans Prepared to Support the EPA Hydraulic Fracturing Study

1.0: INTRODUCTION

U.S. Environmental Protection Agency (EPA) has posted each of the approved Quality Assurance Project Plans (QAPPs) with disclaimers that the documents are considered internal planning documents. By providing these documents, EPA is sharing what its projects are and how they will be accomplished. As of May 4, 2012, 17[42] separate QAPPs have been provided to the public by EPA to describe activities that will be conducted in support of the hydraulic fracturing study plan (EPA, 2011). A team of Battelle technical and quality assurance (QA) staff conducted a review of these documents (Table E-1) to assess technical robustness, the adequacy of QA and quality control (QC) procedures, and the documentation and data management procedures used to ensure that documents used and results developed during the study are traceable, reproducible, and retrievable. As stated in the hydraulic fracturing study plan, intentional and successful application of the EPA quality system principles and requirements within each QAPP will result in "a credible approach that relies on the best available science, as well as independent sources of information" and a "transparent, peer-reviewed process that will ensure the validity and accuracy of the data."

- The technical review focused on the scientific method applied to each project. The review assessed whether the technical approach and task descriptions were adequate to address the individual project objectives and, to the extent possible, the overall study objectives.[43]
- The QA review was based on the requirements of EPA policy CIO 2105.0 (formerly EPA Order 5360.1 A2) *Policy and Program Requirements for the Mandatory Agency-Wide Quality System* (EPA, 2000) and QA/R-5, *EPA Requirements for QAPPs* (EPA, 2001). The review assessed whether there was evidence of a systematic planning process and if the QAPP sections provided enough detail to demonstrate that policies, processes, and procedures were defined to assure data quality.
- The documentation review was conducted as part of both the technical and QA reviews. The intent of this review was to verify that the documents and records maintained and the data management practices described in the QAPPs were sufficient to ensure that data developed by EPA are traceable, reproducible, and retrievable.

As part of this review, each QAPP was assessed for completeness, clarity, and compliance with the EPA quality system as defined in *EPA Quality Manual for Environmental Programs* (EPA, 2000) and *Overview of the EPA Quality System for Environmental Data and Technology* (EPA, 2002a). The results of the QAPP review are summarized in four sections:

Section 1.0: Introduction: This section defines the 17 QAPPs included in the review and the review approach.

Section 2.0: Summary of QAPP Reviews: This section provides an overall summary of the results of the QAPP reviews.

[42] Twenty documents are posted on the EPA QAPP Web page. Of these, the disinfection by-products QAPP and the supplemental well file QAPP are posted twice under two different names and the Bakken Shale/Dilldeer County QAPP is posted as both the original and revised document. Thus, 17 QAPPs applicable to the EPA hydraulic fracturing projects are posted.

[43] Each QAPP addresses specific activities that are part of the overall study plan; however, in most cases, these documents do not show direct linkages to the *EPA Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources* (EPA/600/R-11/122/November 2011/www.epa.gov/research).

Section 3.0: Detailed Review of QAPPs Prepared by EPA for the Hydraulic Fracturing Study: This section summarizes the review of each of the 17 QAPPs. Section 3.1 provides an overview of the five retrospective case study QAPPs and the issues common among them. Section 3.2 identifies issues specific to each case study QAPP. Sections 3.3 through 3.14 provide a detailed review of the other 12 QAPPs.

Section 4.0: References

Table E-1. Summary of Reviews of EPA Quality Assurance Project Plans

Section	Document Title on EPA Web Page (Document Title)	Document Date and Version	Prepared by
3.2.1	**Marcellus Shale/Washington County, PA** (Hydraulic Fracturing Retrospective Case Study, Marcellus Shale, Washington County, PA)	July 2011 Rev 0[44]	EPA/Shaw
3.2.2	**Barnett Shale/Wise County, TX** (Hydraulic Fracturing Retrospective Case Study, Wise and Denton Co., TX)	August 22, 2011 Rev 0[3]	EPA/Shaw
3.2.3	**Bakken Shale/Killdeer County Revised** (Hydraulic Fracturing Retrospective Case Study, Bakken Shale, Killdeer and Dunn County, ND)	August 14, 2011 Rev 1	EPA/Shaw
3.2.4	**Raton Basin** (Hydraulic Fracturing Retrospective Case Study, Raton Basin, CO)	September 20, 2011 Rev 0	EPA/Shaw
3.2.5	**Marcellus Shale/ Bradford County, PA** (Hydraulic Fracturing Retrospective Case Study, Bradford-Susquehanna Counties, PA)	March 12, 2012 Rev 1	EPA/Shaw
3.3	**Enhancement of Analytical Chemistry Methods** (Quality Assurance Project Plan for the Chemical Characterization of Select Constituents Relevant to Hydraulic Fracturing)	August 31, 2011 Rev 0	EPA-ORD-NERL-ESD
3.4	**Data Collection for Scenario Evaluation - Shaw Environmental & Infrastructure** (Data Collection/Mining for Hydraulic Fracturing Case Studies)	May 2011 Rev 0[3]	Shaw
3.5	**Formation of Disinfection By-Products from Hydraulic Fracturing Fluid Constituents**[45] (Formation of Disinfection By-Products from Hydraulic Fracturing Fluid Constituents)	June 9, 2011[46] Rev 0	EPA-ORD-NRMRL-WSWRD
3.6	**Organization of Data from Hydraulic Fracturing Service Companies - Eastern Research Group** (Evaluation of Information on Hydraulic Fracturing)	January 12, 2011 Rev 0	ERG
3.7	**Statistical Assessment of Data from Hydraulic Fracturing Service Companies - WESTAT** (Quality Assurance Project Plan for Hydraulic Fracturing)	July 14, 2011 Rev1.1	Westat
3.8	**Surface Water Transport Modeling of Discharge of Treated Wastewater**	February 21,	EPA-ORD-NRMRL-

[44] A revised version of this document was developed and posted after the Battelle QAPP review period.
[45] Also posted on the EPA Web page as Evaluation of Disinfection By-Products from Hydraulic Fracturing Fluid Constituents
[46] Final approval signatures October 2011.

Table E-1. Summary of Reviews of EPA Quality Assurance Project Plans (Continued)

Section	Document Title on EPA Web Page (Document Title)	Document Date and Version	Prepared by
	(Quality Assurance Project Plan for Surface Water Transport of Hydraulic Fracturing-Derived Waste Water)	2012 Rev 1	GWERD
3.9	**Well File Review Focusing on Well Design and Construction, and Hydraulic Fracturing Planning and Operations** (National Hydraulic Fracturing Study Evaluation of Existing Production Well File Contents)	January 4, 2012 Rev 0	EPA-ORD-OSP
3.10	**Supplemental Well File Review - The Cadmus Group, Inc. (Supplemental Programmatic Quality Assurance Project Plan for Work Assignment 4-58: National Hydraulic Fracturing Study Evaluation of Existing Well File Contents)**	March 2, 2012 **Rev 1**	Cadmus
3.11	**Environmental Justice Analysis (Quality Assurance Project Plan for Environmental Justice in Hydraulic Fracturing Analysis)**	July 13, 2011 **Rev 0**	MIT Washington Summer Intern/ EPA-ORD-OSP
3.12	**Health and Toxicity (Quality Assurance Project Plan Health and Toxicity Theme Hydraulic Fracturing Study)**[47]	January 2012 Rev 0	EPA-ORD-IONCEA
3.13	**Modeling Impact of Hydraulic Fracturing on Water Resources Based on Acquisition Scenarios** (Modeling the Impact of Hydraulic Fracturing on Water Resources Based on Water Acquisition Scenarios)	February 6, 2012 Rev 0	Cadmus/AQUA TERRA/Texas A&M
3.14	**Hydraulic Fracturing Scenario Modeling - Lawrence Berkeley National Laboratory (**Analysis of Environmental Hazards Related to Hydrofracturing EPA Interagency Agreement No. DW-89-92235901-C LBNL Interagency Agreement No. BG854806**)**	December 1, 2011 Rev 0	**Lawrence Berkeley National Laboratory**

[47] This QAPP was incorporated into a recently posted, broader QAPP as a SQAP Appendix.

2.0: SUMMARY OF QAPP REVIEWS

The EPA hydraulic fracturing study plan states that "each research project must have a QAPP, which outlines the necessary QA procedures, QC activities, and other technical activities that will be implemented for a specific project. Projects using existing data are required to develop data assessment and acceptance criteria for this secondary data. Secondary data will be assessed to determine the adequacy of the data according to acceptance criteria described in the QAPP. All project results will include documentation of data sources and assumptions and uncertainties inherent within those data." The EPA hydraulic fractioning study plan further states that "for each case study (retrospective and prospective), EPA will write and approve a QAPP before starting any new data collection." This section summarizes the over-arching compliance of the EPA hydraulic fracturing study QAPPs with these requirements. Observations are categorized in terms of technical soundness, quality and documentation.

2.1 Technical Soundness

- The retrospective case study QAPPs refer to site visits and interviews with home owners (Tier 1 of the study plan) but do not present the results of Tier 1 and the rationale for Tier 2 sampling including:
  - The rationale for selection of sampling locations such that they are representative of groundwater conditions and consider the hydrologic conditions as part of the sampling design;
  - A discussion of background conditions and how they will be established for the critical parameters of interest;
  - The rationale for selected critical and non-critical chemicals of interest;
  - How evidence of potential drinking water contamination will be determined
  - The development of conceptual site models (CSMs);
  - The development, calibration, and testing of fate and transport models.
- The retrospective case study QAPPs do not reference the sources of historical information used to define the project objectives or incorporate the information within the QAPPs.
- The retrospective case study QAPPs do not adequately identify or discuss other potential source(s) of groundwater contamination in the area and do not define how contamination from those sources will be differentiated from potential hydraulic fracturing contamination.
- None of the retrospective case study QAPPs define the numeric project action limits (i.e., screening criteria) that will be used as the basis of assessing the impact of hydraulic fracturing activities on drinking water resources.
- Project-required detection limits are not defined in either the retrospective QAPPs or the analytical chemistry QAPP. Thus, it is not possible to determine if the analytical methods are sensitive enough to answer the study questions.
- Although the retrospective case study QAPPs all describe sampling and analysis that will be conducted by the same organizations, there are discrepancies between them. These QAPPs should be reviewed and corrected to be consistent. A few examples include:
  - The Washington County and Raton Basin QAPPs list the volatile organic compound (VOC) SOP as either Robert S. Kerr (RSK) Environmental Research Center (ERC) RSKSOP-229 or -259, whereas the other three case study QAPPs list only RSKSOP-229. Other SOP discrepancies were noted for major cations, major anions, and stable isotopes.

- The instrument for O and H stable isotopes analysis is listed as isotope ratio mass spectrometer for Washington County and Raton Basin, cavity ring down for Barnett Shale, and either method for Bradford County.
- The Bradford County QAPP specifies the use of dedicated sample tubing for surface water collection; other QAPPs specify only that the tubing be clean.
- Unlike the other four QAPPs, the Barnett Shale QAPP does not define a unique sample identification scheme.
- Neither the Barnett Shale nor Bakken County QAPPs define the field equipment calibration standards. The other three QAPPs detail these requirements.
- QC acceptance for field blanks vary among QAPPs:
  - The Washington and Bakken County QAPPs relative percent difference (RPD) criteria are >30% if concentrations are > reporting limit (RL)
  - The Barnett Shale QAPP RPD criteria are <30% if concentrations are five times the RL
  - The Raton Basin and Bradford County RPD criteria are >30% and five times the RL
- The RSKERC QC criteria defined for metals lack distinguishing details:
  - The Washington County and Barnett Shale QAPPs list two sets of criteria each for digested and undigested metals but do not indicate which criteria are for filtered samples and which are for unfiltered samples.
  - The Bakken County QAPP lists one criterion for "metals" and does not distinguish between filtered, unfiltered, digested, and undigested samples.
- The surrogate recovery acceptance criteria are not consistent for semivolatile organic compound (SVOC) samples. The criteria are listed as 60 to 130% recovery for Washington County and Bakken Shale samples but as based on Department of Defense (DoD) testing limits for the other three studies.
- The laboratory control standard (LCS) criteria for Washington County and Barnett Shale are defined as 70 to 130 for diesel range organics (DRO) and the same as the "supplier limits" for gasoline range organics (GRO). For the other three case study QAPPs, the DRO and GRO LCS criteria are defined as the standard reference material (SRM) values.
- The Barnett Shale and Bradford County QAPPs define data qualifiers, the other three do not.

- The QAPP for Enhancement of Analytical Chemistry Methods (Section 3.3; Table 7) does not describe the method used to identify critical vs. non-critical compounds and does not discuss how the data will be used or assessed as usable. The discussion of instrument calibration and QC samples does not provide sufficient detail and it appears that errors exist. QC criteria are applied generically to several types of samples that are not appropriate. Similarly, instrument calibration requirements are not detailed and the acceptance criteria defined in the document appear too generic and broad for the wide variety of compounds proposed for analysis.

- The QAPP for Data Collection for Scenario Evaluation (Data Collection/Mining) (Section 3.4; Table 8) does not describe the overall quality objective(s) and scope. It is not clear how the QAPP tasks are linked to the overall hydraulic fracturing study plan objectives and other QAPPs. Although the QAPP is entirely focused on the collection and management of secondary data, the document does not address how secondary data will be collected, assessed as acceptable, and managed. The QA/QC procedures for review of data entry are not sufficient and gaps in data management procedures may result in untraceable data.

- The QAPP for Formation of Disinfection Byproducts from Hydraulic Fracturing Fluid Constituents (Section 3.5; Table 9) does not appear to be coordinated with other parts of the hydraulic fracturing study plan. It focuses on a very specific drinking water issue, disinfection

byproducts, and does not describe the relationship between hydraulic fracturing and bromide. The sampling program is not well defined and the experimental design seems to be misaligned with the research needs. The data generated by this project will not provide definitive information on whether hydraulic fracturing affects disinfection byproduct levels in drinking water facilities.

- The QAPP for Organization of Data from Hydraulic Fracturing Service Companies (Section 3.6; Table 10) does not provide essential links between the statistical methods QAPP prepared by Westat and the data collection and mining QAPP prepared by Shaw Environmental. In general, procedures for data management, data review, assessment and verification activities are not sufficient to ensure the quality of work products.
- The QAPP for Statistical Assessment of Data from Hydraulic Fracturing Service Companies (Section 3.7; Table 11) includes a sampling design for the hydraulic fracturing survey that is not adequate to accomplish the study objectives. Nine service companies and 1,150 operators were surveyed representing only 0.8% of the current operators. The data request focused on well construction, design, and well operation practices for oil and gas wells that were hydraulically fractured from 2009 to 2010 rather than focusing on a specific geographical area or type of formation or water resource concern. As such, it may not be possible to extrapolate from this dataset to meet the specific study objectives. There are no clear linkages between the survey objectives and the "key questions" outlined in Section 3.7.1.
- The QAPP for Surface Water Transport Modeling of Discharge of Treated Wastewater (Section 3.8; Table 12) does not adequately define the specific purpose of the modeling and does not present a clear relationship between modeling and case studies. It does not detail procedures for sensitivity and uncertainty analysis, nor how the modeling fits into the overall study plan. The QAPP lacks detail on the relationships between surface water and groundwater and geospatial information that is important for modeling the intensity of hydraulic fracturing activities in conjunction with other activities that might impact water quality and fate and transport within a given watershed or basin.
- The scope of the QAPP for Well File Review (Section 3.9; Table 13) is to standardize the examination of hydrocarbon production well files received from nine oil and gas operating companies by EPA's contractors (ERG, Cadmus, and Westat) and EPA employees from Office of Research and Development (ORD), Region 2 and Region 6. It is not clear how the data obtained from this information request will be used to meet the specific study objectives. Significant efforts of three contractors and EPA staff are being expended to repackage data that do not seem to be connected to the case studies or directed at answering the specific charge of the study. The QAPP mentions acceptance criteria for inclusion of data, but does not provide information on how that information will be applied in developing the database or interpreting the findings.
- The supplemental programmatic QAPP for Well File Review (Section 3.10; Table 14) is intended to ensure the quality of secondary data used under this work assignment and to describe how Cadmus will collect, compile, and analyze data to assess whether there may be impacts on drinking water resources due to hydraulic fracturing activities. The project goal is to "assess whether drinking water resources are impacted by HF" and The Cadmus Group will review and evaluate the well files to "assess the key drinking water resources risk factors potentially related to well design, construction, operation and maintenance" but it is not clear how the evaluation will be conducted and reported. The EPA Project-wide QAPP states that once the data are loaded into the worksheet, queries will be constructed to address the project objectives listed in that document; however, there is no discussion of query development in this supplemental QAPP.

- The QAPP for Environmental Justice Analysis (Section 3.11; Table 15) considers issues of "environmental justice" within a very narrow definition. The study relies purely on demographic statistics compared against the national average to ascertain whether or not certain sub-segments of the population are being disenfranchised. The methodology being proposed is not complex enough to examine the actual cost/benefit analysis, including alternative land-use value, economic impact of value-added activity, etc., weighed against the potential costs.
- The QAPP for Health and Toxicity (Section 3.12; Table 16) is described as a Software Quality Assurance Plan (SQAP) and covers the software development portion of the task, but the purpose section of the document describes development of a master database and querying of the database as additional tasks. It is noted that a recent revision of this document includes the SQAP (this document), an appendix to a larger QAPP. This document may provide the context and detailed discussion of the task requirements not covered in the SQAP.
- The primary objective of the QAPP for Modeling Impact of Hydraulic Fracturing on Water Resources (Section 3.13; Table 17) is to determine the relative impacts of hydraulic fracturing on stream flow and groundwater recharge. However, there is no discussion/description for how relative impact will be determined or quantified for current conditions (2010) or the future scenarios. For example, under the current conditions (2010), water use for hydraulic fracturing activities and the most current U.S. Geological Survey (USGS) for competing water use will be incorporated into a baseline conditions model. It is not clear how model predicted results associated with changes in USGS water use between baseline and current conditions will be separated from model predicted results associated with hydraulic fracturing activities.
- The purpose of the QAPP for Hydraulic Fracturing Scenario Modeling (Section 3.14; Table 18) is to evaluate potential problems (i.e., failure scenarios) associated with hydraulic fracturing operations that could lead to the contamination of freshwater aquifers. While the QAPP is generally well written and detailed, it does not address the specific plan by which data would be evaluated to determine usability in the modeling project. In addition, the QAPP alludes to the use of the model beyond what would be appropriate. For instance, the QAPP states the models "may in the future be used to evaluate proposed HF projects to ensure that such unintended consequences are avoided." This type of prediction is beyond the capabilities of the described model although it might provide evidence of possible prospective failures, in conjunction with other methods, especially if it can be calibrated against field data.

2.2 Quality

- It does not appear that the hydraulic fracturing study as currently described in the 17 QAPPs has implemented the EPA quality system project planning process consistently.
  - There is no evidence that the EPA data quality objective (DQO) process was used as the basis of project design. EPA policy CIO 2105.0 (formerly EPA Order 5360.1 A2) *Policy and Program Requirements for the Mandatory Agency-Wide Quality System* (EPA, 2000) requires "Use of a systematic planning approach to develop acceptance or performance criteria for all work covered by this Order. (See Section 3.3.8 of the *EPA Quality Manual for Environmental Programs*.)"
  - The 17 QAPPs reviewed have been developed to describe specific activities to be conducted to support the EPA hydraulic fracturing study plan. With four exceptions, the QAPPs were developed and approved prior to the approval of the study plan (November

2011) and the posted EPA Quality Management Plan (QMP) (January 2012). The relationship among the various QAPPs, how they are linked, and how data will be managed to meet the objectives of the overall study plan are unclear.
    - The study plan states that data from nine hydraulic fracturing service companies and nine randomly chosen oil and gas well operators were requested in 2011. While aspects of data collection and management for the oil and gas operator surveys are described in several QAPPs, the QAPPs do not reference each other and the collection and management of data from the nine hydraulic fracturing service companies is not clearly described.
    - The QAPP for data collection and mining (Shaw, 2011) is focused on collecting data to support the five retrospective case studies. However, the retrospective case study QAPPs do not reference this data management QAPP or describe the 'hand-off' of data between different aspects of the studies.
  - The need for an over-arching hydraulic fracturing study QMP is critical given the number of organizations participating in the study with diverse quality systems. However, the QMP review (Battelle, 2012) revealed that the document does not define over-arching minimum quality system standards for the study participants. Further, it does not define the QAPP interrelationships needed to define roles and responsibilities for data handling, management, and use among the various projects. While QAPPs have been developed for the retrospective case studies, analytical chemistry, data collection, survey data, statistical analysis, surface water modeling, and disinfection studies, the documents do not reference each other leading to confusion about their scope, interrelationships, relative importance, and application towards meeting the study objectives.
  - Neither the final study plan nor the final QMP describes how the various study elements and data will be managed.
  - Overall coordination, linkages, and data management and control are not defined in the hydraulic fracturing QMP. For instance, the retrospective case studies do not reference the analytical chemistry QAPP and the analytical chemistry QAPP does not define its scope and application within the study; therefore, it is not clear whether all analytical chemistry data will comply with the requirements of the QAPP. Similarly, the modeling QAPPs seem to be disconnected from the case studies and the analytical chemistry efforts. It is therefore not possible to determine the method(s) used to manage and control data among the individual studies. It is critical that a study of this magnitude implements consistent approaches across all projects, particularly for QAPP sections common to all activities (e.g., QC requirements, data management, assessments, verification and validation), thereby reflecting central management and control and ensuring data comparability. However, there is little consistency among QAPPs in defining specific procedures.
  - EPA QA/R-5 states, "If the designated methods are well documented and are readily available to all project participants, citations are adequate; otherwise, detailed copies of the methods and/or SOPs must accompany the QAPP either in the text or as attachments." For this study, field, laboratory, data management, and assessment activities should be defined in SOPs that establish consistent procedures. However, with a few exceptions, SOPs are not referenced in the QAPPs nor is the level of detail provided such that a qualified individual could perform the procedure independently.

- The retrospective case study QAPPs do not consistently define QC requirements for sample analysis and the procedures to prepare and analyze QC samples. The QC measurement quality objectives (MQOs; acceptance criteria) for critical data are sometimes missing, not consistent or questionable. Instrument calibration acceptance criteria are not defined.

- EPA QA/R-5 states that if non-measurement data (secondary data) are used in a project, then the QAPP should "define the acceptance criteria for the use of such data in the project and specify any limitations on the use of the data." This requirement is reiterated in the study plan. However, criteria to assess the quality and usability of secondary data are missing or vague in all QAPPs. Screening criteria for these studies should include temporal and spatial boundaries and detection limits and QC criteria for analytical chemistry data. For instance,
  - The Shaw Environmental Data Collection/Mining QAPP states "data will be collected from acceptable sources and assessed for suitability" but does not define how acceptability and suitability will be determined.
  - The retrospective case studies include statements such as "at this stage of the project there are no non-direct measurements anticipated. Limited water quality data were provided by some of the homeowners. Because these data will not be reported as part of this project, but instead used as background information for the site, data quality will be considered acceptable if it has met QA/QC requirements of the labs that performed the analyses." However, the study plan states that during Tier 1, activities will include evaluating existing data and information from operators, private citizens, and state agencies; conducting site visits; and interviewing stakeholders and interested parties. It is important that existing data, the results of interviews, and background data are reliable but the QAPP does not describe how these data will be assessed.
- The assessment criteria defined to assess data quality are not consistent with EPA Category I requirements (50% review; http://www.epa.gov/nrmrl/qa/chapter2.html) and are often vague without clear definition of the amount of data to be reviewed and the frequency of the reviews.
- The procedures to assess data usability are not detailed and often not linked back to the project objectives.
- Many of the QAPPs do not describe the overall quality objectives and the scope (e.g., it is not clear how the tasks described in the QAPP for data collection/mining for hydraulic fracturing case studies are linked to the overall hydraulic fracturing study plan objectives and other QAPPs and it is not clear whether data being collected by other entities and agencies will be managed by the contractor defined in this QAPP or whether there are multiple databases).

2.3 Documentation

- In general, the discussion of documents and records is not adequate in any of the QAPPs. Most QAPPs do not have a clear discussion of the documents that will be used in the project or the records that will be developed and maintained.
- The data management section of every QAPP is weak and does not address the critical elements required to ensure that data are maintained systematically, under control to avoid loss, and named uniquely to ensure version control. Procedures are not defined for how data will be processed, compiled, and analyzed; data reporting conventions, including qualifiers and units are not defined; confidentiality procedures are not specified; procedures for data recording, transcribing, digitizing, downloading, storing, transformation and reduction (mathematical operations) are not cited or described. The QAPPs do not reference the QMP requirements. SOPs, forms or checklists to ensure that data are handled consistently throughout the project are not cited. Procedures for version control and change control are not described or cited.
- The topics of documents and records and data management are best discussed at the study level in the QMP to provide guidance to all study participants.

3.0: DETAILED REVIEW OF QAPPS PREPARED BY EPA FOR THE HYDRAULIC FRACTURING STUDY

This section summarizes the results of each of the 17 QAPPs reviewed by Battelle for the hydraulic fracturing study plan. Section 3.1 provides an overview of the five retrospective case study QAPPs, including benefits/positives and big-picture data gaps. Section 3.2 provides a detailed assessment of the five case study QAPPs. Sections 3.3 through 3.14 provide an overview of the other 12 QAPPs. Specific section-by-section review comments for each QAPP are presented in Tables D-2 through D-18.

3.1 Overview of Retrospective Case Study QAPPs

3.1.1 Overall Summary. Five retrospective case studies were identified by EPA to assess the potential impact of hydraulic fracturing on domestic wells, groundwater and surface water. A separate QAPP was developed for each case study. The five QAPPs generally present the same information in a consistent format, indicating that all were prepared from the same basic template. All five retrospective case study QAPPs were approved before the final study plan and EPA hydraulic fracturing QMP and before sampling was conducted. In spite of that, the QAPPs appeared to follow the QMP requirements although the QMP does not actually provide much specific direction for QAPPs. The QAPPs reference site visits and interviews with home owners (Tier 1 of the study plan) but do not present the results of Tier 1. The QAPPs focus on Tier 2 sampling. Discussion of development of a CSM and the development of analytical models is not included in the documents, which state that the QAPPs will be revised after an evaluation of the data or whenever revisions are necessary. All provide good detail for specific areas such as laboratory analysis but both general and specific data gaps were identified across the documents. These are summarized below and detailed for each QAPP in Section 3.2.

3.1.2 Observations

- The five retrospective case study QAPPs follow the EPA QA/R-5 (2001) outline for preparation of QAPPs. As such, the overall study objectives, sampling design, sampling and analysis procedures, and QA/QC requirements are outlined.
- Each QAPP clearly defines the primary objectives and critical data; all but the Washington County QAPP also define the secondary objectives.
- Most sample collection procedures and analytical methods are described in detail adequate enough to support the objectives and to communicate the requirements. However, see Section 3.1.3 for discussion of the lack of SOPs.
- Comprehensive descriptions of the analytical laboratory qualifications and the analytical methods that will be used for the project are provided.
- The QAPPs contain tables that provide the details needed to define the QA/QC requirements for field sampling and analysis. Many of the tables provide good supporting details; analytical methods and equipment are described.
- For some laboratories, QC criteria are defined along with corrective action.

3.1.3 Big-Picture Data Gaps. The biggest data gap identified across all retrospective case study QAPPs is that the EPA DQO process does not appear to have been followed to design the studies to ensure that the right type and quantity of data needed to answer the study questions would be collected.

- The rationale for how the retrospective case study sites and sample locations were selected out of the initial pool of potential study locations should be discussed in detail.
- The EPA study plan describes a four-tiered process for the retrospective case studies:

Tier	Goal	Critical Path
1	Verify potential issue	• Evaluate existing data and information from operators, private citizens, and state agencies • Conduct site visits • Interview stakeholders and interested parties
2	Determine approach for detailed investigations	• Conduct initial sampling: sample wells, taps, surface water, and soils • Identify potential evidence of drinking water contamination • Develop conceptual site model describing possible sources and pathways of the reported contamination • Develop, calibrate, and test fate and transport model(s)
3	Conduct detailed investigations to evaluate potential sources of contamination	• Conduct additional sampling of soils, aquifer, surface water and surface wastewater pits/tanks (if present) • Conduct additional testing: stable isotope analyses, soil gas surveys, geophysical testing, well mechanical integrity testing, and further water testing with new monitoring points • Refine conceptual site model and further test exposure scenarios • Refine fate and transport model(s) based on new information
4	Determine the source(s) of any impacts to drinking water resources	• Develop multiple lines of evidence to determine the source(s) of impacts to drinking water resources • Exclude possible sources and pathways of the reported contamination • Assess uncertainties associated with conclusions regarding the source(s) of impacts

  However, the QAPPs do not describe the results of the Tier 1 verification or initial Tier 2 sampling and resulting CSM. Rather, the objectives and planning begin at the Phase 1 and 2 field sampling associated with Study Plan Tier 3.

- The QAPPs do not provide an initial CSM as specified in the EPA DQO process (EPA QA/G-4, 2006). A CSM should be the basis for exploratory sampling in wells, taps, surface water, and soils. Further, some QAPPs do not include a complete discussion of local geology and hydrology or potential fate and transport mechanisms. The study plan states that development of a CSM is part of the Tier 2 process but development of a CSM is not discussed in the QAPPs.
- The case study scopes, sampling scopes, and rationale are not described.
- The QAPPs do not provide the timeline for when hydraulic fracturing occurred and when associated complaints were issued within the vicinity of the sample locations at each of the retrospective locations.
- The QAPPs do not discuss background conditions, how differences in pre and post hydraulic fracturing activities will be identified, and does not discuss how baseline water quality characteristics compare to drinking water maximum contaminant levels (MCLs) and clean water act acute and chronic values.
- The rationale for the sampling design and selection of sampling locations to ensure that they are representative of groundwater conditions is not detailed and thus it is unclear if the sampling plans and sampling locations are adequate to address the main study objectives. In addition, it does not appear that statistical and hydrologic conditions were considered in the sampling program design.

- The QAPPs do not adequately identify or discuss other potential source(s) of groundwater contamination in the area and do not define how contamination from those sources will be differentiated from potential hydraulic fracturing contamination.
- In general, the documents do not discuss potential indicators of hydraulic fracturing.
- Most QAPPs do not describe how the data or study results will be reconciled with the study objectives and how uncertainties and limitations will be identified and reported.
- EPA QA/R-5 requires that SOPs be referenced for detailed sample collection and analysis procedures and that SOPs be attached to the QAPP. Most sample collection and analysis procedures are not referenced to SOPs for details and few SOPs are provided as QAPP attachments.
- The QAPPs do not discuss how "impact" of hydraulic fracturing to domestic wells will be assessed or defined.
- The National Risk Management Research Laboratory (NRMRL)- Groundwater and Ecosystems Restoration Research Division (GWERD) General Procedures and Shaw laboratories on site at RSKERC are responsible for many of the critical parameters. The QAPP does not detail the QC samples that will be analyzed with samples, and the QC criteria, the instrument calibration procedures, frequency, and requirements.
- The retrospective case study QAPPs do not define corrective action for failures in any of the NRMRL-GWERD laboratory procedures. The QAPP references SOPs for missing information but the SOPs are not included as attachments. EPA QA/R-5 specifically states that if SOPs are referenced for details, the SOPs must be provided with the QAPP.
- The QC samples and criteria for the Marcellus Washington case study are not the same for three critical parameters (semi-volatiles [SVOA], DRO, and GRO) as the other four case studies although the analyses are being performed by the same laboratory (e.g., the Marcellus Washington case study does not include the use of statistical limits for SVOA surrogate spike recoveries, expands the RPD criteria for SVOA matrix spike/matrix spike duplicate (MS/MSD); and does not define a default recovery criteria of 70 to 130% for GRO laboratory control samples).
- Sample collection and processing details vary between the retrospective case study projects. For example, the Bradford-Susquehanna QAPP specifies that domestic well water samples will be collected either from a homeowner tap upstream of the pump or directly from the well using a separate submersible pump. The Marcellus Washington QAPP does not define the sampling location for domestic wells. The Bradford-Susquehanna QAPP does not define criteria for determining stabilization after installation of a domestic groundwater well; the Marcellus Washington QAPP includes these criteria. The sampling procedure for dissolved gasses in the Bradford-Susquehanna QAPP calls for using a bucket and inverting the sampling containers; the Bradford QAPP calls for preservations with sulfuric acid and a crimp cap vial. In addition, clear protocols for well-purging criteria are not provided.
- The lack of detail in several critical detail in sections of the retrospective case study QAPPs may result in inconsistent acceptance of field and analytical data or the inability to critically assess data usability.
- The need for more consistent data management control and organization across the studies was identified as a consistent theme, including if and how data generated for these studies will be incorporated into the database being managed by another contractor.

Section 3.2 provides further detail; Tables D-2 through D-6 contains specific comments for each QAPP.

3.1.4 Recommendations for Improvement

- All retrospective case study QAPPs would be improved by systematic application of the EPA DQO process to the sampling design. This process would result in clear definition of the questions to be answered, the data input, decision criteria, the need for new data, a defensible data collection process with defined statistical uncertainty, and a traceable, defensible sampling plan.
- The documents would benefit from more detail in describing the background, including additional site geology and hydrogeology, detailed descriptions of the historical analytical and field data used to select the scope of the study, increased emphasis on the assessment of indicator parameters in groundwater and methods to assess fate and transport to provide clear linkages between the study plan, site selection criteria, and site investigations.
- Historical analytical and field data used to select the scope of the project should be provided as an appendix or the published reports referenced.
- The QAPPs should include a discussion of other potential sources of contamination and the methods that will be used to distinguish between those sources and natural background contaminant levels vs. hydraulic fracturing activities.
- The sampling locations for each study should be clearly defined on a map along with the footprint of hydraulic fracturing activities and existing conventional and non-conventional wells. A table with the station names and northing/eastings coordinates should be included in each QAPP.
- The sample collection, processing and QC should be clarified and standardized across studies.
- QA/QC procedures for the NRMRL-GWERD General Procedures and Shaw laboratories on site at NRMRL-GWERD should be provided at the same level of detail as the other analytical laboratories or else the relevant SOPs should be attached to the QAPP as specified in EPA QA/R-5. Section 3.2 provides further detail; Tables D-2 through D-6 contain specific comments for each QAPP.

3.2 Detailed Assessment of the Five Hydraulic Fracturing Retrospective Case Study QAPPs

3.2.1 Detailed Review of the Marcellus Shale/Washington County, PA QAPP

3.2.1.1 Overview. The Hydraulic Fracturing Retrospective Case Study, Marcellus Shale, Washington County, PA QAPP describes sample collection at domestic wells to address complaints about appearance, odors and taste associated with well water. The document contains both general and specific data gaps; general issues are described in Section 3.1. This section provides comments specific to the Marcellus Shale, Washington County, PA QAPP. Table E-2 contains document-specific comments.

3.2.1.2 Big-Picture Data Gaps. Overall, the QAPP for the Marcellus Shale, Washington County Site is lacking a significant amount of information necessary to develop a sampling and analysis plan to support the study objectives. In addition to the issues identified in Section 3.1, the following issues specific to this case study QAPP are identified:

- The original QAPP date was July 2011. The first round of groundwater and surface water sampling was also conducted in July 2011. Approval of the QAPP pre-dated approval of the final study plan and QMP. The impact of completing the QAPP and initial sampling prior to these over-arching documents is not known. Since the QMP defers to the individual EPA and extramural organizations for many QA/QC functions, the impact may be minimal.
- The rationale for how the retrospective case study site was selected out of the initial pool of potential study locations was not discussed in detail.
- The QAPP describes activities for Phase I and Phase II sampling. For Phase I, the QAPP does not provide any information for gas sampling/detection within the headspace of the wells.
- The QAPP does not discuss background conditions or compare analytes of drinking and surface water concentrations with background levels.
- The QAPP provides no information regarding the construction details (or boring logs) for each of the groundwater sampling locations (and does not even specify the exact sampling locations). Typically, this information is collected during development of the QAPP, so the investigation can be duplicated by an independent party.
- QC requirements and criteria are not consistent with other retrospective case study QAPPs although the same laboratories are performing the analyses.

3.2.1.3 Recommendations for Improvement. The general recommendations identified in Section 3.1 apply to this case study. Table E-2 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

3.2.2 Detailed Review of the Barnett Shale/Wise County, TX QAPP

3.2.2.1 Overview. The Hydraulic Fracturing Retrospective Case Study, Wise and Denton Co., TX (Barnett Shale) QAPP was approved in August 2001. It describes sample collection at three locations to address complaints about appearance, odors and taste associated with water in domestic wells. Overall, the QAPP describes the general approach of the study, however the document is lacking in detail in areas of background, rationale and secondary data handling to support the study objectives. The document contains both general and specific data gaps; general issues are described in Section 3.1. This section provides comments specific to the Wise and Denton Co., TX QAPP. Table E-3 contains document-specific comments.

3.2.2.2 Big-Picture Data Gaps. The QAPP for Barnett Shale is lacking a significant amount of information necessary to develop a sampling and analysis plan to support the study objectives. In addition to the issues identified in Section 3.1, the following issues specific to this case study QAPP are identified:

- The original QAPP date was August 2011. The first round of groundwater and surface water sampling was conducted in September 2011. Approval of the QAPP pre-dated approval of the final study plan and QMP. The impact of completing the QAPP and initial sampling prior to these over-arching documents is not known. Since the QMP defers to the individual EPA and extramural organizations for many QA/QC functions, the impact may be minimal.
- Rationale for how the Barnett Shale site was selected out of the initial pool of potential study locations is not discussed in detail.

- The sampling scope is not clearly defined. It is not clear what the scope of the sampling at Locations A, B, and C is. Thus, it is unclear if the sampling plan is adequate to address the main objective of this study, which is to determine if the groundwater resources in Wise County, TX have been impacted by hydraulic fracturing processes. A comprehensive discussion of local site geology and hydrogeology is not included.
- Analytical data, formal complaints used to select the location(s) and scope of the project are not provided in the QAPP. However, complaints and analytical reports are referenced throughout the report as decision-making criteria.
- The QAPP does not discuss background conditions or compare analytes of drinking and surface water concentrations with background levels.
- Comprehensive discussion of local site geology and hydrogeology is not included.
- The QAPP did not describe the process to confirm that the groundwater sampling networks within each study area will intercept actual migration paths of potential contaminants and how the local geology and hydrogeology will be closely analyzed. It is imperative that the groundwater sampling network is designed in such a manner that it will be able to identify any subsurface contamination.
- The QAPP defines Phase 1 and Phase 2 sampling. It appears that only preexisting groundwater wells will be used in the study in Phase 1, which is generally intended to locate any potential impacts to water resources by hydraulic fracturing activities. Thus, due to the limited number of proposed sampling points, it is imperative that the sampling points used in the Phase 1 portion of this study are located in areas that maximize the likelihood that they will come into contact with groundwater that may have been in communication with hydraulic fracturing fluids, should this interaction exist.
- The rationale for why the selected sampling points were chosen over other preexisting sampling points or the installation of additional monitoring wells is not discussed in detail. Baseline data are not provided and the statistical procedures that will be used to analyze results are not defined.
- Data used to select the location(s) and scope of the project are not provided. Analytical data, formal complaints, etc. are not provided in text or presented in the reference section in the QAPP; however, complaints and analytical reports are referenced throughout the report as decision-making criteria.
- Details of the hydraulic fracturing-related activities, including volumes, dates, chemical makeup of fracturing fluids, etc. are not documented in the QAPP nor is the process of determining and evaluating this information specified. Hydraulic fracturing currently occurring within the footprint of the study areas is not identified. During Phase 1, the study boundaries are limited to 10 drinking wells and two surface water sites where alleged impact has been reported. The QAPP states that if additional locations are sampled during Phase 2, then the QAPP will be revised to identify them. However, the use of a systematic planning process for selecting additional sample locations is not discussed.
- There are no details on transition of Phase 1 sampling to Phase 2 in the QAPP.
- There is no mention of whether the effects on water quality are immediate, if they occur over a relatively short period of time, or if they are long term. Thus, it is unknown if the sampling frequency is time critical.

- Sampling in conjunction with nearby hydraulic fracturing activities, or at times when the production well owner notices changes in water quality, may be more beneficial than a quarterly groundwater monitoring schedule.
- The basis for the selection of the number of sampling points (10 domestic wells and two surface water locations) is not discussed.
- The location, documentation, and delineation of possible contaminant sources other than hydraulic fracturing-related activities to the extent practical are not described.
- The EPA-defined purpose of this study is to assess if the water resources within the three Barnett Shale study sites have been impacted by hydraulic fracturing activities. The locations of gas wells that have been worked in the past within the footprint of the study areas are not documented. Details of the hydraulic fracturing-related activities, including volumes, dates, chemical makeup of fracturing fluids, etc. are not described. Any current hydraulic fracturing occurring within the footprint of the study areas is not defined.

3.2.2.3 Recommendations for Improvement. The general recommendations identified in Section 3.1 apply to this case study. In addition:

- The rationale and supporting analysis for the sampling design, sample locations and events should be described.
- The QAPP should clarify the project schedule and milestones.
- Historical analytical and field data used to select the scope of the project should be provided as an appendix or the published reports referenced. More details on how the secondary data will be validated and used should be included in the QAPP.
- The Phase 1 and historical sampling locations should be clearly defined on a map and table with the station name and northing/eastings coordinates defined.
- The location of gas wells within the study footprint should be documented.
- The QAPP should identify and discuss the impact of other activities that could be potential sources of groundwater contamination.

Table E-3 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

3.2.3 Detailed Review of the Bakken Shale/Killdeer County QAPP

3.2.3.1 Overview. The Hydraulic Fracturing Retrospective Case Study, Bakken Shale, Killdeer and Dunn County, ND QAPP was initially approved in June 2011 and revised in August 2011. The QAPP describes an investigation of potential groundwater and surface water contamination associated with a blowout during fracturing operations near Killdeer. The document adequately describes how the primary objective (evaluate if the Killdeer Aquifer was impacted by the blowout that occurred during the fifth stage of a 23 stage fracturing operation when a 7-inch intermediate casing burst) and secondary objective (determine the mechanism(s) of how the Killdeer Aquifer was impacted if there was an impact) will be achieved. Comprehensive descriptions of the analytical laboratory qualifications and the analytical methods that will be used for the project are provided. The document contains both general and specific data gaps; general issues are described in Section 3.1. This section provides comments specific to the Bakken Shale, Killdeer and Dunn County, ND QAPP. Table E-4 contains document-specific comments.

3.2.3.2 Big-Picture Data Gaps. Overall, the Bakken Shale QAPP presents a fairly complete plan for site assessment activities. However, the document is lacking a significant amount of information necessary to develop a sampling and analysis plan to support the study objectives. In addition to the issues identified in Section 3.1, the following issues specific to this case study QAPP are identified:

- The original QAPP date was June 2011. The first round of groundwater and surface water sampling was conducted in July 2011. Approval of the QAPP pre-dated approval of the final study plan and QMP. The impact of completing the QAPP and initial sampling prior to these over-arching documents is not known. Since the QMP defers to the individual EPA and extramural organizations for many QA/QC functions, the impact may be minimal.
- The rationale for how the retrospective case study site was selected out of the initial pool of potential study locations is not discussed in detail.
- The QAPP does not discuss background conditions or compare analytes of drinking and surface water concentrations with background levels.
- A demonstration of spatial scope is lacking. The QAPP outlines procedures that may adequately characterize the types of contamination that may be present as a result of the well blowout. However, because the spatial distribution of the sampling points with relation to the potential contaminant source is not clearly provided in the report as the figures are blacked out, it is difficult to agree with the scope of the sampling network. It is also not clear from the QAPP if the sampling will include surface water sampling as part of Phase I.
- Data used to select the scope of the project are not provided. Historic analytical and field data collected by the contractor handling the assessment of the site, Terracon, are not provided in text or present in the reference section in the QAPP; however, work conducted at the site by Terracon is referenced throughout the report as decision-making criteria. Reports submitted by Terracon relating to the Franchuk 44-20SH blowout have not been made available for review.
- It is not clear if the unauthorized release (spill) which occurred during the well blowout impacted the soil at the site from the given text, or if soil delineation activities have been conducted at the site since the well blowout.
- Soil sampling is not adequately addressed in this QAPP. Soil sampling at the site is necessary in order to adequately characterize the type and state of possible contaminants at the site. The QAPP does not indicate whether soil sampling has been conducted in the past at this site.
- The QAPP states that glycol data generated by the EPA Region III laboratory will be treated as screening data until the analytical method is validated. However, the method validation procedures and criteria are not defined or referenced to a SOP or laboratory manual.

3.2.3.3 Recommendations for Improvement. The general recommendations identified in Section 3.1 apply to this case study. In addition,

- Historical analytical and field data used to select the scope of the project should be provided as an appendix or the published reports referenced.
- The Phase I and historical sampling locations should be clearly defined on a map and table with the station name and northing/easting coordinates defined.
- The spatial distribution of sampling locations should be defined.

- A discussion of soil sampling should be added.

Table E-4 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

3.2.4 Detailed Review of the Raton Basin QAPP

3.2.4.1 Overview. The Hydraulic Fracturing Retrospective Case Study, Raton Basin, CO QAPP was approved in September 2012. It describes sample collection in Las Animas and Huerfano Counties to address complaints about appearance, odors and taste associated with water in domestic wells. The document contains both general and specific data gaps; general issues are described in Section 3.1. This section provides comments specific to the Raton Basin, CO QAPP. Table E-5 contains document-specific comments.

3.2.4.2 Big-Picture Data Gaps. Overall, the Raton Basin QAPP describes the general approach of the study, however the document is lacking a significant amount of information necessary to develop a sampling and analysis plan to support the study objectives. In addition to the issues identified in Section 3.1, the following issues specific to this case study QAPP are identified:

- The original QAPP date was September 2011. The first round of groundwater and surface water sampling was conducted in October 2011. The QAPP was revised in April 2012 before the scheduled second round of sampling (but had not been made available to the public). Approval of the QAPP pre-dated approval of the final study plan and QMP. The impact of completing the QAPP and initial sampling prior to these over-arching documents is not known. Since the QMP defers to the individual EPA and extramural organizations for many QA/QC functions, the impact may be minimal.
- Discussion on how the Raton Basin site was selected out of the initial pool of potential study locations is not discussed.
- The specific scope of sampling to be conducted within Las Animas and Huerfano Counties is not outlined, along with the rationale behind the selection of the scope of sampling. A comprehensive discussion of local site geology and hydrogeology is not included.
- The QAPP does not discuss background conditions or compare analytes of drinking and surface water concentrations with background levels.
- The QAPP does not describe the process to confirm that the groundwater sampling networks within each study area will intercept actual migration paths of potential contaminants and how the local geology and hydrogeology will be closely analyzed. It is imperative that the groundwater sampling network is designed in such a manner that it will be able to identify any subsurface contamination.
- It appears that only preexisting groundwater wells will be used in the study in Phase I, which is generally intended to locate any potential impacts to water resources by hydraulic fracturing activities. Due to the limited number of proposed sampling points, it is imperative that the sampling points used in the Phase I portion of this study are located in areas that maximize the likelihood that they will come into contact with groundwater that may have been in communication with hydraulic fracturing fluids, should this interaction exist. The rationale for why the selected sampling points were chosen over other pre-existing sampling points or the installation of additional monitoring wells should be discussed in detail.

- Data used to select the location(s) and scope of the project is not provided. Analytical data, formal complaints, etc. are not provided in text or present in the reference section in the QAPP; however, complaints and analytical reports are referenced throughout the report as decision-making criteria.
- There is no mention of whether the effects on water quality are immediate, if they occur over a relatively short period of time, or if they are long term. Thus, it is unknown if the sampling frequency is time critical.
- Sampling in conjunction with nearby hydraulic fracturing activities, or at times when the production well owner notices changes in water quality may be more beneficial than a quarterly groundwater monitoring schedule.
- The location, documentation, and delineation of possible contaminant sources other than hydraulic fracturing-related activities to the extent practical are not described.
- The locations of gas wells that have been worked in the past within the footprint of the study areas are not documented. Details of the hydraulic fracturing-related activities, including volumes, dates, chemical makeup of fracturing fluids, etc. are not described. Any current hydraulic fracturing occurring within the footprint of the study areas is not defined.

3.2.4.3 Recommendations for Improvement. The general recommendations identified in Section 3.1 apply to this case study. In addition:

- Historical analytical and field data used to select the scope of the project should be provided as an appendix or the published reports referenced.
- A discussion of current hydraulic fracturing activities, particularly those occurring within the study footprint, should be included.
- The sampling locations should be clearly defined on a map and table with the station name and northing/easting coordinates defined.

Table E-5 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

3.2.5 Detailed Review of the Marcellus Shale/Bradford County, PA QAPP

3.2.5.1 Overview. The Hydraulic Fracturing Retrospective Case Study, Bradford-Susquehanna Counties, PA QAPP was approved in September 2011 and revised in April 2012. According to EPA, the QAPP describes sample collection in Bradford and Susquehanna Counties to address homeowner complaints regarding appearance, odors, and possible health impacts associated with water from domestic wells. This review contains both general and specific data gaps; general issues are described in Section 3.1. This section provides comments specific to the Bradford-Susquehanna Counties, PA QAPP. Table E-6 contains document-specific comments.

3.2.5.2 Big-Picture Data Gaps. Overall, the QAPP for the Bradford-Susquehanna Counties Site is lacking a significant amount of information necessary to develop a sampling and analysis plan to support the study objectives. In addition to the issues identified in Section 3.1, the following issues specific to this case study QAPP are identified:

- The original QAPP date was September 2011. The first round of groundwater and surface water sampling was conducted in October/November 2011. The document was revised in

April 2012 before the scheduled second round of sampling. Approval of the QAPP pre-dated approval of the final study plan and QMP. The impact of completing the QAPP and initial sampling prior to these over-arching documents is not known. Since the QMP defers to the individual EPA and extramural organizations for many QA/QC functions, the impact may be minimal.

- The rationale for how the retrospective case study location was selected out of the initial pool of potential study locations is not discussed in detail.
- The QAPP does not discuss background conditions or compare analytes of drinking and surface water concentrations with background levels.
- It is not clear how "impact" will be assessed. The study design does not include "reference" wells and surface water where other sources of contamination could originate that are not related to hydraulic fracturing.
- The QAPP does not include an assessment of industry or other activities unrelated to hydraulic fracturing that could impact water quality.

3.2.5.3 Recommendations for Improvement. The general recommendations identified in Section 3.1 apply to this case study. In addition,

- Comprehensive analysis of local site geology and hydrogeology should be added.
- Potential sources of contamination should be described along with methods that will be used to distinguish between those sources vs. hydraulic fracturing activities.
- The sampling locations should be clearly defined on a map and table with the station name and northing/easting coordinates defined.
- QA/QC procedures for the RSKERC General Procedures and Shaw laboratories on site at RSKERC should be provided at the same level of detail as the other analytical laboratories or the relevant SOPs should be attached to the QAPP.

Table E-6 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

3.3 QAPP for the Enhancement of Analytical Chemistry Methods

3.3.1 Overall Summary. The QAPP for the Chemical Characterization of Select Constituents Relevant to Hydraulic Fracturing describes analytical laboratory procedures for a large suite of critical and non-critical compounds that may be associated with hydraulic fracturing. It was prepared by EPA-ORD-National Exposure Research Laboratory (NERL) Environmental Sciences Division (ESD) and approved in August 2011. It describes the process for developing methods for non-standard chemicals and the instrumentation and QC procedures for each compound class. The presentation of QC samples, acceptance criteria, and corrective action when criteria are not achieved is weak and confusing. Project action limits and detection limits that will ensure data usability are not established. The description of data verification and validation procedures is not sufficiently detailed.

3.3.2 Observations

- The QAPP follows the EPA QA/R-5 (2001) outline for preparation of QAPPs and adequately addresses most sections.

- Analytical methods are described in sufficient detail for the analyses to be performed for each laboratory.
- The sample handling and control procedures are adequate to maintain traceability.
- Many of the tables provide good supporting details.
- Section B5 provides a thorough overview of the method development process.

3.3.3 Big-Picture Data Gaps

- The QAPP does not describe the method used to identify critical vs. non-critical compounds and does not discuss how the data will be used or assessed as usable. The assessment of usability is limited to the results of QC samples.
- The discussion of instrument calibration and QC samples does not provide sufficient detail and it appears that errors exist. QC criteria are applied generically to several types of samples that are not appropriate. Similarly, instrument calibration requirements are not detailed and the acceptance criteria defined in the document appear too generic and broad for the wide variety of compounds proposed for analysis.
- Project-required detection limits are not defined and because DQOs have not been developed, even if the detection limits were defined it would not be possible to determine if the analytical methods were sensitive enough to answer the study questions. In order for data to be used to meet the project objective (to assess the impact of hydraulic fracturing on surface and groundwater), project action limits should be established and detection limit requirements then established to ensure that the action limits can be achieved.
- The data management procedures described in the document do not address most elements established in EPA QA/R-5 to ensure document control and data traceability.
- The assessment and oversight section does not discuss corrective action procedures; the amount of data included in audits of data quality and the audit frequency are not defined.

3.3.4 Recommendations for Improvement

- The QAPP should describe the method used to determine which targeted compounds are considered critical. The QAPP defines critical analytes as those that support the primary objective of site investigation.
- The QC acceptance criteria defined in Table 3 should be reviewed and revised. Currently, the same criteria are generically applied to all compound classes but it is unlikely that each method and analysis will be able to achieve the sample accuracy and precision criteria.
- The corrective action requirements should be corrected to provide for each type of QC sample.
- The preparation of QC sample types should be described or the preparation procedures referenced. Similar comments apply to the need to improve the description of instrument calibration procedures, standards, and requirements.
- Project detection limits should be defined based on the project action limits and intended use of the data.
- Data management procedures should be reviewed and revised to address the topics included in EPA QA/R-5, including standard record-keeping procedures; document control; data flow,

control, and management; and data storage, retrieval, and security systems that will be used throughout the project life-cycle.

- The assessment and oversight section should be revised to discuss corrective action and provide additional detail for data quality audits.

Table E-7 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

3.4 QAPP for Data Collection for Scenario Evaluation

3.4.1 Overall Summary. The Data Collection/Mining for Hydraulic Fracturing Case Studies QAPP was prepared by Shaw Environmental & Infrastructure and approved in January 2011. It describes data collection activities focused on existing water supplies, water quantity, and possibly water quality for hydraulic fracturing activities related to natural gas production. The data will be collected from available sources from two regions: Susquehanna River Basin/Marcellus Shale in Pennsylvania and Garfield County/Piceance Basin in Colorado. The scope of the work does not include physical sampling or methodology. Although the QAPP is entirely focused on the collection and management of secondary data, the document does not address how secondary data will be collected, assessed as acceptable, and managed. The QA/QC procedures for review of data entry are not sufficient and gaps in data management procedures may result in untraceable data.

3.4.2 Observations

- The QAPP incorporates collection of data from control areas within each study area that have similar conditions and have no oil and gas development and compares them to areas with hydraulic fracturing activity.

3.4.3 Big-Picture Data Gaps

- The QAPP does not describe the overall quality objective(s) of the tasks described therein and the scope of the QAPP. For instance, it is not clear how the QAPP tasks are linked to the overall hydraulic fracturing study plan objectives and other QAPPs. It is not clear if data being collected by other entities and agencies under the hydraulic fracturing study plan will be managed by Shaw according to this QAPP, i.e., whether there are one or multiple databases. These links and the overall study structure should be described in a study QMP.
- The data quality criteria presented in Section 2.9 are not sufficient to screen secondary data to determine if they meet the DQOs of the study. For analytical chemistry data, the DQOs (sic) are defined as the method requirements — the methods listed as "EPA, USGS, ASTM, SMWW, federal governmental approved or universally accepted." The minimum numeric criteria for accuracy, precision and detection limits should be specified in the QAPP so that data gatherers can verify that data meet the study criteria.
- The level of data review proposed in the QAPP is not consistent with the EPA requirements for Category I projects (50%) (EPA ORD NRMRL QMP Chapter 2.1 http://www.epa.gov/nrmrl/qa/chapter2.html.
- The data management section does not adequately address data management (downloading, transformation, transmittal, storage, and retrieval) and version control.
- The QAPP does not describe the database and documentation to be maintained for it (e.g., relationship tables, entity relationship diagram, data dictionary, etc.).

3.4.4 Recommendations for Improvement

- The QAPP should define how the data collection QAPP is linked to the modeling QAPP, analytical chemistry QAPP, and case study QAPPs. Most data errors and project issues arise when data, responsibilities, or project steps are handed off between people or organizations.
- Data users and their role in providing input to data needs, products, and database format should be defined. This communication is critical to ensure that the right type and quantity of data are collected and stored in a usable format.
- Task discussions should reference QAPPs that will be developed for the retrospective and prospective case studies so there is a link between those studies and the methods used to collect data for them.
- The QAPP should establish screening criteria for secondary data to determine if data are acceptable for inclusion in the database. These should include requirements for geospatial and elevation accuracy; acceptable analytical methods; minimum data quality indicators, MQOs and acceptance criteria.
- To the extent possible by the data sources, it would be helpful to include more information on water quality data besides pH, temperature and conductivity. For example, information on chemicals commonly used in the hydraulic fracturing process is useful.
- The validation methods need further clarification because data from available sources may require stringent validation techniques. Similar data from multiple sources should be compared for accuracy and completeness and to identify any major discrepancies that warrant further investigation.
- The frequency and timing of QA/QC data reviews and the amount of data included should be reviewed vs. EPA requirements and clarified in the QAPP.

Table E-8 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

3.5 QAPP for Formation of Disinfection By-Products from Hydraulic Fracturing Fluid Constituents

3.5.1 Overall Summary. The Formation of Disinfection By-Products (DBP) from Hydraulic Fracturing Fluid Constituents QAPP was approved in October 2011. This QAPP appears twice on the EPA Web page, once as "Formation of Disinfection By-Products (DBP) from Hydraulic Fracturing Fluid Constituents" and once as "Evaluation of Disinfection By-Products (DBP) from Hydraulic Fracturing Fluid Constituent"; upon opening, the two documents appear to be identical. The QAPP describes evaluation of the effects of high total dissolved solids (TDS) upon chlorination, chloramination, or ozonation of hydraulic fracturing-impacted waters and an investigation to assess specific organic chemicals used during hydraulic fracturing activities, in particular biocides. The QAPP was prepared through NRMRL's Water Supply and Water Resources Division (WSWRD) and does not appear to be coordinated with other parts of the hydraulic fracturing study plan. It focuses on a very specific drinking water issue, disinfection byproducts, but does not discuss the relationship between hydraulic fracturing and bromide. The literature study focuses on the effects of bromide and is not specific to hydraulic fracturing activities or byproducts. The sampling program is poorly defined and the experimental design seems to be misaligned with the research needs. The data generated by this project will add to the already extensive databases on disinfection byproduct formation, but will not provide definitive information on whether hydraulic fracturing affects disinfection byproduct levels in drinking water facilities.

3.5.2 Observations

No notable observations; see detailed observations in Table E-9.

3.5.3 Big-Picture Data Gaps

- The QAPP does not provide justification or rationalization for the selection of the field sampling locations and the field sampling team does not appear to be listed in the QAPP distribution.
- The QAPP does not establish a clear relationship between sample collection and the hydraulic fracturing case studies (retrospective or prospective).
- The study design described in the QAPP does not provide evidence of linkages between bromide levels and disinfection byproducts in drinking water and hydraulic fracturing activities.
- The overall emphasis is on chemistry of disinfection byproducts versus source water characteristics or conditions that are likely to exist in drinking water treatment facilities.
- The scope of analytical methods defined in the QAPP is inconsistent with current (and proposed) National Primary Drinking Water Regulations under the Safe Drinking Water Act.
- The QAPP does not provide information on why biocide disinfection/oxidation will be investigated and how the data will be relevant to drinking water systems.

3.5.4 Recommendations for Improvement

- It is important that the sampling effort and bench-scale tests are designed to address issues specific to hydraulic fracturing. There is a significant amount of background data on this topic which could be used to address the general questions of disinfection byproduct formation. A clear rationale is needed for the sampling program.
- A systematic approach is needed to identify the chemicals that will be tested, the testing conditions, and the type of data that are needed to answer the research questions.
- Consistent information should be provided for all analytes and should be cross-referenced to the appropriate EPA methods or standard methods.
- All QC information should be incorporated into one section and all information on the selection of analytes should be included in the experimental section.

Table E-9 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

3.6 QAPP for Organization of Data from Hydraulic Fracturing Service Companies

3.6.1 Overall Summary. The QAPP for Evaluation of Information on Hydraulic Fracturing was prepared by ERG, Inc. and approved in January 2011. It describes management of data from an EPA-designed survey of nine hydraulic fracturing companies, and analysis of public comments. The project scope is limited to assisting EPA in tracking and analyzing the nine questionnaire responses and tracking and summarizing public comments related to EPA's hydraulic fracturing study design. This QAPP addresses each of the elements required for EPA Category 1 QAPPs. It provides general guidance and requirements for the collection of secondary data but lacks some significant details. The links between

this document, the statistical methods QAPP prepared by Westat, and the data collection and mining QAPP prepared by Shaw Environmental are unclear. In general, procedures for data management, data review, assessment and verification activities are not sufficient to ensure the quality of work products.

3.6.2 Observations

- The survey collects a large amount of information useful for identifying and tracking hydraulic fracturing companies, the chemical composition of the formulations and mixtures used, and the standard practices.
- The tracking process for the nine hydraulic fracturing company surveys and public comments is rigorous; each is assigned a unique identifier and tracked.
- The QAPP describes an appropriate process for maintaining confidential business information.

3.6.3 Big-Picture Data Gaps

- The relationship between the ERG QAPP (approved in January 2011) and the statistical QAPP developed by Westat (approved in July 2011) is unclear. The final QMP was approved in January 2012, after the QAPP, and does not provide linkages among QAPPs and the various study elements.
- The QAPP does not address the handling, screening or quality assessment of data such as maps and chemical formulation/mixture analysis provided as attachments or referenced in the industry questionnaires or public comments. The procedures and criteria used to evaluate water specifications vs. water quality criteria and to assess water quality data vs. the human health impacts of chemicals within fracturing are not defined.
- No reference is made as to who will be using, summarizing, and analyzing the data to be collected and entered into databases by ERG and what quality procedures are adhered to for these activities. While it is possible that these quality procedures are referenced in a separate QAPP, it is important that this QAPP recognize who will be using the data, how the data will be provided in formats that facilitate the end use of the data, and note procedures that will be in place to ensure the integrity of the data as they are transferred to the user.
- The questionnaire and public comment acceptance criteria (QAPP Tables 2 and 3) do not define acceptance criteria or the corrective action procedure if specifications are not achieved. The criteria include qualitative terms such as “majority,” “relevant,” and “most accurate.” The document should define these terms so that assessments are consistent.
- There do not appear to be any SOPs that staff use as references to perform QA-related activities such as verification of entered data. Such SOPs are necessary because details on the procedures are not provided within the QAPP.
- The QA procedures are weak. The QAPP does not include independent data audits, reports to management of data quality issues by either QA or technical peer reviews, or a corrective action to implement improvements such that errors are not repeated.

3.6.4 Recommendations for Improvement

- Include discussion of the handling, screening or quality assessment of data such as maps and chemical formulation/mixture analysis provided as attachments or referenced in the industry questionnaires or public comments.
- Provide a context for the data, including who will be using, summarizing, and analyzing the data to be collected and entered into databases by ERG.
- QA/QC procedures should be reviewed and revised to include 100% review of hand-entered data and QC checks for entry of public comments. These procedures should be defined in SOPs.
- The quality objectives and criteria defined in QAPP Tables 2 and 3 should include corrective action if criteria are not achieved.
- The methods used to determine "majority" "relevant" and "most accurate", along with the terms themselves, should be defined to ensure consistency.
- The link between other study QAPPs and inter-project communication should be described.
- Procedures to handle confidential business information (CBI) data should be specified.

Table E-10 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

3.7 QAPP for Statistical Assessment of Data from Hydraulic Fracturing Service Companies

3.7.1 Overall Summary. The QAPP for Hydraulic Fracturing was prepared under EPA Contract EP-C-10-023 for EPA's Office of Water by Westat, Rockville, MD and approved in July 2011. The EPA objective is to study the potential impact that hydraulic fracturing may have on drinking water. The purpose of the QAPP is to assess the representativeness of hydraulic fracturing companies from responses received from nine hydraulic fracturing companies from a survey distributed by EPA during 2010; and to advise on the design and analysis of samples of oil and gas companies involved in hydraulic fracturing activity and the hydraulic fracturing-associated wells of those companies.

The 2010 survey objectives were to:

- Identify key industry operators;
- Obtain contact information for persons within each company most familiar with hydraulic fracturing operations and for companies that have been contracted for hydraulic fracturing;
- Gain information on the location and services performed for past and future hydraulic fracturing operations;
- Obtain the names and formulations/mixtures of hydraulic fracturing fluids;
- Obtain chemical and proppant constituent information for each formulation/mixture of hydraulic fracturing fluid;
- Define policies, practices, and SOPs for common operations; and
- Identify water specifications for each formulation/mixture.

Westat is conducting an assessment of representativeness of the 2010 EPA survey, and is advising on the design and analysis of samples of oil and gas companies involved in hydraulic fracturing activity and the hydraulic fracturing-associated wells of those companies sampled to help answer nine key questions:

1. How representative are the hydraulic fracturing companies that responded to its 2010 survey?
2. How many wells should be included in the 2011 survey of oil and gas companies?
3. How should the oil and gas companies be selected?
4. How does hydraulic fracturing affect drinking water quality, especially drinking water aquifers and surface water bodies?
5. How does hydraulic fracturing and the associated dewatering affect hydrogeology, such as structural stability and subsidence?
6. What practices are established to control groundwater/drinking water impacts?
7. What methods are being used for chemical analyses of the hydraulic fracturing fluid?
8. How does hydraulic fracturing differ across the country?
9. How does hydraulic fracturing differ across different geologic formations and industry companies?

3.7.2 Observations. The QAPP contains all the appropriate QAPP required components. Westat identifies the appropriate parameters for using survey data to produce population estimates.

3.7.3 Big-Picture Data Gaps. It is unclear if the drinking water source data from the case studies (Shaw QAPP) and the data Westat is analyzing(questionnaire data from nine oil and gas companies) are for the same location.

There are several concerns with this QAPP:

- The introduction does not specifically identify the target population (or domain) for which characteristics are to be estimated to address EPA's objective to study potential impacts of hydraulic fracturing on drinking water resources. In the background and introduction, some subpopulations mentioned are:
  - Hydraulic fracturing companies that responded to the initial 2010 questionnaire;
  - Oil and gas clients of hydraulic fracturing companies that responded initially;
  - Wells of oil and gas clients of hydraulic fracturing companies that responded initially.

  However, the target population should be all wells associated with hydraulic fracturing activities of all hydraulic fracturing companies.
- There are reasons to question whether the respondents to the questionnaire are representative of all hydraulic fracturing companies.
- There is no description of how Westat will determine how representative the respondents are of all hydraulic fracturing companies.
- Westat mentions reviewing industry materials. The risk of relying on this strategy for assessment is that the available information from Web sites or industry sources could be biased. This does not constitute a statistically based analysis of the population of hydraulic fracturing companies or of the domain of wells associated with hydraulic fracturing activities.
- The QAPP does not sufficiently address how the initial questionnaire provides a suitable frame for the target population.

- The process for selecting the oil and gas companies to be surveyed is derived from a September 2010 survey of nine hydraulic fracturing companies. The 2010 survey identified 1,150 operators who, collectively, fractured approximately 25,000 wells between 2009 and 2010. Nine of the 1,150 operators (0.8%) were surveyed in the follow-up request that is the source of the data to be analyzed under this QAPP and EPA is anticipating receiving data on about 350 wells (~1.4% of the 25,000 wells identified in the initial survey and an insignificant fraction of the total number of wells). Although this step-wise procedure is providing a wide range of data, there is no clear-cut method for evaluating whether the data are representative of actual conditions, and there is not adequate detail to demonstrate the statistical validity of the well-selection approach.
- The QAPP is a post facto analysis of the results of a questionnaire. However, no information is provided on the content of the questionnaire. Thus, it is not clear if the dataset that will be used contains the appropriate information. No mention is made of inherent biases that might be associated with the dataset. The solicitation of information from nine companies does not have any statistical basis, rather it is based on the limitations of obtaining information from 10 or more entities, as mandated by the Paperwork Reduction Act of 1995.[48] Therefore, there is no clear relationship between the survey respondents and the ability to ascertain representativeness.
- No information is provided on the content of the questionnaire. No mention is made of inherent biases that might be associated with the dataset.
- There are no clear linkages between the survey objectives and the "key questions". The QAPP mentions supplementing the survey data with information from EPA studies, Web sites, and third-party databases. However, it is not apparent how that approach can be used to evaluate "representativeness".
- Ideally, the information obtained from the survey could be used to inform the other activities that are planned as part of EPA's study plan. However, no evidence is provided of the relationship of this project to the other projects.
- There is no schedule provided within the QAPP. Since the survey was administered in 2010, it would be important to analyze the data fairly quickly as the landscape for hydraulic fracturing continues to advance and the conclusions may be rapidly outdated.

3.7.4 Recommendations for Improvement

- Provide details on the content of the survey and the methods that will be used to analyze the information.
- Provide details on how the key questions will be addressed by the study.
- Demonstrate how this project fits into the overall hydraulic fracturing study.
- Use a more complete sampling frame for all wells with associated hydraulic fracturing activity which is important to obtaining a representative sample.
- If the study is constrained to the initial survey of the nine hydraulic fracturing companies for a sampling frame, then the QAPP should include a plan for how to assess the biases that might be associated with this limited frame.

[48] http://www.archives.gov/federal-register/laws/paperwork-reduction/

Table E-11 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

3.8 QAPP for Surface Water Transport Modeling of Discharge of Treated Waste Water

3.8.1 Overall Summary. The QAPP for Surface Water Transport of Hydraulic Fracturing-Derived Waste Water was prepared through NRMRL's GWERD; revision 1 was approved in February 2012. The project is based on applying existing surface water modeling techniques to simulate conditions "under which disposal of hydraulic fracturing wastes might cause negative impacts on drinking water resources". The QAPP was written to explain the modeling approach designed to assess short- and long-term impacts of the disposal of hydraulic fracturing wastes into surface water. Two sub-objectives were identified to determine these impacts: (1) simulating a "generic river" situation to provide "a first order view of problematic conditions" and (2) simulating one or more actual river networks. The method selected for the first sub-task is an empirical model that will be fitted to six available USGS tracer studies, with a seventh study used to test the formulas derived from this method. An extensive explanation of this method is available in the QAPP. The scenario conceptual model (sub-task 2) will be simulated using a numerical model. The authors list three numerical models (WASP, QUAL2K, and RMA4) and state others are under consideration for these procedures. Overall the QAPP is strong in the areas of documentation, describing the empirical model theory, and routine procedures (e.g., QA auditing) but weaker in areas of model testing and calibration (where necessary), describing the numerical models, non-measured data selection, and, perhaps most importantly, describing model acceptance criteria in any specific or meaningful way.

The QAPP appears to have some redundancy with other parts of the hydraulic fracturing study plan, particularly in mining data from the literature. Discussion on model selection, validation, and interpretation lacks detail. It appears that the bulk of the work will be done by a "to be decided (TBD)" contractor and will be completed by December 2012.

3.8.2 Observations

- The documentation and record-keeping process is sufficient, rigorous and defensible. In addition, the authors clearly provide all directories where documentation and related model input, code, and output files will be located. This list looks comprehensive and indicates foresight for adequate record keeping.
- The QAPP provides a thorough description of the QA auditing process. The description includes assessment and oversight strategies, participants, responsibilities, scope of authority, and reports generated with a disclosure list. The process appears adequate to assure quality and identify deficiencies and includes monthly conference calls.
- The description of the theory behind the empirical model is well described. The description includes pertinent equations, input data needs, and provides acceptable ranges of input values. The description of the use of a sensitivity analysis in the QAPP will help to ensure that the implementation of this system will be done in an efficient way by allowing modelers to only vary parameters that will significantly impact the solution.

3.8.3 Big-Picture Data Gaps.

- The most serious gap in the QAPP is the vague description of the model acceptance criteria. Acceptance of the empirical model was said to be based on visual methods and "professional opinion." This type of vague acceptance criteria does not instill confidence in the conclusions drawn from the model; whether these conclusions are valid or invalid, the

selection of this method leaves the possibility of a bias in the interpretation of the professional, especially in an experiment that is designed in a way that assumes an effect.

- QAPP does not consider the possibility of observing no effect.
- The QAPP does not adequately describe the specific purpose of the modeling.
- The QAPP contains a thorough description of the theory of the empirical model. However, descriptions of the numerical codes under consideration are not provided and, in addition, some are not even mentioned by name. The selection of a numerical model is said to be contingent on the conditions of the river; however, these conditions and the process of selection are not described. The calibration process for numerical models was inadequate. The vagueness with which they described the qualitative analyses left out the objectives of calibrations, details on the data used for calibration, the types of output generated, and the necessary corrective action if the calibration criteria were not met.
- The selection criteria for non-measured data are inadequate. The authors simply state that the data they intend to use is of sufficient quality because they intend to use data from peer-reviewed and state- and federally-accepted published sources. Analysis of the quality of the secondary data, including the methods by which it was collected, the original intended use of the data, and the thoroughness of record keeping should be established to ensure that the data are accurate and usable for the purpose intended in this study.
- There is no clear relationship between this modeling and case studies (retrospective or prospective).
- The QAPP lacks a detailed discussion of sensitivity analysis, uncertainty analysis, and how the modeling fits into the overall study plan.
- The QAPP lacks information on relationships between surface water and groundwater.
- The QAPP lacks geospatial information that is important to model the intensity of hydraulic fracturing activities in conjunction with other activities that might impact water quality and fate and transport within a given watershed or basin.

3.8.4 Recommendations for Improvement.

- The calibration criteria, when discussed, were vague and general. Providing more information about these would help complete the QAPP.
- The numerical models were not described at all and, in fact, not all of them were listed. Creating a complete list of the models under consideration, providing descriptions of the models, and describing the selection process for the models will help complete the QAPP.
- The reports that will be written during this project are mentioned in the milestones list, but it is unclear if this list is complete. Report contents are not described. Providing a more robust list with descriptions will help complete the QAPP.
- The lack of quantitative acceptance criteria, which is not discussed for the empirical model and only vaguely discussed for the numerical models, does not inspire confidence in model acceptance. Quantitative assessment and acceptance criteria should be included prior to work being conducted. The qualitative assessment, which is said to be based on “professional judgment,” is vague and not defensible.
- The non-measured data should be vetted internally for quality, the usefulness in the tasks described in this QAPP, and the thoroughness of record keeping.

- The EPA Guidance for QAPP for Modeling (EPA/240/R-02/007) should be reviewed and the QAPP updated to incorporate some of the critical QA factors.
- The program models should be developed to inform sample collection and interpretation of results from field activities rather than hypothetical scenarios.
- The modeling effort should be coordinated with other components of the hydraulic fracturing study plan to ensure that modeling results are meaningful and relevant.

Table E-12 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

3.9 QAPP for Well File Review Focusing on Well Design and Construction, and Hydraulic Fracturing Planning and Operations

3.9.1 Overall Summary. The National Hydraulic Fracturing Study Evaluation of Existing Production Well File Contents QAPP was prepared to standardize the examination of hydrocarbon production well files received from nine oil and gas operating companies by EPA's contractors (ERG, Cadmus, and Westat) and EPA employees from ORD, Region 2 and Region 6. The QAPP was finalized in January 2012. Each of the EPA contractor's have prepared QAPPs that describes how they will conduct their contract assignments; the overall focus of this QAPP is "to provide an overarching document to assist with coordinating and integrating the work of all individuals working on the evaluation of existing production well files, regardless of their organizational affiliation." The QAPP defines specific responsibilities and points of contact for each organization and lays out a schedule for developing spreadsheets and database input between November 2011 (prior to QAPP finalization) and March 2012. The QAPP defines data acceptance criteria that will be used during the data review and it references two other components of EPA's hydraulic fracturing study: development of a database by ERG, and conducting geographic information system (GIS) mapping by Cadmus.

3.9.2 Observations

- The QAPP is clearly written and defines specific responsibilities; procedures to handle confidential business information are established.
- The QAPP fills a need in establishing consistent data management and review procedures to ensure consistency among multiple organizations.
- The nine subject areas covered by the surveys are well defined and a technical expert reviewer is assigned to each subject area. The acceptance criteria for well file data are appropriate and clearly defined, with specification and response actions if the criteria are not achieved.

3.9.3 Big-Picture Data Gaps. There are several concerns with this QAPP:

- The process for selecting the oil and gas companies to be surveyed is derived from a September 2010 survey of nine hydraulic fracturing companies. The 2010 survey identified 1,150 operators who, collectively, fractured about 25,000 wells between 2009 and 2010. Nine of the 1,150 operators (0.8%) were surveyed in the follow-up request that is the source of the data to be analyzed under this QAPP and EPA is anticipating receiving data on about 350 wells (~1.4% of the 25,000 wells identified in the initial survey and an insignificant fraction of the total number of wells). Although this step-wise procedure is providing a wide range of data, there is no clear-cut method for evaluating whether the data are representative

of actual conditions, and there is not adequate detail to demonstrate the statistical validity of the well-selection approach.

- The QAPP mentions acceptance criteria for inclusion of data, but does not provide information on how that information will be applied in developing the database or interpreting the findings.
- It is not clear how the data obtained from this information request will be used to meet the specific study objectives. Significant efforts of three contractors and EPA staff are being expended to repackage data that do not seem to be connected to the case studies or directed at answering the specific charge of the study.
- It is not clear why the focus of the information request is on wells that were hydraulically fractured between 2009 and 2010 versus focusing on a specific geographical area or type of formation or water resource concern. As such, it may not be possible to extrapolate from this dataset to meet the specific study objectives.
- Ideally, the information obtained from the survey could be used to inform the other activities that are planned as part of EPA's study plan. However, no evidence is provided of the relationship of this project to these associated activities.
- The quality objectives for accuracy and precision of data entry are 100% but the QA/QC procedures described in the QAPP are not designed to achieve these objectives.
- There are discrepancies between the Section A.6.2 text describing the data to be abstracted from the well files and the documentation of the spreadsheet files to be used for entering data (shown in Appendix 3).
- The data management section does not define file naming procedures, methods to maintain version control, the storage location of data received from the surveys, and data reduction and compilation procedures.
- Section A7 states that data which are obviously inconsistent will be precluded from analysis. This section should define mathematical or statistical procedures (such as outlier analyses or goodness-of-fit tests) that will identify whether individual data values within existing data sets should be rejected, transformed, or otherwise qualified before any statistical analysis.

3.9.4 Recommendations for Improvement:

- Provide details on how the key questions will be addressed by the study.
- Demonstrate how this project fits into the overall hydraulic fracturing study.
- Resolve the discrepancies between the text describing the data abstracted from the well files (QAPP Section A.6.2) and the documentation of the spreadsheet files used for entering data (QAPP Appendix 3).
- The project objectives are listed as 12 questions. The objectives should be re-stated and should define how the survey data will be used to answer the study questions.
- QA/QC activities should be revised to include (1) a rationale for reviewing only 10% of data entries; (2) a defined procedure for double-entering data; (3) action levels for increased QC if data reviews identify systematic issues; (4) a tiered approach whereby critical data received heightened levels of review; and (5) implementation EPA data audit requirements for Category 1 projects (50%).

Table E-13 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

3.10 Supplemental Well File Review

3.10.1 Overall Summary. The QAPP for Supplemental Well File Review was developed for EPA by The Cadmus Group, Inc. and approved in March 2012. This QAPP is a supplement to the EPA project-wide QAPP, *National Hydraulic Fracturing Study Evaluation of Existing Production Well File Contents: Quality Assurance Project Plan*. It describes the tasks that The Cadmus Group, one of three EPA contractors working on this project, will conduct as part of the well file review team. Specifically, Cadmus is responsible for reviewing and evaluating well files obtained from owners/operators to assess the key drinking water resources risk factors potentially related to well design, construction, operation and maintenance. Cadmus will review the files collected from the nine production companies and use publically available water quality data and other information to assess potential impacts of hydraulic fracturing operations on drinking water.

This QAPP is intended to describe procedures to ensure the quality of secondary data used and to describe how Cadmus will collect, compile, and analyze data to assess whether there may be impacts on drinking water resources due to hydraulic fracturing activities. QA provisions defined in the project-wide QAPP are applicable to all procedures described in this document.

Two additional tasks are described in this QAPP with a note that they will be conducted at the direction of EPA. These include a GIS mapping task to locate drinking water resources within a half mile from approximately 335 production well point locations in 13 states. The GIS task is described in the EPA project-wide QAPP. The other task, which is not described in the EPA project-wide QAPP, is to assist in the acquisition and analysis of well record data contained in files submitted to the public disclosure database, FracFocus.

3.10.2 Observations

- The document effectively dovetails with the EPA program-wide QAPP for the well file review activities and provides detail on the tasks to be conducted by The Cadmus Group.

3.10.3 Big-Picture Data Gaps

- The product of the task itself is not well described. It is clear that Cadmus will input water quality-related data collected from operator surveys and public databases to the project database but it is not clear how the evaluation of the data will be accomplished. The project goal is to "assess whether drinking water resources are impacted by HF" and Cadmus will review and evaluate the well files to "assess the key drinking water resources risk factors potentially related to well design, construction, operation and maintenance," but it is not clear how the evaluation will be conducted and reported. The EPA project-wide QAPP states that once the data are loaded into the worksheet, queries will be constructed to address the project objectives but there is no discussion of query development in this supplemental QAPP.
- The stated purpose of the QAPP is to ensure the quality of secondary data used under this work assignment; however, acceptance criteria for secondary data use are not defined. It is not clear how data obtained from public sources and operator well files will be screened for fitness and usability. The QAPP states that data which are obviously inconsistent will be excluded from analysis, but the section does not define mathematical or statistical procedures (such as outlier analyses or goodness-of-fit tests) that will identify whether individual data

values within existing data sets should be rejected, transformed, or otherwise qualified before use.

- The GIS and FracFocus tasks are described as optional but in some sections are included as established tasks. No schedule is provided for these tasks and it is not clear if completion of these tasks is required.
- The data management section does not define file naming procedures, methods to maintain version control, the storage location of data received from the surveys, and data reduction and compilation procedures.

3.10.4 Recommendations for Improvement

- The project task description should include the study objectives provided in the project-wide QAPP to provide better context.
- The final product(s) of the evaluation should be clearly defined and the steps taken to achieve that product defined.

Table E-14 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

3.11 QAPP for Environmental Justice Analysis

3.11.1 Overall Summary. The QAPP for **Environmental Justice in Hydraulic Fracturing Analysis** was prepared by a summer intern from MIT in conjunction with EPA-ORD-Office of Science Policy (OSP) and approved in August 2011. Overall, the study considers issues of "environmental justice" within a very narrow definition. The study relies purely on demographic statistics compared against national averages to determine whether or not certain sub-segments of the population are being disenfranchised. The methodology proposed is not complex enough to begin to examine the actual cost/benefit analysis, including alternative land-use value, economic impact of value-added activity, etc., weighed against the potential costs. This method described in the QAPP appears to almost be a "self-fulfilling prophecy" based on the regions of the nation in which the vast majority of hydraulic fracturing occurs. In other words, due to the rural nature in which these natural resources are found, the analysis will uncover, not surprisingly, that the vast majority of the population will be classified as socio-economically disadvantaged in comparison to the national norm because of the rural nature of the population.

3.11.2 Observations

No notable observations; see detailed observations in Table E-15.

3.11.3 Big-Picture Data Gaps

- The proposed disparity index measurement compares the sample population to the demographics of the entire nation. A comparison such as this will skew the data due to the realities of where the natural resource is located. The study should instead take into account the demographics of the region in which the natural gas wells are located and then compare that smaller population set to the locations where the wells have been sited. This will then provide an unbiased answer as to whether the wells have been disproportionally co-located near low income, minority, indigenous, young, or elderly populations.

- The data analysis does not expand beyond traditional demographic statistics to take into account any form of cost/benefit analysis, including alternative land-use value, economic impact of value-added activity, etc., weighed against the potential costs.

13.11.4 Recommendations for Improvement

- Expand the methodology to examine the actual costs and benefits associated with hydraulic fracturing activities, including alternative land-use value, economic impact of value-added activities, etc., weighed against the potential costs, including potential environmental degradation.
- Ensure that the methodology used for the environmental justice component normalizes the data to take into account the predominately rural nature of the population subset where the natural resource is located.

Table E-15 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

3.12 QAPP for Health and Toxicity

3.12.1 Overall Summary. The QAPP for the **Health and Toxicity Theme Hydraulic Fracturing Study** was prepared by EPA-ORD-Immediate Office (IO) National Center for Environmental Assessment (NCEA) and approved in January 2012. This QAPP covers a short duration (3 week) task to develop software to obtain toxicity values from Web-based resources. This QAPP is identified as a SQAP and was developed in compliance with the Institute of Electrical and Electronics Engineers (IEEE) Standard 730-2002. Adherence to the IEEE standard was used for this review. The QAPP was retrieved from the EPA Web site on May 2, 2012 and identified with the document control number QAPP-NCEA-IO-HFS-HTT/2012/01-r00. An updated version of the QAPP has since been posted on the EPA Web site. The new version, QAPP-NCEA-IO-HFS-HTT/2012/02-r00, includes the original document as an SQAP appendix to a more general QAPP. All of the QAPP language is new. The new document was not reviewed in detail, but appears to address some of the concerns noted below, especially those concerning context, task descriptions and schedules.

3.12.2 Observations

- This document contains and adequately address the majority of elements defined in the IEEE Standard 730-2002.

3.12.3 Big-Picture Data Gaps

- It is not clear how the organizational chart relates to the project team. The “roles and responsibilities” description includes team members who are not on the organizational chart. Clear lines of authority and accountability are needed to delineate roles and responsibilities.
- Specific tasks are listed, but not well described. The project description lacks context overall.
- The document is described as an SQAP and covers the software development portion of the task, but the purpose section of the document describes development of a master database and querying of the database as additional tasks. It is noted that a recent revision of this document includes the SQAP (this document) as an appendix to a larger QAPP. This may provide context and a more detailed discussion of all task requirements.

- Several critical documents describing quality procedures are mentioned in text, but not formally referenced. These documents (NCEA QMP, Agency guidance, and the Git software version control system) appear to provide critical elements of the quality system but are not accessible to users of this SQAP.

13.12.4 Recommendations for Improvement

- The updated version (posted but not reviewed) may address several of the areas noted as deficient or incomplete.

Table E-16 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

3.13 QAPP for Modeling the Impact of Hydraulic Fracturing on Water Resources Based on Water Acquisition Scenarios

3.13.1 Overall Summary. The QAPP for **Modeling the Impact of Hydraulic Fracturing on Water Resources Based on Acquisition Scenarios** was prepared by The Cadmus Group and approved in February 2012. The QAPP was written to explain the modeling approach designed to evaluate the relative impacts of large volume withdrawals associated with hydraulic fracturing within the Susquehanna River Basin and the Upper Colorado River Basin. For each basin, baseline (pre-hydraulic fracturing activities), current (year 2010), and future water acquisition scenarios (business as usual, energy max, and green technology) will be completed to assess the relative impacts on stream flow and groundwater recharge. Each basin will utilize a previously completed, calibrated, and tested/validated model for the project.

Future scenarios consider four factors: growth in number of hydraulic fracturing wells, hydraulic fracturing water best management practices (BMPs), competing drinking water demand; and environmental flow management. All other major water uses will remain at same levels in the current (2010) scenario. Changes in land use are tightly associated with population changes and are included in the futures scenarios. The future scenarios will be based upon a "future predicted peak gas production time" to be determined as part of this project. Relative impacts to stream flow and groundwater recharge will be assessed by comparison of the current conditions (2010) and future scenarios to baseline conditions.

3.13.2 Observations

- The project objective and with sub-objectives are defined.
- The models selected are appropriate for the project objectives.
- The methods for determining the underlying quality of data are described; acceptance criteria include data reasonableness, data completeness, data representativeness, and data comparability. The Susquehanna and Upper Colorado River Basin models developed for the EPA 20 Watersheds Study by Tetra Tech serve as the starting point for this study; acceptance criteria for input data used to develop these models were held in common and are described in the QAPP for that project.
- The overall approach of comparing model results, which include water withdrawals for hydraulic fracturing activities, to baseline conditions prior to the commencement of hydraulic fracturing activities is a good approach for assessing relative differences in stream flow and groundwater recharge.

- The model codes employed for each basin (HSPF and SWAT) are appropriate for use.
- The approach for each basin utilizes previously completed, calibrated, tested/validated models for each basin.
- A good description of model calibration, validation and verification is presented in the QAPP in general terms and as each relates to the current effort. A discussion of the important features for each model is included.
- The documentation and record-keeping process is sufficient, rigorous and defensible. In addition, the authors clearly define all directories where documentation and related model input, code, and output files will be located. This list looks comprehensive and shows foresight for adequate record keeping.
- The QAPP provides a description of the QA auditing process. The description covers points of potential error or contention including, but not limited to: assessment and oversight strategies, participants, responsibilities, scope of authority, and reports generated with a disclosure list. The process appears adequate to assure quality and identify deficiencies and includes monthly conference calls.
- Comparison of the Susquehanna Basin model with the Chesapeake Bay Watershed Model will provide another measure of baseline model calibration, especially within the sub-basins included in the model.

3.13.3 Big-Picture Data Gaps

- The primary objective of this project is to determine the relative impacts of hydraulic fracturing on stream flow and groundwater recharge. However, there is no discussion or description of how relative impact will be determined or quantified for current conditions (2010) or the future scenarios. For example, under the current conditions (2010) water use for hydraulic fracturing activities and the most current USGS data for competing water use will be incorporated into the baseline conditions model. The QAPP does not describe how model-predicted results associated with changes in USGS water use between baseline and current conditions will be separated from model-predicted results associated with hydraulic fracturing activities.
- An initial evaluation of the models' ability to meet the stated objectives is not described and appears to not have been performed. The approach relies on the use of existing and calibrated models for two large basins. The QAPP approach notes that water withdrawals for hydraulic fracturing activities is a small fraction of water use in most regions, but some areas (at sub-basin scale), at certain times of the year, may have justified concerns. The regional models selected for use in this evaluation may not have the appropriate resolution as currently constructed to evaluate relative impacts to stream flow or groundwater recharge at the sub-basin level at certain times of the year.
- The QAPP does not describe the rationale for selection of the baseline condition (2000) beyond the statement that this represents the time period prior to hydraulic fracturing operations through horizontal/directional well completions. The modeling effort will compare water withdrawals for hydraulic fracturing under different scenarios with a baseline condition (2000) to assess the relative impact of those withdrawals on two basins. Therefore, an understanding of the baseline condition (2000) is critical (for example, whether flow conditions are representative of a wet year, average year, or dry year [will be determined as part of the study]; whether water withdrawals are typical, high or low relative to historical data [no mention of whether or not this will be determined]).

- No acceptance criteria are provided to determine the need for recalibration of the baseline condition (2000) model following comparison to the Chesapeake Bay Watershed Model (Susquehanna Basin only) or as each are modified to include the changes noted in the QAPP ("A fine tuning of the calibration will be performed and documented as necessary"). In general, the need to perform any recalibration efforts is left to the professional judgment of the modeling team performing the work.
- The current conditions (2010) scenario includes all enhancements to the baseline model, adds in 2010 water withdrawals for hydraulic fracturing operations, and revises water use to the most recent data published by USGS in its 2009 report. There is no mention of updating weather data (e.g., precipitation), land use, population, etc. in the current conditions (2010) scenario or if only changes in water uses will be superimposed on the baseline (2000) model.
- Existing models for both basins cover a 20-year simulation timeframe. Segregating simulation years into drought, dry, median, wet, and very wet conditions can be misleading based only upon this 20-year period. Comparing long-term weather data with weather data for the 20-year simulation period would permit better understanding/context around segregation of the simulation years.
- Performance metrics and acceptance criteria are limited to model calibration and model uncertainty, both expressed in relative terms. Model calibration outputs will be ranked on a scale ranging from "poor" to "very good" based upon relative percent difference. Further, the QAPP notes "The level of uncertainty determined in calibration and validation will be documented to aid the decision makers in interpretation of results." It is unclear how the level of uncertainty in model calibration and validation will be quantified.
- No quantitative measure of model uncertainty will be completed. Uncertainty exists within the model input parameters (for example, the volume of water used in a hydraulic fracturing job is noted to range from 1 million to 5 million gallons; applying 5 million gallons to all hydraulic fracturing jobs in the future scenarios vs. 1 million gallons would give different relative results), within model conceptualization, and within the simplifying assumptions necessary to assemble and calibrate numerical models. The QAPP notes that performing quantitative uncertainty analysis for complex models is resource intensive and not justified for this study which is to define relative impacts. Rather, the QAPP notes that the project team will rely on decades of experience applying models to provide a qualitative assessment of overall model uncertainty and to compare and rank the sources of uncertainty. Water withdrawals for hydraulic fracturing are noted in the QAPP as a small fraction of the water use in most regions, but in some localities and some periods, there can be concerns at the subbasin level. In most regions, therefore, the impacts of water withdrawals for hydraulic fracturing may fall within the uncertainty of model input parameters and would not be discernible.
- There is a wide range of possible and plausible inputs into the future scenarios that add an additional level of uncertainty surrounding the futures scenarios. For example, 2010 BMPs are much different in 2012 as industry has adapted a policy for recycling a much larger percentage of flowback and produced water and is considering other sources of water (e.g., pre-treated acid mine drainage water) for hydraulic fracturing operations. Therefore, the 2010 BMPs overestimate the volume of water used per hydraulic fracturing job relative to the 2012 BMPs. Applying water use based upon 2010 practices to the maximum development scenario will multiply this effect across the entire model input and overestimate impacts from hydraulic fracturing operations.

- Reporting for the project is limited and includes only a Draft and Final QAPP, monthly progress reports, technical system audits for each model, journal manuscripts, and final model and other data files.

3.13.4 Recommendations for Improvement. Improvements to the QAPP focus on the need for more specific information:

- Define how relative impacts to stream flow and groundwater recharge from water withdrawals associated with hydraulic fracturing activities will be determined.
- Quantify the uncertainties in model predictions and assess under what conditions the model(s) can provide meaningful results that are clearly distinguished from uncertainties inherent in the predictions.
- Assess whether the existing basin models can meet the stated performance objectives or require modification to meet the objectives at a more refined scale.
- A description of how results will be reported would benefit reader understanding of the ultimate use and presentation of the modeling activities. The discussion of reporting could include data assessment reports, model science formulation report, peer review reports, model assessment reports, interim progress reports, code standards, code auditing and testing, interim project progress, model calibration and evaluation.

Table E-17 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

3.14 QAPP for Hydraulic Fracturing Scenario Modeling

3.14.1 Overall Summary. The QAPP for Analysis of Environmental Hazards Related to Hydrofracturing was prepared for EPA by the Lawrence Berkeley National Laboratory and approved in December 2011. The purpose of this modeling approach is to evaluate potential problems (i.e., failure scenarios) associated with hydraulic fracturing operations that could lead to the contamination of freshwater aquifers. Five different "failure scenarios" are discussed: improper casing, movement through abandoned wells, fracturing of overburden, fracturing of overburden and mixing with overlying conventional oil and gas reservoirs, and contaminant migration through sealed fault/fractures activated during stimulation. The modeling approach seeks to provide an evaluation of each of the five "failure scenarios," and will include information about the physical likelihood of an event occurring, the conditions (e.g., geological, geochemical, and casing properties) that could result in each of the failure scenarios, possible extent of the impact, short- and long-term effects, and the sensitivity of factors influencing each failure scenario.

3.14.2 Observations

- The QAPP is generally well written and detailed. It presents a credible approach to examine the likelihood and short- and long-term impacts of the described failure scenarios.
- The objectives and goals of the study are clearly defined and reasonable.
- The approach is objective and is not slanted toward finding an impact.
- The chosen modeling method is realistic, defensible, and includes the components important to any modeling approach (e.g., testing, verification, and a sensitivity analysis).

- The selected coupled models (TOUCH+ and FLAC3D) are peer reviewed, widely accepted, and are designed for the simulation of contaminant transport.
- While not all "failure scenarios" are likely to occur, the approach addresses this through the following evaluation criteria: physical likelihood of an event occurring, the conditions (e.g., geological, geochemical, and casing properties) that could result in each of the failure scenarios, possible extent of the impact, short- and long-term effects, and the sensitivity of factors influencing each failure scenario
- The modeling approach includes rigorous model testing and acceptance criteria that are described in the QAPP. The descriptions present a strong case for the defensibility of the data inputs and results.
- Model acceptance and testing criteria are clearly identified, rigorous and appropriate.
- Data needs and input parameters are clearly identified.
- Work is neatly split into nine discrete categories and a time table is applied to each of them. A detailed schedule of events is included: start and stop time of tasks, due dates of interim and final reports, and due dates of project deliverables.

3.14.3 Big-Picture Data Gaps

- The QAPP does not provide enough information to determine the process by which some of the work would be completed. For example:
  - The specific plan to evaluate data usability for the project is not described;
  - Data for determining input values are to be provided by a previous EPA study (and a citation of this study is included) but does not describe how the data were collected and whether the data are appropriate for the current use based on the original DQOs;
  - The QAPP does not define the focus of the technical systems audit or how the success criteria will be determined.
- The QAPP alludes to the use of the model beyond what would be appropriate. For example, the QAPP states the models "may in the future be used to evaluate proposed hydraulic fracturing projects to ensure that such unintended consequences are avoided." This confident prescience is beyond the capabilities of the described model; however, in conjunction with other methods, it might indeed provide evidence of possible prospective failures, especially if it can be calibrated against field data.

Several big-picture data gaps are important to the transparency of the process and quality of the data. These include:

- The data gathering procedures and the DQOs for the project cited as the source of input data are not discussed.
- The QAPP states that data will be evaluated for usability but the evaluation process and criteria are not detailed.
- While the code testing procedures are rigorous, the QAPP does not describe how the results of testing will be reported to assure that the code is running properly and the conclusions are defensible.

3.14.4 Recommendations for Improvement

- The most recurrent problem in the QAPP was the lack of discussion about DQOs and the process data evaluation. While the data are cited as being from a reliable source, a discussion of the DQOs and methods of collection would aid in the transparency of the QAPP and augment the validity of the claims resulting from the study.
- The process of data evaluation for usability in the current study is crucial. This process should be more than a line item in the QAPP and needs significant attention in interim and final reports.
- While the described procedures are rigorous, there is no plan to report on the results of model testing. Model testing is a crucial stage in the project and should be reported to assure the code was properly compiled and is running correctly.
- The QAPP lists "contaminant-laden deeper water rising to potable water aquifers through fractures faults, imperfectly completed wellbores, and compromised abandoned wells" as a potential part of the analysis of groundwater contamination. This statement is vague and implies a disregard for the chemical and physical properties of contaminants. These types of results should be reported with this disclaimer if the model does not account for contaminant and geochemical properties.
- Finally, the figures of the five potential failure scenarios (Figures 1 through 5) are not drawn to scale (and this is not indicated) and the overburden is depicted as smaller than it actually would be in a figure drawn to scale. Figures used in public reports or publications should either have a disclaimer stating they are not drawn to scale and/or clearly indicate a break in the size of the overburden and state that it is larger than it is depicted in the figure.

Table E-18 contains document-specific comments; addressing the issues raised will improve the clarity of the document.

Section 4.0: REFERENCES

Battelle, 2012. Detailed Analysis of the Quality Management Plan Prepared to Support the EPA Hydraulic Fracturing Study.

US EPA, 2000. EPA policy CIO 2105.0 (formerly EPA Order 5360.1 A2) Policy and Program Requirements for the Mandatory Agency-Wide Quality System. May 2000.

U.S, EPA. 2001. Requirements for Quality Assurance Project Plans, EPA QA/R-5. EPA/240/B-01/003. U.S. Environmental Protection Agency, Office of Environmental Information, Washington, D.C. March 2001.

US EPA, 2002a. Overview of the EPA Quality System for Environmental Data and Technology. EPA/240/R-2/003. U.S. Environmental Protection Agency, Office of Environmental Information, Washington, D.C. November 2002.

U.S, EPA. 2002b. Guidance for Quality Assurance Project Plans for Modeling, EPA QA/G-5M. EPA/240/R-02/007. U.S. Environmental Protection Agency, Office of Environmental Information, Washington, D.C. December 2002.

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

Table E-2. Detailed Review of the QAPP for Marcellus Shale/Washington County, PA

Page	Section	QAPP Comments Marcellus Shale/Washington County, PA
	General	The original QAPP date was July 2011. The first round of groundwater and surface water sampling was also conducted in July 2011. Approval of the QAPP pre-dated approval of the final study plan and QMP. The impact of completing the QAPP and initial sampling prior to these over-arching documents is not known. Since the QMP defers to the individual EPA and extramural organizations for many QA/QC functions, the impact may be minimal.
8	1.2	It is strongly recommended that a timeline be developed for the hydraulic fracturing activities in the area relative to the "complaints about appearance, odors and taste associated with water in domestic wells", especially considering the more habitual residential and/or agricultural practices in the area could likely impact drinking water resources.
8	1.2	The last paragraph states: "On the other hand, if anomalies are found, confirmation sampling would be planned, but also additional studies and methods might be adopted to track the source of contamination, whatever they might be." The QAPP should specify that any revisions to the document will be posted and distributed to ensure all participants and stakeholders are informed of the changes.
9	1.2	In addition to aqueous sampling during Phase I, it is recommended that headspace measurements be collected from the well vault/head during the sampling event to determine if methane gas has collected within the well.
9	1.2	Phase I sampling was scheduled for late October 2011. The results of this sampling have not been made available to stakeholders and a revised QAPP for Phase II has not been posted.
10	1.3	The sampling rationale for each location should be based on a systematic planning process. The QAPP does not describe the reason that sampling locations were selected (e.g., alleged contamination [specify type of contamination], in close proximity to hydraulic fracturing activities, background or reference location, upgradient, downgradient, or cross-gradient location, or depth of the well screen interval) such that meaningful comparisons or relationships can be evaluated between locations. If the location was selected based on alleged contamination, then the timing of water quality changes in relation to hydraulic fracturing activities should be presented as part of the rationale.
11	1.3	The rationale for identifying the analytes presented in Table 2 as critical analytes should be presented because many of the critical analytes are naturally occurring and/or could be released to the environment via other activities besides hydraulic fracturing.
11	1.5	The last paragraph states: "Competency may be demonstrated through documentation of certification/accreditation or some other means as determined to be acceptable by project participants." Determination of laboratory acceptability should be objective not subjective. The QAPP should specify what 'other means' are acceptable to the project.
12	1.5	The analytical method for glycol analysis is being developed and validated by an EPA Region III laboratory. The QAPP does not specify that the method will be documented as a SOP and be available so that the analysis can be replicated by an independent laboratory.
12	1.6	The field and laboratory documentation generated for this study should be made available to stakeholders to ensure the transparency of the research process and results. The QAPP does not indicate that records will be made available to the public.
13	2.1.1	It is not clear if the groundwater analytical data reported by William et al. (1993) be used as the background or reference values for the study in Washington County. If not, the source for the background or reference values to be used for the study should be defined.
14	2.1.2	The QAPP does not define the exact sample collection point (e.g., well tap, homeowner tap, or down-hole pump) at each location such that the sampling event can be replicated by other parties.

Table E-2. Detailed Review of the QAPP for Marcellus Shale/Washington County, PA (Continued)

Page	Section	QAPP Comments Marcellus Shale/Washington County, PA
14	2.1.2	The QAPP states "Sampling locations were selected by interviewing individuals about their water quality and timing of water quality changes in relation to gas production activities." This is hear-say evidence and qualitative. The QAPP does not present data to support these interview statements.
14	2.2.1	The desired depth and/or location of the down-hole pump in the well during the purging process should be specified (e.g., 3 ft from bottom of well, middle of screened interval, middle of saturated screened interval).
14	2.2.1.1	The model, accuracy, and maintenance procedures for the handheld device used for collecting GPS coordinates should be specified, such that these locations can be accurately mapped and located in the future.
14	2.2.1.1	The QAPP does not define the decontamination procedures for the submersible pump (as well as any other non-dedicated equipment, e.g., water level indicator). Triple rinsing after sample collection to ensure that there is no cross-contamination between sampling locations is standard procedure: (1) rinse with potable water; (2) wash with Liquinox detergent and potable water and clean with a stiff-bristle brush; (3) rinse three times with deionized water; and (4) place on clean surface and air dry.
14	2.2.1.1	The QAPP does not describe the process by which the well construction diagrams and boring logs for each groundwater sampling location will be made available to interested parties.
14 & 15	2.2.1.1	The QAPP does not clarify whether geochemical parameters (i.e., pH, ORP, specific conductance, DO, and temperature) will only be collected during the purging process if the length of the well screen is ***unknown.*** The last paragraph states: "In cases where the screen volume can be calculated, three screen volumes will be targeted as the purge volume. In cases where the length of screen is not known or is too large (thus making purging of three screen volumes impractical), professional judgment will be used and the well will be purged until stabilization of geochemical parameters occurs." Typically, if three screen volumes are purged, then stabilization of geochemical parameters are unnecessary. Regardless, the 'geochemical parameter stabilization purging method' should be implemented at each groundwater sampling location such that a consistent sampling technique is employed at each location and that representative water quality parameters are collected from the well to evaluate groundwater or aquifer conditions.
15	2.2.1.1 (1)	The water sampling procedures described in this QAPP vary from those described for the Bradford-Susquehanna project in specific instances. Examples are listed below.
15	2.2.1.1 (4b)	Sampling procedure for dissolved gasses in this QAPP differ from the Bradford QAPP, which calls for using a bucket and inverting the sampling containers. The Bradford QAPP calls for preservations with sulfuric acid and a crimp cap vial.
16	2.2.1.1 (4i)	The QAPP does not define the filter pore size for dissolved samples and doesn't provide details that exist in the Bradford QAPP.
16	2.2.1.1 (4k)	Bradford QAPP lists samples for capillary electrophoresis (CE) sulfate, chloride, bromide and fluoride as filtered (dissolved) samples.
16	2.2.1.1 (4l)	Bradford QAPP lists samples for nitrate + nitrite and ammonium analysis as a filtered sample.
17	2.2.1.1 (4o)	Bradford QAPP lists samples for analysis of $\delta^{18}O$ and $\delta^{2}H$ of water using isotope ratio mass spectroscopy (IRMS) analysis as filtered samples. The sampling processing procedures should be verified as accurate.
17	2.2.1.1 (4p)	Bradford QAPP lists samples for strontium (Sr) isotope analysis using thermal ionization mass spectroscopy analysis as filtered samples. The sampling processing procedures should be verified as accurate.
18	2.2.1.2	The QAPP does not describe best practices for the collection of unfiltered surface water samples. These are best collected by extracting water from beneath the surface with dedicated tubing attached to a peristaltic pump (or equivalent). This methodology will minimize the potential loss of preservative placed in the sample container/bottle prior to

Table E-2. Detailed Review of the QAPP for Marcellus Shale/Washington County, PA (Continued)

Page	Section	QAPP Comments Marcellus Shale/Washington County, PA
		shipment out to the field. Using a grab sample technique, it would be difficult to control the flow rate into the sample container, thus increasing the potential of flushing the preservative out of the bottle as well as creating undesirable aeration of the sample.
18	2.2.1.2	The rationale for collecting geochemical parameters (until stabilization) from surface water sampling locations is not provided in the QAPP. Unlike groundwater locations (i.e., domestic wells), surface water sampling locations are significantly more dynamic; thus, it would be difficult to achieve parameter stabilization as well as replicate sampling at the exact same location in the future.
18	2.2.1.2	The rationale for using a high-capacity groundwater filter to be used to collect samples from monitoring wells for metals, anion, nitrate+nitrite, DIC/DOC, and all stable isotope analyses is unclear. For domestic wells, only metals analysis require unfiltered ***and*** filtered samples (see Section 2.2.1.1).
19	2.3.2	The QAPP does not specify immediate notification of the Principal Investigator if sample temperatures at receipt are >12ºC.
20	2.3.2	The text incorrectly references Region VIII rather than Region 3. This appears to be a carry-over from another QAPP.
21	2.4.1	The text should clarify which analyses will be conducted by Isotech for groundwater samples (i.e., domestic and monitoring wells) and surface water samples.
34	2.9	The QAPP states the limited secondary data supplied by homeowners and used as background information was considered usable if the laboratory QC requirements were achieved. There is no mention of determining who collected the data and if appropriate sample collection and handling procedures were used. Further, there is no discussion of laboratory accreditation in the methods used for analysis.
34	2.10.3	The QAPP does not specify the frequency of electronic data checks. Rather the QAPP states that data will be spot checked. The QAPP should specify both the frequency and amount of data to be checked.
34	2.10.3	The QAPP does not specify the frequency of spot checks between original data reports and data spreadsheets. The QAPP should specify both the frequency and amount of data to be checked.
40	6.0	Table 2: The reason that each analyte is a critical analyte for the project should be justified.
40	6.0	Table 2: The Bradford-Susquehanna County QAPP lists either RSKSOP-299v1 or 259v1 for analysis of volatile organic compounds (VOCs).
43	6.0	Table 4: The methodology for glycol analysis should be documented and provided to stakeholders as soon as available.
45	6.0	Table 6: Compounds analyzed by RSKSOP-259v1 are not listed and therefore detection limits are not defined.
49 - 52	6.0	Table 7: Detection and control limits are not provided for numerous SVOC compounds. The QAPP should define the detection limits and control criteria that will be applied to these compounds or describe plans to develop limits prior to sample analysis.
56	7.0	Table 9: The Bradford-Susquehanna County QAPP defines surrogate recovery criteria for semi-volatile organic analysis (SVOA) based on a DoD statistical study, not 60 to 130% as defined here. Since the same laboratory is performing analysis for both studies, the criteria should be the same.
56	7.0	Table 9: Reference to a solvent blank is not included in the Bradford-Susquehanna County QAPP Table 9. Since the same laboratory is performing analysis for both studies, the criteria should be the same.
56	7.0	Table 9: Criteria for LCS DRO, GRO don't mention SRMs.
56	7.0	Table 9: For the ICAL and CCV, the Table does not define standard criteria for extracted ion current profile (EICP) areas nor the initial multi-level calibration requirements.
56	7.0	Table 9: The second source standard criteria for SVOA are not the same as Bradford-Susquehanna County QAPP (70 - 130 for ICV1). Since the same laboratory is performing analysis for both studies, the criteria should be the same.

Table E-2. Detailed Review of the QAPP for Marcellus Shale/Washington County, PA (Continued)

Page	Section	QAPP Comments Marcellus Shale/Washington County, PA
56	7.0	Table 9: Criteria for LCS DRO, GRO don't mention SRMs as does the Bradford-Susquehanna QAPP. Since the laboratories performing the analyses are the same, the same QC samples and criteria should be cited in all the retrospective case study QAPPs.
56	7.0	Table 9: For DRO, the QAPP states that the LCS criteria should be applied to the MS. Since the laboratories performing the analyses are the same, the same QC samples and criteria should be cited in all the retrospective case study QAPPs.
56	7.0	Table 9: The MS/MSD criteria for SVOC RPD in the Bradford-Susquehanna QAPP are 30%. In this QAPP the criteria is 20%. Since the same laboratory is performing the analyses for both projects, the criteria should be the same.
57	6.0	Table 10: This table should be updated to include detection limits and reporting limits of glycols as soon as available and provided to stakeholders such that the analysis can be replicated by an independent party.
61	7.0	Table 14: The laboratory duplicate criteria and frequency in this QAPP are not the same as in the Bradford-Susquehanna QAPP.
62	7.0	Figure 1: All individuals listed in Section 1.1 should be illustrated so that responsibility, accountability, and communication pathways are clear.
63	7.0	Figure 2: It is strongly recommended that each sampling location be designated with "SWPAGWxx" or "SWPASWxx" prior to field sampling activities to minimize any potential error of designating the same sample ID to different locations, especially if multiple sampling teams are in the field during the same event.
63	7.0	Figure 2: It is recommended that other pertinent information be included in the site map (e.g., roads, locations of agricultural activities, locations of hydraulic fracturing activities, and gas pad locations) such that the proximity of sampling locations to potential source(s) of contamination can be evaluated as part of the study.

Table E-3. Detailed Review of the QAPP for Barnett Shale/Wise County, TX

Page	Section	QAPP Comments Barnett Shale/Wide County, TX
		The original QAPP date was August 2011. The first round of groundwater and surface water sampling was conducted in September 2011. Approval of the QAPP pre-dated approval of the final study plan and QMP. The impact of completing the QAPP and initial sampling prior to these over-arching documents is not known. Since the QMP defers to the individual EPA and extramural organizations for many QA/QC functions, the impact may be minimal.
		The document title page does not include basic information needed to define the document, e.g., client ID and person/organization that prepared the QAPP. The QAPP preparer did not sign the QAPP.
2	0	Section 4 is missing from the table of contents (TOC).
6	1	The organization chart is incomplete. The chart does not show reporting lines for QA staff and subcontractors. Both direct and indirect reporting needs to be defined.
7	1.2	The section does not provide any discussion of milestones, deliverables, or schedule of sampling. Later sections briefly discuss field schedule and refer to Table 2, which provides almost no information on schedule other than groundwater, surface water and soil sampling. The section does not define any regulations that may be affecting the work. Overall, there is little discussion on the final report contents.
7	1.2	The specific criteria used in selecting the Barnett Shale as a case study location over the initial pool of potential case study locations are not defined.
8	1.2.1	Phase 1 sampling, which is intended to determine if water resources have been impacted within the study areas, appears to have taken place in September 2011. The QAPP does not discuss if the hydraulic fracturing process is currently being conducted within any gas wells adjacent to the Phase 1 sampling points.
8	1.2.1	A timeline outlining the hydraulic fracturing operations conducted within the gas wells in the vicinity of the three study sites may be beneficial. The QAPP does not discuss when the most recent hydraulic fracturing activities were concluded within the adjacent gas wells. The details of the hydraulic fracturing process should be noted (volume and consistency of the fracturing fluid, fracturing date, etc.).
8	1.2.1	If domestic water well owners have noticed changes with produced water over time (i.e., water quality and production volumes fluctuating between acceptable/unacceptable), a water quality data set collected over time would be more representative of site conditions. Omitting a sampling point from the Phase 2 sampling group after one to two rounds of sampling may be premature if this is the case. Additionally the QAPP states in Section 2.1.2 that each data point will be sampled a minimum of four times. Domestic well owner observations in conjunction with a review of groundwater gradients, water well production logs, and regional aquifer conditions may be useful to determine fate and transport characteristics of potential contaminants of concern.
9	1.2.4	The QAPP does not discuss if the domestic water wells (i.e., sample points) fall within the subsurface footprint that would be expected to be impacted by the potential source areas at Location A (eight production wells, spill/leak locations, unauthorized solid/liquid release points, fractioning ponds, etc.).
9	1.2.4	The QAPP does not discuss if the current groundwater sampling network contains the scope needed to adequately detect any possible contamination associated with Location A.
9	1.2.4	The locations of the production wells, spill locations, and any other potential contaminant sources should be labeled on the Location A figure.
9	1.2.4	The QAPP does not discuss the specific criteria used in selecting Location A within the Barnett Shale (documents outlining the property owner concerns to drinking water, surface water, odors, and leaks and spills).
9	1.2.4	The QAPP does not indicate if the analytical data rendered from private testing conducted on the property owners drinking wells have been reviewed and if that data are presented.

Table E-3. Detailed Review of the QAPP for Barnett Shale/Wise County, TX (Continued)

Page	Section	QAPP Comments Barnett Shale/Wide County, TX
9	1.2.4	The QAPP does not reference existing records outlining complaints, documenting spills, etc. for the stated potential impacts from the oil and gas operations in the area surrounding Location A.
9	1.2.4	Soil sampling has been mentioned in previous sections of this QAPP. The QAPP does not indicate if surface soil sampling is planned at Location A due to the reported spill/leak/unauthorized disposal history at the site and does not provide a site map showing soil sampling locations and outlining the scope of the sampling.
9	1.2.5	The QAPP does not define the initial scope of the sampling to be conducted at Location B.
9	1.2.5	The QAPP does not define the factors considered when selecting the scope of study Location B.
10	1.2.5	A map plotting the production wells, domestic wells, salt water injection well, and any possible source areas (holding ponds, rigs, etc.) would be useful.
10	1.2.5	Well records for the salt water injection well should be reviewed for injection interval(s), injection rates and volumes, etc.
10	1.2.6	The QAPP does not define the initial scope of the sampling to be conducted at Location C.
10	1.2.6	The QAPP does not define the factors considered when selecting the scope of study Location C.
10	1.2.6	The location of the sampling points along with any potential sources should be plotted to show the spatial relationship.
10	1.2.6	The QAPP does not indicate if the available analytical data indicating a "possible problem" will be made available in the spirit of transparency with stakeholders.
10	1.2.6	The QAPP does not specify what the “possible problem” at Location C is referred to in this section.
10	1.3	The QAPP does not define the factors involved with selecting the scope of this project (sampling of 10 domestic wells and two surface water locations).
10	1.3	The QAPP does not present the rationale that led to the conclusion that the selected scope of the study would adequately address the primary objective of the study: to determine if the groundwater resources in Wise County, TX have been impacted by hydraulic fracturing processes.
10	1.3	Hypothesis testing and applicable regulations are not discussed.
11	1	The document does not reference any systematic planning conducted to design the sampling plan. The QAPP references internal laboratory SOPs for details. These documents are not publically available and are not attached to the QAPP.
11	1.4	This section does not discuss overall project quality objectives or use of the DQO process to determine the type and quantity of data needed to answer the study questions. The two sentences in the section are focused on analytical chemistry data rather than the overall project objectives.
11	1.5	The first paragraph states: "Competency may be demonstrated through documentation of certification/accreditation or some other means as determined to be acceptable by project participants. This could include quality documentation, such as laboratory manuals, Quality Management Plans, and detailed SOPs." Laboratory competency should be based on objective evidence of demonstrated capability rather than documentation. Minimum criteria should be defined, e.g., successful analysis of two PE samples each year and analyst demonstrations of capability. The analytical method for glycol analysis is being developed and validated by an EPA Region III laboratory. The QAPP does not specify that the method will be documented as a SOP and be available so that the analysis can be replicated by an independent laboratory.
11	1.6	The document contains vague and generic statements on document control. There is no discussion on how records will be handled (not addressed in PPM 13.2) or what the retention time of records will be. Although schedule 501 is publically available, it is not readily accessible. Therefore, storage times should be defined.

Table E-3. Detailed Review of the QAPP for Barnett Shale/Wise County, TX (Continued)

Page	Section	QAPP Comments Barnett Shale/Wide County, TX
13	2.1	The document does not outline sampling design or rationale in detail. It only briefly addresses monitoring activities. The document does not clearly define the sampling plan transition from Phase 1 to Phase 2.
14	2.1.2	The history of hydraulic fracturing within the vicinity of the three study locations should be documented and outlined.
14	2.1.2	Any hydraulic fracturing-related activities that occur over this time (fall 2011 to spring 2013) should be documented. The details on the history of hydraulic fracturing within the vicinity of the three study locations is missing. The information will add to the rationale of the experimental design. Details on any hydraulic fracturing-related activities that occur during the sampling activity (fall 2011 to spring 2013) is missing.
14	2.1.2	The QAPP does not describe the process used to determine the number of groundwater sampling events (4).
15	2.2.1.1	The QAPP does not specify that headspace readings will be taken at the well head prior to sampling.
15	2.2	Very few SOP citations are provided, and those included are not publically available.
20	2.4	The discussion of analytical procedures is limited to the analytical equipment and references to internal SOPs and EPA methods. The SOPs are not provided to detail how the methods will be implemented.
22	2.5	The discussion of detection limits does not describe the methods used to establish detection and reporting limits for the critical and non-critical parameter classes.
25	2.6	The section for instrument/equipment testing, inspection, and maintenance refers to SOPs for all information, but the SOPs are not publically available documents and therefore this information cannot be determined. This information should be summarized here or appended to the end of the document.
26	2.7	The section on instrument/equipment calibration and frequency refers to SOPs for all information, but the SOPs are not publically available documents and therefore this information cannot be determined. This information should be summarized here or appended to the end of the document.
27	2.9	The QAPP states the limited secondary data supplied by homeowners and used as background information was considered usable if the laboratory QC requirements were achieved. There is no mention of determining who collected the data and if appropriate sample collection and handling procedures were used. Further, there is no discussion of laboratory accreditation in the methods used for analysis.
27	2.10	• There is no reference to standard record keeping procedures, EPA schedules (which is noted earlier in the document), and only provides very basic equipment information (e.g., computer systems for analysis/storage). • The section indicates that 10% of the manually entered data will be verified by the Principal Investigator. This is insufficient. Either 100% of hand-entered data should be verified or a random sampling method designed to ensure accuracy to a defined level of confidence should be established. • Data will be entered in the Principal Investigator's computer by others. This raises questions about data access and the integrity of the computer. Further, the method and frequency of transferring data from the computer to the network "M" drive that will be backed up is not defined. Also, the frequency of backup is not defined. • The section does not provide any discussion on the verification and validation of data, statistical calculations, software, etc.

Table E-3. Detailed Review of the QAPP for Barnett Shale/Wise County, TX (Continued)

Page	Section	QAPP Comments Barnett Shale/Wide County, TX
29	3.1	The assessment and oversight section lacks detail that is provided in other case study QAPPs. The QAPP states that ADQs will be conducted on a representative sample of data, but no criteria for what is considered representative is discussed, or how the data will be assessed. There is a discussion on the preparation of audit reports, but it does not include what will be discussed in the audit reports or what the timeframe is for personnel to address comments in audit reports or how these findings will be reported to management.
31	4.1	The section describes data verification for each laboratory that will perform analysis for the study. The QAPP should establish minimum, consistent verification procedures for the study such that all data receive the same level and type of review within the laboratory.
31	4.2	The section states that a contractor will validate a representative sample of critical analytes. The amount of data to be validated, how the data will be selected for validation, and the validation level are not defined The text does not clearly define who will apply data qualifiers for each type of data.
32	4.3	The section does not define how critical vs. non-critical data will be used. It does not describe how flagged data and outliers will be treated.

Table E-4. Detailed Review of the QAPP for Bakken Shale/Killdeer County

Page	Section	QAPP Comments Bakken Shale/Killdeer County
1	0	The document title page does not include basic information needed to define the document, e.g., client ID and person/organization that prepared the QAPP. The QAPP preparer did not sign the QAPP.
2	0	Section 4 is missing from the TOC.
6	1.1	The organization chart is incomplete. The chart does not show reporting lines for QA staff and subcontractors. Both direct and indirect reporting needs to be defined.
8	1.2	The section does not provide any discussion of milestones, deliverables, or schedule of sampling. The schedule for field activities is listed in Table 4. The section does not define any regulations that may be affecting the work. Overall, there is little discussion on the final report contents. It is not clear if the sampling will include surface water sampling as part of Phase I or Phase II sampling.
8	1.2	Assuming that other well blowout sites were included within the initial pool of potential study sites, the QAPP does not define the criteria used in selecting the Bakken Shale site as a case study location.
9	1.2	The monitoring well network at the site was installed in September 2010 and expanded in April 2011; however, the QAPP states that it is unknown if groundwater contamination occurred and what the extent of the groundwater contamination might have been. The QAPP does not discuss if the groundwater monitoring network has been sampled to date and the availability of the analytical data.
9	1.2.1	It is not clear from the given text if the unauthorized release (spill) which occurred during the well blowout impacted the soil at the site. Given the provided well screen intervals at the site along with the approximated blowout depth, it is possible that soils could be impacted. Soil sampling should occur at the site in order to adequately characterize the type and state of possible contaminants at the site. If soil sampling has been conducted in the past at this site, this should be discussed in the QAPP.
10	1.3	Hypothesis testing and applicable regulations are not discussed.
10	1.3	The monitoring well network at the site was installed in September 2010 and expanded in April 2011. It is unclear whether the expansion was due to the inadequacy of a sound monitoring network.
11	1.4	The QAPP does not discuss whether the contractor overseeing the assessment of the site, Terracon, has submitted any reports such as groundwater monitoring reports, site assessment reports, well installation reports, etc. If so, these reports should be reviewed and referenced as the content would likely be very informative in this study.
11	1.4	The groundwater monitoring reports, site assessment reports, well installation reports, and references have not been included in the document. The QAPP references internal laboratory SOPs for details. These documents are not publically available and are not attached to the QAPP.
11	1.5	The first paragraph states: "Competency may be demonstrated through documentation of certification/accreditation or some other means as determined to be acceptable by project participants. This could include quality documentation, such as laboratory manuals, Quality Management Plans, and detailed SOPs." Laboratory competency should be based on objective evidence of demonstrated capability rather than documentation. Minimum criteria should be defined, e.g., successful analysis of two performance evaluation samples each year and analyst demonstrations of capability. The analytical method for glycol analysis is being developed and validated by an EPA Region III laboratory. The QAPP does not specify that the method will be documented as a SOP and be available so that the analysis can be replicated by an independent laboratory.

Table E-4. Detailed Review of the QAPP for Bakken Shale/Killdeer County (Continued)

Page	Section	QAPP Comments Bakken Shale/Killdeer County
12	1.6	The document contains vague and generic statements on document control. There is no discussion on how records will be handled (not addressed in PPM 13.2) or what the retention time of records will be. Although schedule 501 is publically available, it is not readily accessible. Therefore, storage times should be defined.
14	2.1	As the figures are blacked out, it is unclear if the spatial distribution of the sampling design is adequate. Monitoring well completion diagrams and boring logs for the monitoring wells being used in this study have not been included in the document.
14	2.1	The QAPP states that it will be revised to address additional sampling events. The QAPP does not describe the distribution and posting of the revised QAPPs for these additional sampling events.
15	2.1.2	Monitoring well completion diagrams and boring logs for the monitoring wells being used in this study would be beneficial.
16	2.2	Very few SOP citations are provided, and those included are not publically available.
19	2.2.1.2	The QAPP does not state if well diameter, well depth, screen interval, or pump flow rate data were recorded during the July 2011, October 2011, or November 2011 sampling events. These data would be of interest to the stakeholders.
23	2.4	The discussion of analytical procedures is limited to the analytical equipment and references to internal SOPs and EPA methods. The SOPs are not provided to detail how the methods will be implemented.
25	2.5	The discussion of detection limits does not describe the methods used to establish detection and reporting limits for the critical and non-critical parameter classes.
28	2.6	The section for instrument/equipment testing, inspection, and maintenance refers to SOPs for all information, but the SOPs are not publically available documents and therefore this information cannot be determined. This information should be summarized here or appended to the end of the document.
29	2.7	The section on instrument/equipment calibration and frequency refers to SOPs for all information, but the SOPs are not publically available documents and therefore this information cannot be determined. This information should be summarized here or appended to the end of the document.
30	2.9	The QAPP states the limited secondary data supplied by homeowners and used as background information was considered usable if the laboratory QC requirements were achieved. There is no mention of determining who collected the data and if appropriate sample collection and handling procedures were used. Further, there is no discussion of laboratory accreditation in the methods used for analysis
30	2.10	• There is no reference to standard record keeping procedures, EPA schedules (which is noted earlier in the document), and only very basic equipment information (e.g., computer systems for analysis/storage). • The section indicates that 10% of the manually entered data will be verified by the Principal Investigator. This is insufficient. Either 100% of hand-entered data should be verified or a random sampling method designed to assure accuracy to a defined level of confidence should be established. • Data will be entered in the Principal Investigator's computer by others. This raises questions about data access and the integrity of the computer. Further, the method and frequency of transferring data from the computer to the network "M" drive that will be backed up is not defined. Also, the frequency of backup is not defined. • The section does not provide any discussion on the verification and validation of data, statistical calculations, software, etc.

Table E-4. Detailed Review of the QAPP for Bakken Shale/Killdeer County (Continued)

Page	Section	QAPP Comments Bakken Shale/Killdeer County
33	3.1	The assessment and oversight section lacks detail that is provided in other case study QAPPs. The QAPP states that ADQs will be conducted on a representative sample of data, but no criteria for what is considered representative is discussed, or how the data will be assessed. There is a discussion on the preparation of audit reports, but it does not include what will be discussed in the audit reports or what the timeframe is for personnel to address comments in audit reports or how these findings will be reported to management.
35	4.1	The section describes data verification for each laboratory that will perform analysis for the study. The QAPP should establish minimum, consistent verification procedures for the study such that all data receive the same level and type of review within the laboratory.
35	4.2	The section states that a contractor will validate a representative sample of critical analytes. The amount of data to be validated, how the data will be selected for validation, and the validation level are not defined. The text does not clearly define who will apply data qualifiers for each type of data.
36	4.3	The section does not define how critical vs. non-critical data will be used. It does not describe how flagged data and outliers will be treated.
70	Fig 2	The locations of the sampling points and the Franchuk 44-20SHW cannot be identified on this map (aerial view). The geographic locations of the sampling points in relation to the potential source area is important when determining if the scope of the project is sufficient to detect any possible contaminants.
72	Fig 4	A map with better resolution should be provided. Figure 4 (Locations of Monitoring well network for Franchuck 44-20SWH) is illegible.

Table E-5. Detailed Review of the QAPP for Raton Basin

Page	Section	QAPP Comments Raton Basin
NA	General	The original QAPP date was September 2011. The first round of groundwater and surface water sampling was conducted in October 2011. The document was revised in April 2012 before the scheduled second round of sampling (but has not been made available to the public). Approval of the QAPP pre-dated approval of the final study plan and QMP. The impact of completing the QAPP and initial sampling prior to these over-arching documents is not known. Since the QMP defers to the individual EPA and extramural organizations for many QA/QC functions, the impact may be minimal.
NA	NA	The document title page does not include basic information needed to define the document, e.g., client ID and person/organization that prepared the QAPP. The QAPP preparer did not sign the QAPP.
5	1.1	The organization chart is incomplete. The chart does not show reporting lines for QA staff and subcontractors. Both direct and indirect reporting needs to be defined.
7	1.2	Assuming other potential case study areas also involved complaints concerning appearance, odors and taste associated with water in domestic wells, the QAPP does not define the criteria used in selecting the Raton Basin as a case study location over the initial pool of potential case study locations (number of domestic water well owner complaints, domestic water well owner complaint subject matter, geographic distribution of complaints, historic analytical data results and/or availability, etc.).
7	1.2	Additional potential sources of groundwater contamination should also be noted (coal outcrops, coal mines and vents, natural seeps, etc.).
8	1.2	The QAPP does not discuss whether hydraulic fracturing-related activities are the only source of contamination that have the possibility to impact the selected sampling points, within reason.
8	1.2	The QAPP does not state whether domestic water well owners have noticed changes within produced water over time (i.e., water quality and production volumes fluctuating between acceptable/unacceptable). If so, a water quality data set collected over time would be more representative of site conditions. Omitting a sampling point from the Phase II sampling group after one to two rounds of sampling may be premature if this is the case. Additionally, Section 2.1.2 states that a minimum number of sampling events to determine if an impact is present is estimated to be four sampling events.
8	1.2	Domestic well owner observations in conjunction with a review of groundwater gradients, water well production logs, and regional aquifer conditions may be useful to determine fate and transport characteristics of potential contaminants of concern.
8	1.2	Phase I sampling, which is intended to determine if water resources have been impacted within the study areas, appears to have taken place in October 2011. The QAPP should discuss whether the hydraulic fracturing process was currently being conducted within any gas wells adjacent to the Phase I sampling points.
8	1.2	A timeline outlining the hydraulic fracturing operations conducted within the gas wells in the vicinity of the two study sites may be useful. The most recent hydraulic fracturing activities concluded within the adjacent gas wells should be determined and defined. If any hydraulic fracturing activities have been conducted within adjacent gas wells in the past, the details of the hydraulic fracturing process should be noted (volume and consistency of the fracturing fluid, fracturing date, etc.) in the QAPP.
9	1.3	Hypothesis testing and applicable regulations are not discussed.
10	1.4	The document does not reference any systematic planning conducted to design the sampling plan. The QAPP references internal laboratory SOPs for details. These documents are not publically available but are not attached to the QAPP.

Table E-5. Detailed Review of the QAPP for Raton Basin (Continued)

Page	Section	QAPP Comments Raton Basin
10	1.5	The first paragraph states: "Competency may be demonstrated through documentation of certification/accreditation or some other means as determined to be acceptable by project participants. This could include quality documentation, such as laboratory manuals, Quality Management Plans, and detailed SOPs." Laboratory competency should be based on objective evidence of demonstrated capability rather than documentation. Minimum criteria should be defined, e.g., successful analysis of two performance evaluation samples each year and analyst demonstrations of capability. The analytical method for glycol analysis is being developed and validated by an EPA Region III laboratory. The QAPP does not specify that the method will be documented as a SOP and be available so that the analysis can be replicated by an independent laboratory.
11	1.6	The document contains vague and generic statements on document control. There is no discussion on how records will be handled (not addressed in PPM 13.2) or what the retention time of records will be. Although schedule 501 is publically available, it is not readily accessible. Therefore, storage times should be defined.
12	2.1	The document does not outline sampling design or rationale and only briefly addresses monitoring activities.
8	1.2	The section does not provide any discussion of milestones, deliverables, or schedule of sampling. Later sections briefly discuss the schedule and refer to Table 3, which provides almost no information on schedule other than that the groundwater and surface water sampling will occur over 4 months. The section does not define any regulations that may be affecting the work. Overall, there is little discussion on the final report contents.
9	1.2	According to the QAPP, vertical separation between production intervals of coal bed methane and interference with water supply wells is correlated. The document does not indicate whether the vertical separation between production intervals of coal bed methane and water supply wells being used in the two study areas has been assessed.
9	1.3	The QAPP does not define the specific scope of the Phase I sampling to be conducted at each of the two study areas within the Raton Basin.
9	1.3	The QAPP does not explain specifically why the two case study sites (Las Animas and Huerfano Counties) within the Raton Basin were selected (decreased groundwater quality in conjunction with increased hydraulic fracturing activities, recent increases in methane entrained in produced groundwater, number of domestic water well owner complaints, domestic water well owner complaint subject matter, geographic distribution of complaints, historic analytical data results and/or availability, etc.).
9	1.3	The QAPP does not explain specifically why the gas-producing fields of North Fork Ranch Area and Little Creek Field were selected.
9	1.3	The QAPP states that the total number of possible sampling locations exceeds what can realistically be sampled and delivered to the analytical laboratories in one week of sampling but does not quantify the possible number of sampling locations. Possible sampling locations transposed over a map containing the actual sampling locations, along with potential sources of contamination, may be useful in visualizing all known possible sampling locations.
9	1.3	The QAPP does not define the specific criteria used to omit the possible sampling locations from the selected sampling locations.
9	1.3	The QAPP does not define the factors involved in selecting the scope of the sampling event.
9	1.3	It is not clear whether the water sample obtained from the production well will be used as a baseline.
9	1.3	The QAPP does not clearly discuss whether contaminants of concern have ever been detected in water produced from the production well.
9	1.3	The QAPP does not reference any analytical history on record for the selected production well – e.g., the constituents of concern sampled for in the selected well in the past, and the sampling time interval used.

Table E-5. Detailed Review of the QAPP for Raton Basin (Continued)

Page	Section	QAPP Comments Raton Basin
9	1.3	The QAPP does not specify whether the results collected from the production well will be used for both study areas.
9	1.3	The QAPP does not describe whether both study areas draw water from this single production well.
9	1.3	The QAPP does not discuss whether the water produced from this well are representative of both Raton Basin study areas.
9	1.3	The QAPP does not discuss whether the production well will be sampled for the duration of this study, on occasion, or once.
9	1.3	Due to the fact that the provided figures are blacked out, it is unknown by the reader where the production well is located.
9	1.3	The QAPP does not discuss whether the location of potential contaminant source(s) in relationship to the sampling points was considered when selecting the sampling points, or whether the sampling point selection was based upon reported water quality concerns only.
9	1.3	The QAPP does not discuss whether any of the domestic water wells selected for use in this study were selected at random (i.e., wells selected without a history of water quality/production degradation).
9	1.3	In the QAPP provided, the sampling sites are blacked out in the provided figures. Thus, the spatial distribution and locations of the sampling points cannot be addressed. A copy of the figures would help to fully comprehend the study.
9	1.3	The QAPP does not define the criteria used to confirm that the selected scope of sampling for the Raton Basin, defined as the sampling of one production well, three monitoring wells, 14 domestic wells, and one surface water location, would be adequate in order to detect any possible impacts to the water resources.
15	2.1.2	Domestic wells which have no documented history of adverse water quality/production impacts within the study areas may also provide valuable data (regional aquifer water quality data, horizontal distribution of possible contaminants of concern, etc.). Including domestic water wells believed to be non-impacted wells within the study area should be considered.
15	2.1.2	If any hydraulic fracturing activities occur at wells within the footprint of the study areas during the course of the study, the activities should be noted.
15	2.2	Very few SOP citations are provided, and those included are not publically available.
15	2.2.1	The QAPP does not discuss whether head space readings within the well vault/well house/etc. will be collected by field personnel during sampling activities and visual inspections.
15	2.2.1	The QAPP does not define at what depth within the water column in the well the pump inlet be placed.
19	2.2.2	The QAPP does not define at what depth within the water column in the well the pump inlet be placed. In certain situations, possible contaminants of concern may be found in higher concentrations at different zones within the water column.
22	2.4	The discussion of analytical procedures is limited to the analytical equipment and references to internal SOPs and EPA methods. The SOPs are not provided to detail how the methods will be implemented.
26	2.5	The discussion of detection limits does not describe the methods used to establish detection and reporting limits for the critical and non-critical parameter classes.
30	2.6	The section for instrument/equipment testing, inspection, and maintenance refers to SOPs for all information, but the SOPs are not publically available documents and therefore this information cannot be determined. This information should be summarized here or appended to the end of the document.
31	2.7	The section on instrument/equipment calibration and frequency refers to SOPs for all information, but the SOPs are not publically available documents and therefore this information cannot be determined. This information should be summarized here or appended to the end of the document.

Table E-5. Detailed Review of the QAPP for Raton Basin (Continued)

Page	Section	QAPP Comments Raton Basin
32	2.9	The QAPP states the limited secondary data supplied by homeowners and used as background information was considered usable if the laboratory QC requirements were achieved. There is no mention of determining who collected the data and if appropriate sample collection and handling procedures were used. Further, there is no discussion of laboratory accreditation in the methods used for analysis.
33	2.10	• There is no reference to standard record keeping procedures, EPA schedules (which is noted earlier in the document), and only very basic equipment information (e.g., computer systems for analysis/storage). • The section indicates that 10% of the manually entered data will be verified by the Principal Investigator. This is insufficient. Either 100% of hand-entered data should be verified or a random sampling method designed to ensure accuracy to a defined level of confidence should be established. • Data will be entered in the Principal Investigator's computer by others. This raises questions about data access and the integrity of the computer. Further, the method and frequency of transferring data from the computer to the network "M" drive that will be backed up is not defined. Also, the frequency of backup is not defined. • The section does not provide any discussion on the verification and validation of data, statistical calculations, software, etc.
35-36	3.1	The assessment and oversight section lacks detail that is provided in other case study QAPPs. The QAPP states that ADQs will be conducted on a representative sample of data, but no criteria for what is considered representative is discussed, or how the data will be assessed. There is a discussion on the preparation of audit reports, but it does not include what will be discussed in the audit reports or what the timeframe is for personnel to address comments in audit reports or how these findings will be reported to management.
37	4.1	The section describes data verification for each laboratory that will perform analysis for the study. The QAPP should establish minimum, consistent verification procedures for the study such that all data receive the same level and type of review within the laboratory.
37	4.2	• The section states that a contractor will validate a representative sample of critical analytes. • The amount of data to be validated, how the data will be selected for validation, and the validation level are not defined. • The text does not clearly define who will apply data qualifiers for each type of data.
39	4.3	The section does not define how critical vs. non-critical data will be used. It does not describe how flagged data and outliers will be treated.
45	6.0	Table 2: The reason that each analyte is a critical analyte for the project should be justified in the text.
47	6.0	Table 4 does not list the critical parameter group "Major Cations" (Ca, Mg, Na, K) analyzed by Shaw.
49	6.0	Table 5 states that the Principal Investigator will determine if field QC failures are significant relative to the sample data. The criteria used to perform this assessment are not defined. Objective criteria should be defined for this assessment.
59	6.0	Table 8 states that corrective action for QA/QC failures is defined in the SOP. However, the QAPP should define the corrective action appropriate for the project since the SOPs are not attached to the document.
59	6.0	Table 8. The calibration and QC criteria for dissolved inorganic carbon/dissolved organic carbon (DIC/DOC) and O, H stable isotopes of water do not agree with the revised Bradford-Susquehanna QAPP and should be updated in the next version of the QAPP.
59	6.0	Table 8 states that corrective action for QA/QC failures is defined in the SOP. However, the QAPP should define the corrective action appropriate for the project since the SOPs are not attached to the document.

Table E-5. Detailed Review of the QAPP for Raton Basin (Continued)

Page	Section	QAPP Comments Raton Basin
62	6.0	Table 9 does not define corrective action.
NA	6.0	Several laboratories do not incorporate a laboratory control sample into their QC sample suite. A laboratory control sample is recommended so that matrix interference with spiked recoveries can be assessed.
64	6.0	Table 10: This table should be updated to include detection limits and reporting limits of glycols as soon as available and provided to stakeholders such that the analysis can be replicated by an independent party.

Table E-6. Detailed Review of the QAPP for Marcellus Shale/Bradford County, PA

Page	Section	QAPP Comments Hydraulic Marcellus Shale/Bradford County, PA
NA	General	The original QAPP date was September 2011. The first round of groundwater and surface water sampling was conducted in October/November 2011. The document was revised in April 2012 before the scheduled second round of sampling. Approval of the QAPP pre-dated approval of the final study plan and QMP. The impact of completing the QAPP and initial sampling prior to these over-arching documents is not known. Since the QMP defers to the individual EPA and extramural organizations for many QA/QC functions, the impact may be minimal.
NA	General	The rationale for how the retrospective case study location was selected out of the initial pool of potential study locations is not discussed in detail.
NA	General	The QAPP does not discuss background conditions or compare analytes of drinking and surface water concentrations with background levels
NA	General	It is not clear how "impact" will be assessed. The study design does not include "reference" wells and surface water where other sources of contamination could originate that are not related to hydraulic fracturing.
NA	General	The QAPP does not include an assessment of industry or other activities unrelated to hydraulic fracturing that could impact water quality.
	General Comments	The QAPP provides no information regarding the construction details (or boring logs) for each of the groundwater sampling locations (and does not even specify the exact sampling locations). Typically, this information is collected during development of the QAPP, so the investigation can be duplicated by an independent party.
	General Comments	The QAPP does not describe the use of critical vs. non-critical data and the rationale for including compounds in these categories.
	General Comments	The QAPP does not discuss background conditions or compare analytes of drinking and surface water concentrations with background levels.
	General Comments	SOPs are listed for field sampling, RSK general, and Shaw-RSK procedures but are not provided as attachments to the QAPP in accordance with EPA QAPP requirements. This is particularly important for several procedures where detailed procedures, acceptance criteria and/or corrective actions are not included in the QAPP but rather reference the SOPs.
	General Comments	There is no reference to field safety procedures (e.g., a Site-specific Health and Safety Plan, Activity Hazard Analyses) except for HAZWOPER training.
7	1.2	The text does not describe the decision and selection process for any additional locations identified for sampling during Phase 2.
7	1.2	All potential sources of groundwater contamination should be discussed in the QAPP.
10	1.5	The first paragraph states: "Competency may be demonstrated through documentation of certification/accreditation or some other means as determined to be acceptable by project participants. This could include quality documentation, such as laboratory manuals, Quality Management Plans, and detailed SOPs." Laboratory competency should be based on objective evidence of demonstrated capability rather than documentation. Minimum criteria should be defined, e.g., successful analysis of two performance evaluation samples each year and analyst demonstrations of capability.
10	1.5	The analytical method for glycol analysis is being developed and validated by an EPA Region III laboratory. The QAPP does not specify that the method will be documented as a SOP and be available so that the analysis can be replicated by an independent laboratory.
11	1.6	The field and laboratory documentation generated for this study should be made available to stakeholders to ensure the transparency of the research process and results. The QAPP does not indicate that records will be made available to the public.
11	1.6	Field data forms are typically provided as QAPP attachments unless a separate SAP will be prepared for sampling events. Since no SAP is referenced, the field forms should be attached to the QAPP.

Table E-6. Detailed Review of the QAPP for Marcellus Shale/Bradford County, PA (Continued)

Page	Section	QAPP Comments Hydraulic Marcellus Shale/Bradford County, PA
11	2.1.1	The source and analytical characterization of the background groundwater is not discussed or provided. These data should be used for comparison with sample results collected during the Phase I activities.
11	2.1.1	The median concentrations of total dissolved solids, dissolved barium, and dissolved chloride levels in restricted flow zones are defined but the median concentrations of these analytes in unrestricted flow zones are not. These concentrations should be defined so that a quantitative (instead of qualitative) comparison can be made to the values presented for restricted flow zones.
12	2.1.2	The QAPP does not describe a systematic planning process used to develop the sampling rationale for each location The QAPP states that groundwater and surface water monitoring locations were selected by interviewing individuals about their water quality and timing of water quality changes in relation to gas production activities. The discussion does not indicate if sampling locations were selected due to alleged contamination (specify type of contamination), in close proximity to hydraulic fracturing activities, background or reference location, upgradient, downgradient, or cross-gradient location, or depth of the well screen interval such that meaningful comparisons or relationships can be evaluated between locations. If the location was selected based on alleged contamination, then the timing of water quality changes in relation to hydraulic fracturing activities should be presented as part of the rationale.
12	2.1.2	The QAPP does not define the exact sample collection point (e.g., well tap, homeowner tap, or down-hole pump) at each location such that the sampling event can be replicated by other parties. However, dedicated sampling tubing and fittings/adapters, as applicable, will be left in place by ORD to facilitate follow-up sampling by other stakeholders.
12	2.2.1	The depth and/or location of the submersible pump in the well during the purging process is not defined (e.g., 3 ft from bottom of well, middle of screened interval, middle of saturated screened interval).
13	2.2.1.1	The model, accuracy, and maintenance requirements for the handheld device used for collecting GPS coordinates are not defined.
13	2.2.1.1	The QAPP does not describe the process by which the well construction diagrams and boring logs for each groundwater sampling location will be made available to interested parties.
13	2.2.1.1	The decontamination procedures for the submersible pump (as well as any other non-dedicated equipment, e.g., water level indicator, indicates that the pump will be thoroughly rinsed with distilled water between sampling wells. The QAPP should define 'thoroughly' since this is subjective.
15	2.2.1 (m)	The section indicates that a water sample for archiving will be collected and shipped to GWERD for future use. The QAPP should clarify that data generated from this sample will not be used to meet the project objectives if holding times and conditions defined by published methods will not be met. The shipping address for GWERD is not defined in Section 2.3.2.
19	2.4.1	The revised QAPP contains new italicized text that appears to be from a laboratory statement of work because it contains references to "the vendor" or "the contractor." The use of this terminology confuses the assignment of tasks among laboratories and could indicate that the analytical work may be subcontracted.
24	2.4.1	The section states that the DRO calibration standard will be DF#2 from a Texaco station. However, Method 8015 states that whenever possible, the same type of fuel that is expected in the samples should be used for the calibration. The QAPP should describe how data will be assessed since any DRO detected may not be the same as the DF#2 obtained from the Texaco station.
25	2.5	There is no mention that laboratory control samples will be analyzed by the RSKERC General Procedures and Shaw laboratories on site at RSKERC. A laboratory control sample is typically included in each analytical batch to assess laboratory accuracy and

Table E-6. Detailed Review of the QAPP for Marcellus Shale/Bradford County, PA (Continued)

Page	Section	QAPP Comments Hydraulic Marcellus Shale/Bradford County, PA
		extraction/processing efficiency.
30	2.7	Field equipment and laboratory instrument SOPs, calibration procedures, frequency, acceptance criteria, and corrective action are described in the text but it is difficult to follow the requirements for each parameter and the associated instrument/equipment. This information would be more effectively captured in a table.
32	2.9	The QAPP states the limited secondary data supplied by homeowners and used as background information was considered usable if the laboratory QC requirements were achieved. There is no mention of determining who collected the data and if appropriate sample collection and handling procedures were used. Further, there is no discussion of laboratory accreditation in the methods used for analysis.
32	2.10	The data management section is not adequate and does not address most of the elements required by EPA. There is no mention of data validation and review as there is in other case study QAPPs (e.g., Raton Basin).
32	2.10	The section indicates that 10% of the manually entered data will be verified by the Principal Investigator. This is insufficient. Either 100% of hand-entered data should be verified or a random sampling method designed to ensure accuracy to a defined level of confidence should be established.
32	2.10.2	Data will be entered in the Principal Investigator's computer by others. This raises questions about data access and the integrity of the computer. Further, the method and frequency of transferring data from the computer to the network "M" drive that will be backed up is not defined. Also, the frequency of backup is not defined.
34	3.1	The section states that *audits of data quality (ADQs) will be conducted on a representative sample of data for the critical target analytes* by Neptune and Co. The first data package will be targeted for audit. This statement is too vague. The text should specify how representative data will be identified to avoid bias (e.g., a statistically random sampling design would be appropriate) and how much data will be audited. Further, EPA criteria require that Category I data receive 50% audit.
36	4.1	The section describes data verification for each laboratory that will perform analysis for the study. The QAPP should establish minimum, consistent verification procedures for the study such that all data receive the same level and type of review within the laboratory.
37	4.2	The section states that a contractor will validate a representative sample of critical analytes. The amount of data to be validated, how the data will be selected for validation, and the validation level are not defined.
37	4.2	The text does not clearly define who will apply data qualifiers for each type of data. It states that the Principal Investigator will apply data qualifiers for organic data using the EPA National Functional Guidelines, but it does not define who will qualify other data types and the criteria that will be used.
37	4.3	The section does not define how critical vs. non-critical data will be used. It does not describe how flagged data and outliers will be treated.
	6.0	The control block footer for Section 6 identifies the Revision No. as 0 rather than 1. The date (March 12, 2012) reflects the revised document.
45	6.0	Table 3: The reason that each analyte is a critical analyte for the project should be justified.
47	6.0	Table 5 does not list the critical parameter group "Major Cations" (Ca, Mg, Na, K) analyzed by Shaw.
49	6.0	Table 6 states that the Principal Investigator will determine if field QC failures are significant relative to the sample data. The criteria used to perform this assessment are not defined. Objective criteria should be defined for this assessment.
56-60	6.0	Tables 9 and 10 should list corrective action if control limits are breached.
56	6.0	Table 9 states that corrective action for QA/QC failures is defined in the SOP. However, the QAPP should define the corrective action appropriate for the project since the SOPs are not attached to the document.

Table E-6. Detailed Review of the QAPP for Marcellus Shale/Bradford County, PA (Continued)

Page	Section	QAPP Comments Hydraulic Marcellus Shale/Bradford County, PA
56	6.0	Table 9 does not include analysis of a laboratory control sample. A laboratory control sample should be processed and analyzed with each analytical batch so that matrix interference with spiked recoveries can be assessed.
59	6.0	Table 10: This table should be updated to include detection limits and reporting limits of glycols as soon as available and provided to stakeholders such that the analysis can be replicated by an independent party.
69	7.0	Figure 1: All individuals listed in Section 1.1 should be illustrated so that responsibility, accountability, and communication pathways are clear.
62	7.0	Figure 2: It is strongly recommended that each sampling location be designated with "NEPAGWxx" or "NEPASWxx" prior to field sampling activities to minimize any potential error of designating the same sample ID to different locations, especially if multiple sampling teams are in the field during the same event.

Table E-7. Detailed Review of the QAPP for Enhancement of Analytical Chemistry

Page	Section	QAPP Comments Enhancement of Analytical Chemistry
vi		The list of abbreviations is incomplete; it should include ADQ (p. 20), CCV (p. 8), CF (p. 18), CHL (p. 13), DQA (p. 20), GC-MS, IIQMP (p. 9), LC, LC-MS, NGDP (p. 13), NGDPP (p.13), PE (p. 20), PQL (p. 8), TSA (p. 20), and possibly others.
4	A5	No schedule is provided. Deliverables not defined. The deliverables should include a SOP for each analytical method developed. The text states "Analytical methods will be identified, tested, and modified or developed to detect potential chemicals of concern and their transformation products, including fracturing fluid additives, metals, and radionuclides, in hydraulic fracturing wastewaters." The remainder of the document focuses on analytical chemistry methods and does not address the data uses italicized above.
4-5	A6	The QAPP states that it may be updated if new target analytes are identified. The QAPP should specify the conditions under which a QAPP revision is required.
4-5	A6	The question is defined as determining the chemical components and *physical properties* of hydraulic fracturing fluids (and transformation products) and the analytical approaches that are needed to identify the *reactions, fate, and transport of injected and mobilized constituents.* The remainder of the document focuses on analytical chemistry methods and does not address the information italicized in the question above.
4-5	A6	The endpoint of method development should be a SOP that defines method performance (PARCC) parameters and the method detection limit.
7	A7	The application of representativeness to this study should be described.
7	A7	Comparability statement regarding cleanup and extraction does not address how comparability will be assured. Reference to standard protocols for methods development and the use of SOPs for routine analysis should be described.
7	A7	In the second paragraph on this page, references should be provided to Section D3.2 for the calculation of precision measurements.
7	A7	• In the paragraph on accuracy, it is indicated that SRMs are to be used "if available" to check for accuracy and bias, but no information is provided on how to use them or what the criteria are. • For the paragraph on representativeness, the following text should be added: "Representativeness is addressed primarily in the sample design, through the selection of sampling sites and procedures that reflect the project goals. It is ensured by the proper handling, homogenizing, compositing, and storage of samples and analysis within the specified holding times so that the material analyzed reflects the material collected as accurately as possible." • For the paragraph on comparability, the following sentence should be removed, "In this study, a variety of cleanup/extraction and detection techniques will be utilized," and this sentence added, "Comparability can be measured using split samples or comparing data to historical data." • A paragraph on MDLs should be added and the MDL row removed from Table 3. The paragraph can be as simple as, "Method Detection Limits (MDLs) will be determined specifically for each chemical. • A description of the QC sample types listed in Table 3 should be provided in this section. Many QC names do not always have consistent meanings from lab to lab -- or even project to project. If there is standard usage at this lab, the descriptions do not need to be added, but a reference citation should be provided both in the text of this section and in Table 3.
8	Table 3	The QC checks should be defined (e.g., the difference between laboratory control standard and laboratory field blank). Completeness should be ≥90% to be consistent with page 7.
8	Table 3	The data to calculate precision should be defined. Precision criteria are defined for QC checks that are not typically run in duplicate within an analytical batch of up to 20 samples (e.g.,

Table E-7. Detailed Review of the QAPP for Enhancement of Analytical Chemistry (Continued)

Page	Section	QAPP Comments Enhancement of Analytical Chemistry
		laboratory blank, laboratory control sample).
8	Table 3	The ICAL criteria ($r^2 > 0.99$) is not an appropriate technical criterion for calibration results, especially if the form of that equation is not specified (see comment below regarding Section B7). Even if language is added to the QAPP that all calibration equations must be linear, using r^2 alone is not the best way to evaluate calibration data.
8	Table 3	Each corrective action includes the statement "Samples must be bracketed by acceptable QC or they will be invalidated" which is unclear. Are the QC samples analyzed at the beginning and end of each instrument sequence? Which QC checks will bracket the samples?
9	A8	Documentation of qualifications should be specified.
9	A8	Training in Toxic Substances Control Act (TSCA) CBI should be listed.
10	A9	Since this QAPP focuses on methods development, records should also include instrument analytical programs including temperatures, ramp times, etc.
10	A9	The location of hardcopy records during laboratory retention, and the method of storage is not defined. For example, is there a requirement for limited access? Who is in possession of, and responsible for maintaining the project records?
10	A9	The second sentence in the "Hard Copy Records" paragraph, should be rewritten as follows: "These records, which include but are not limited to recorded information such as the preparation of samples, blanks, calibration standards, and QCs, will be retained in a laboratory notebook that is kept by the researchers."
12	B1	Although field sampling will not be performed, the method validation design process should be defined. For example, how many samples, replicates, concentration levels are analyzed to 'test' a sample processing and analysis procedure? How is the final method verified?
12	B2	The applicability of this section should be limited to the collection of field samples for hydraulic fracturing produced water to be used in testing a method using a 'real world' matrix.
12	B2	No SOPs are cited for sample collection procedures.
12	B2	Procedures to document samples generated within the laboratory are unclear. For example, are sample documentation sheets generated for these samples?
12	B2	It may not be appropriate to include the name of the Environmental Chemistry Branch (ECB) sample control person in the QAPP.
12	B3	According to this section, the procedures in this section are applicable to "real-world" samples. • It appears that internal sample custody is not maintained. • Sample handling (internal or field-related) is not described. • Sample labels are not described.
		The QAPP states "Proper documentation will be maintained, security of samples ensured, and analyst procedures documented. Samples will be properly labeled and stored. The sample storage units (refrigerators and freezers) are monitored with temperatures recorded in a log book." However, proper documentation and labeling are not defined. The monitoring frequency for refrigerators and freezers that hold project samples is not defined and no SOP is cited.
13	B3	In the second paragraph on this page, CHL should be defined.
13	B4	Paragraph 1 of this section states that if a method exists, it and related QC will be used for the project. However, Figure 3 rightly indicates that the QC must be acceptable and, if not, the method will be modified to optimize QC results. The QAPP does not state that modified methods will be documented in modified SOPs.
13	B4	Paragraph 2 of this section states that at least three replicate analyses should be performed. It is unclear if these triplicates are indicated for method development or for routine sample analysis. In addition, it is not clear if this refers to replicate extractions or replicate injections from one extraction.

Table E-7. Detailed Review of the QAPP for Enhancement of Analytical Chemistry (Continued)

Page	Section	QAPP Comments Enhancement of Analytical Chemistry
14 16-17 24	B4 B2.3 D3.4	The paragraph on page 14 beginning "An estimation of the method detection limit (MDL) …" introduces the idea of determining the MDL and provides an appropriate reference. The procedure is then described further in Section B2.3, and the equation is provided in Section D3.4. However, the information is incomplete. For example, the equation in D3.4 defines *S* as the "standard deviation of the replicate analyses", but does not state what is being analyzed nor what the standard deviation is taken from. Thus, an analytical chemist who had never used an EPA method before would be unable to calculate the MDL from the QAPP alone.
15	Fig. 3	On the left side of the flowchart, there is a box with the text, "Spike Sample with COC to Determine % Recovery, Precision, Bias, and Detection Limit". No question is associated with this step to generate either a Yes or No response to move to the appropriate next step.
15-17	B5	The section does not describe the QC samples that should be analyzed during each of the five stages of single-laboratory testing. QA procedures are referenced to Section B2.2 but this section does not describe QA or QC.
15-17	B5	Some text is too general to provide clear direction and ensure consistency (e.g., multiple laboratory control spikes are routinely employed; ruggedness tests also typically require statistical evaluation).
17	B2.4	In the last sentence of the first paragraph, the word "repeatability" should be replaced with "reproducibility".
16-17	B2.1-B2.5	These sections should be numbered B5.1-B5.5.
17	B6	The frequency of instrument preventative maintenance is defined as “as needed.” This is not appropriate because preventative maintenance should be conducted at predefined routine intervals that are defined in a laboratory QA Manual or SOP. Neither document is cited in the QAPP. It is not clear if daily monitoring activities are considered maintenance and if they are documented in the instrument logbook.
17	B7	The section defines general calibration requirements with references to manufacturers’ instructions. However, specific calibration procedures and criteria should be defined for each instrument.
17	B7	Paragraph 4 should be included in Section B6.
17	B7	Paragraph 5 is confusing. It is not clear if the CFs to be analyzed are the CFs of the CCVs or the ICAL standard. The text states “Calibration response factors (CFs) based on each individual standard will be determined by triplicate injections of the same concentration each 8-hr analytical day.” It is not clear if the reference to each individual standard refers to each level of the ICAL. Also, the reference to the CCV in the middle of the paragraph is confusing because it is not clear if the CCV is being reference in relation to the CF criteria. Separate criteria are defined for the CCV in Table 3.
17-18	B7	Information should be added to this section about the calibration itself. For example: • The required spacing of the 5 calibration standards is not defined. (e.g., Is 1X, 1.1X, 1.2X, 1.3X, 1.4X allowed? Is 1X, 10X, 100X, 1000X, 10000X allowed?) • The calibration procedure details are not defined (e.g., linear equations, quadratic equations, or response factors) • Weighting the data points from the calibration standards is not discussed and, if permissible, the criteria for determining whether to do so or not are not defined. • The criteria for accepting a calibration equation are not defined (See comments above regarding Table 3). Some or all of these questions might not have answers that apply universally to all analytes in all methods. In that case, these issues should at least be presented with statements such as "Either linear or quadratic equations may be used, as appropriate, per the results from the calibration standards".
17-18	B7	The text in this section does not describe many/most of the criteria listed in Table 3.

Table E-7. Detailed Review of the QAPP for Enhancement of Analytical Chemistry (Continued)

Page	Section	QAPP Comments Enhancement of Analytical Chemistry
18	B7	The discussion of CCVs (fourth full paragraph on the page) is very confusing. For example: • It appears that there are at least 15 CCV injections on each day: 3 times injecting CCVs (start of day, start of batch, end of day) × 5 concentrations ("based on each analytical standard"). The CF calculated for a single group of 5 CCVs at different concentrations as an equivalent of response factor is not clear (e.g., are 15 separate CF calculations performed per day?). More importantly, having a precision requirement on a set of 5 CF values calculated in this way implies that the calibration is linear with an intercept near zero. It is possible that this behavior is not seen for all analytes. • Table 3 shows a criterion for recovery but it is not discussed in this paragraph. A better (and more commonly used) technical approach is to use the concentration determined from CCV injections to measure the accuracy of the result, reflecting calibration consistency rather than recovery, as described above in the comments regarding Table 3.
18	B7	In the fourth full paragraph on the page, CCV should be defined.
18	B8	This section does not define how the acceptability of supplies will be determined. Minimum purity of solvents and reagents is not defined. The use of Class A volumetric glassware is not specified. The accuracy and calibration verification of pipettes is not discussed.
19	B9	This section does not define the criteria for use of non-measurement data.
19	B10	This section does not adequately describe data management procedures. • Data recording requirements (use of pen, methods for changes to raw data) are not addressed. • Data reporting conventions are not defined. • Data flow, control, management and storage throughout the project life-cycle is not described. • EPA guidance suggests the following content for this section: o Description of the project data management process; o Description or reference to the standard record-keeping procedures and document control, data storage, retrieval, and security systems; o Identification of data handling equipment and procedures to process, compile, and analyze project data; o Discussion of data handling procedures to detect and correct errors and loss during data processing; o Examples of any forms or checklists to be used; o Identification of any specific computer hardware/software performance requirements and how configuration acceptability will be determined; and, o Description of how applicable information resource management requirements will be satisfied.
20	C1	The QAPP states that an ADQ will be performed on representative sample of data for critical target analytes. As a Category I project, an ADQ should be performed on 50% of the data (http://www.epa.gov/nrmrl/qa/chapter2.html).
20	C1	The section does not define what the DQA will review.
20	C1	The section does not discuss response actions appropriate for the types of audits identified: TSA, PE, surveillance, ADQ, and DQA. This should include identification, implementation, and verification of corrective action with a time period for each.
22	D1	This section does not discuss data review, verification and validation at all. It states that "All verification and validation methods will be noted in the analysis provided in the final project report."
22	D2	The text is brief but covers the essentials of the requirement to define data validation and verification procedures and the criteria used to accept or reject the data based on quality.

Table E-7. Detailed Review of the QAPP for Enhancement of Analytical Chemistry (Continued)

Page	Section	QAPP Comments Enhancement of Analytical Chemistry
22	D3	The text provides formulas used to assess QC data (recovery, percent difference, relative percent difference, relative standard deviation, completeness, and MDLs). The text does not summarize how the QC process in Section B5 will be used to assess method validity and therefore data usability. Statistical tools are not described.
23	D3.2	The first two paragraphs of this section should be rewritten as follows: "Precision will be determined through the use of field replicates, spike replicates, and replicate quality control samples. "For duplicates, the precision will be indicated by the Relative Percent Difference (RPD), to be calculated as follows:"
24	D3.3	*n* should be defined here only as "total number of measurements". If there are requirements about how many measurements are needed to provide an appropriate level of confidence, they need to be specified elsewhere in the QAPP (e.g., Section A7).

Table E-8. Detailed Review of the QAPP for Data Collection for Scenario Evaluation

Page	Section	QAPP Comments Data Collection for Scenario Evaluation
	General	To the extent possible by the data sources, it would be helpful to include more information on water quality data besides pH, temperature and conductivity. For example, information on chemicals commonly used in the hydraulic fracturing process is useful.
	General	It is unclear if information from drill sites including sample water will be available.
4	Distribution List	Only Shaw and EPA personnel are listed. Add other program participants if the data collection procedures identified apply to other organizations.
5	1.1	Does not show Shaw QA Officer relationship to data reviewers or EPA QA Manager.
		Does not define any data collection entities other than Shaw.
		Does not discuss interface with data users.
7	1.2	No schedule is referenced or defined.
8	1.3	The task discussions are general and do not mention the relationship to the tasks in this QAPP to other project tasks so that linkages are established (i.e., the scope of the QAPP in relation to the larger EPA effort described in the study plan).
11	1.4	The section does not define data quality indicators or specify minimum data accuracy, precision, completeness, sensitivity or methods to ensure comparability of secondary data.
11	1.4	The section does not define quality objectives for data collection and compilation activities.
12	1.6	The section does not define the controlling of project documents.
12	1.6	The section specifies that working files will be forward to the File Administrator for backup within the EPA network each week. It does not specify how or where working files will be stored and backed up.
14	2.8	The QAPP does not define what types of supplies or consumables are anticipated.
14	2.9	The section states that data will be collected from “acceptable sources” and assessed for suitability but does not define how acceptability/suitability will be determined.
17	2.9.2	Section 2.9.2 states that minimum geospatial data accuracy (locational) is at least the EPA Tier 5 minimum unless there are program-specific procedures to address accuracy and that accuracy must be defined for each scale.
17	2.9.2	Section 2.9.2 states that metadata must meet the requirements of the EPA geospatial metadata standard (FGDC, 1998). This document is 90 pages long and it would be difficult for a data collector to ensure full compliance with the standard without tools such as a checklist, an SOP, or a project-specific list of required metadata.
17	2.9.2	Section 2.9.2 states that elevation data accuracy requirements must be established and that EPA tier levels may be applicable. The QAPP does not provide sufficient guidance to the data collector to determine data suitability.
19	2.9.3	Section 2.9.3 states that physical and analytical water quality data will be collected. Water, temperature, pH, and conductivity are specifically identified. The QAPP indicates that any method approved by a federal organization, or universally accepted methods, are acceptable. However, a wide range of analytical methods are described in agency documents for water quality measurements. Method ‘acceptance’ by an agency does not indicate that the method is suitable to provide data of the level of accuracy, precision, sensitivity, and detection limits required to meet the project objectives (assessing trends and behavior).

Table E-8. Detailed Review of the QAPP for Data Collection for Scenario Evaluation (Continued)

Page	Section	QAPP Comments Data Collection for Scenario Evaluation
19	2.9.3	Section 2.9.3 further states that approved agency or standard methods define data quality objectives (actually data quality indicators – accuracy, precision, detection limits, quantitation limits). This is often not the case. Many agency and standard methods do not establish requirements for accuracy and precision since these should be defined for each project based on the project DQOs. Further, for the water quality measurements listed, detection limits are often instrument specific rather than method specific.
19	2.9.3	The lack of specificity in Tables 2 and 3 will not enable the data collector to determine data suitability or the data reviewer to determine if the data meet QAPP criteria.
22	2.10	Most information described for this section in EPA QA/R-5 and the considerations for secondary data are not defined: • Data management scheme path and storage system. • Data handling equipment (performance requirements and how configuration acceptability will be determined) • Procedures to process, compile, analyst the data. • Data reporting conventions, including qualifiers and units • Confidentiality specifications • Requirements for process and hardware and software equipment for data/information handling and storage throughout the life cycle of the project, i.e., from secondary (existing) data sources, to the office's data or model system. This includes: recording, transcribing, digitizing, and downloading, transformation and transmittal, reduction (mathematical operations), management, storage and retrieval • Examples of any SOPs, forms or checklists to be used to ensure consistency throughout the project. • Naming format used to save data files • How and where data compilation and manipulation will be documented • Methods to maintain electronic data version control • Method to maintain the integrity of the source data file • Change control.
24	3.1	The elements of the Shaw TSA are not defined.
24	3.1	Section 3.1.2 does not define ADQ frequency and what will be included in the audit.
24	3.1	The QAPP indicates that ADQs will be conducted by EPA and later through contract support by Neptune and Co.
26	4.1	The amount of data to be reviewed by the data reviewer is defined in Section 2.10 but the frequency of reviews and when they will occur in the data flow are not defined. For example, it is not clear if manually entered data will be 100% verified before the data are uploaded to a database or if data processing will continue independent of the data review process.
27	4.3	The short discussion of the database does not indicate the documentation that will be developed to support the database (i.e., entity relationship diagram, data dictionary, etc.).

Table E-9. Detailed Review of the QAPP for Formation of Disinfection Byproducts from Hydraulic Fracturing Fluid Constituents

Page	Section	QAPP Comments Formation of Disinfection Byproducts from Hydraulic Fracturing Fluid Constituents
0 to 11	Title Sheet, Sections 1.0 and 3.0	All required components for Group A: Project Management Elements are present.
	Table of Contents	The TOC lists Section 7 as References, but it is a blank page. It remains blank in the revised version.
1	1.0	The distribution list does not include researchers involved in related aspects of the study or the sampling team from Region 3 that will be procuring the water source samples for the study.
7	3.1	An organization chart is not provided. There is only a minimal description of roles and responsibilities. Sam Hayes appears in the text, but not in the table as a named participant in the project.
7	3.2	Includes several unreferenced statements: e.g., *In general, treatment of hydraulic fracturing water occurs through either admixture to normal wastewater inputs or post-treated wastewater.*
8	3.2	Several footnotes (1,2,3) appear to be missing and the reference section is blank in Section 7. Missing footnote references are also noted throughout the document.
8	3.2	The focus is not specific to hydraulic fracturing, e.g., *Literature studies on the effects of bromide.* Footnotes seem to be missing (unless they are the footnotes on pg 54).
8	3.2	The research objectives should be stated more clearly: Not clear what is meant by "hydrofracking impacted waters" • Not clear what the secondary objective means: "differences in blended waters downstream of the discharge point whether added at the headstream of a wastewater treatment plant or post-treatment where a mixed wastewater/hydrofracking discharge blend will occur.
9	3.3	It is noted under Task 2 that synthetic waters will be used for some of the experiment "NOM sources will include both locally obtained natural waters as well as freeze-dried NOM concentrate."
10	3.4	Not clear if schedule refers to fiscal year or calendar year but it implies that work was started prior to QAPP approval.
10	3.5	Very general and does not relate to specific documents and records that will be generated by the project.
11	3.6	Very general and does not relate to specific project activities. Does not include DQOs specific to the study and instead references the overall NRMRL QMP.
11	3.7	Very general and does not relate to specific project activities.
11 to 34	4.0 Data Generation and Acquisition	In general, the experimental designs for Tasks 1, 2, and 3 should provide more detail on the study design and rationale. Certain project-specific details required for B2 Sampling Methods and B3 Sample Handling and Custody are not addressed as described below.
12	4.1.1	Contains several unsubstantiated statements about hydraulic fracturing wastewater.

Table E-9. Detailed Review of the QAPP for Formation of Disinfection Byproducts from Hydraulic Fracturing Fluid Constituents (Continued)

Page	Section	QAPP Comments Formation of Disinfection Byproducts from Hydraulic Fracturing Fluid Constituents
12	4.1.1	For the Task 1 Objective, there is no description of the proposed sampling sites or justification for how the sampling sites and sampling locations will be selected in Region 3. The field sampling program is not well defined: *"We propose to evaluate water samples obtained at varying distances from known resource extraction sites to characterize the nature and extent of flowback water impacts on the character of the water samples….."*
12	4.1.2	**Key ideas:** The focus of this section is on general concepts related to formation of disinfection byproducts in drinking water treatment systems. While this may be an important topic, this section does not identify practices that are specific to hydraulic fracturing.
13	4.1.3	No detail is provided on the sampling design and rationale. It should describe how the sampling locations will be determined, measures to ensure the samples are representative, confounding factors or known site-specific factors that may affect sampling/monitoring procedures, and any planned field analyses and equipment calibration, etc.
13	4.1.4	The QAPP does not cite the specific SOPs that will be relied upon by reference. There is a lack of information on number of samples, sample volumes, type of sample containers to be used, number of duplicates, appropriate holding times, sample preservation, etc. Although some of this may be included in the project SOPs, the information specific to the study should be tabulated in the report.
13	4.1.4	The QAPP does not include sample ID system for uniquely labeling samples.
13	4.1.5	The QAPP lacks specific detail on NOM characterization techniques.
13	4.2.1	The stated objective is not directly related to hydraulic fracturing. In addition, significant information is already available on disinfection byproduct formation under high chloride and bromide conditions.
13	4.2.2	There seems to be some confusion with units in this section since the previous studies encompass the purported range of interest: Pg 13: *In general, the range of concentrations explored in previous literature studies has extended to a maximum of 1-2 mg/L; while the natural range of bromide concentration in the US ranges from 5-429 ug/L.*
14	4.2.2	The following statement is not referenced: Pg 14: *Reports from state agencies in the Marcellus region have suggested concentrations in excess of 500 mg/L of bromide are being detected in flowback waters…*
14	4.2.3	There is limited information on experimental design and expected range of parameters under investigation. SOPs are cited and provided for bench-scale methods for disinfection byproduct formation potentials. No information is provided on number of lab trials, number of samples, frequency of samples anticipated from lab study, sample ids, sample handling, and chain-of-custody.
14	4.2.4	There is a lack of detail on experimental design, statistics, hypothesis testing, etc. There is no information on how the biocides would be selected, what concentration ranges would be used, or the methods that would be used to "assess aqueous stability".
15	4.3.1	The objective does not provide an explanation of why the focus is on biocides.
15	4.3	It is not clear that the research team has conducted a comprehensive review of biocide chemistry or use has been conducted.

Table E-9. Detailed Review of the QAPP for Formation of Disinfection Byproducts from Hydraulic Fracturing Fluid Constituents (Continued)

Page	Section	QAPP Comments Formation of Disinfection Byproducts from Hydraulic Fracturing Fluid Constituents
15	4.3.2	This section is confusing and lacks context with the practice of hydraulic fracturing. The link between biocides, disinfection, and disinfection byproducts needs to be elucidated. The selection of biocides seems somewhat arbitrary. Also, the scope seems to encompass identifying molecules of toxicological interest.
16	4.3.3	There is a lack of detail on experimental design, statistics, hypothesis testing, etc. There is no information on how the biocides would be selected, what concentration ranges would be used under typical conditions, or the methods that would be used to "assess aqueous stability".
16	4.3.4	**Proposed Experiments**: The section lacks detail on experimental design, statistics, hypothesis testing, etc. There is no information on how the biocides would be selected, what concentration ranges would be used, or the methods that would be used to "assess aqueous stability". It is not clear that the research team has conducted a comprehensive review of biocide chemistry or use based on some of the unsubstantiated statements (e.g., *Note that due to the dearth of data regarding degradation of some biocides…..)*
16	4.3.4	No information is given on the rationale for selecting disinfectant concentrations; they do not appear to be based on typical conditions or a systematic approach to evaluate oxidant demand: *The disinfectant concentrations examined will initially be 2, 5, and 10 ppm.*
16	4.3.5	Document numbering is off; it implies that the methods are only for Task 3. The level of detail is inconsistent across the individual analytical methods.
16 to 34	Analytical Methods	Tables do list QC sample type, frequency, acceptance criteria, and corrective actions. Use of blanks is addressed. Detection limits should be noted in QC tables. Tables should address accuracy, precision, detection limits, and completeness for critical measurements. Not clear that all of the disinfection byproducts are addressed in QC tables. Numbering of sections is off. Table 4.3 on QC only seems to refer to trace elements. Table 4.7 is on THMs, Tables 4.8 and 4.9 are on HAAs, and Tables 4.10 and 4.11 are on nitrosamines. Instrument testing, inspection, maintenance, and calibration are addressed under each subsection by SOP reference and critical steps are highlighted in the text and tables. Use of supplies and consumables is discussed. Data management is addressed.
28	4.3.9	Justification is not provided for the list of analytes (Table 4.6). In addition, detection limits and MCLs are not defined in the table.
36	6.0	Definitions and formulas are provided for precision, accuracy, bias, representativeness, comparability, completeness, sensitivity, and verification and validation methods. It is described how the data will be validated against these criteria.

Table E-10. Detailed Review of the QAPP for Organization of Data from Hydraulic Fracturing Service Companies

Page	Section	QAPP Comments Organization of Data from Hydraulic Fracturing Service Companies
iv	Distribution	The EPA QA Coordinator, EPA Alternate WAM, and ERG Technical Reviewers are not listed.
iv	Distribution	Element A.3 does not define how the QAPP will be controlled, and in particular, how staff having access to the QAPP will be ensured access to the current version, including any amendments, and how any old versions will be disposed. (This is also referenced in Element A.9.)
	General Comments	There do not appear to be any SOPs that staff use as references to perform QA-related activities such as verification of entered data. Such SOPs would appear to be necessary, or detail on such procedures should at least be provided within the QAPP, perhaps as attachments.
	General Comments	No reference is made as to who will be using, summarizing, and analyzing the data to be collected and entered into databases by ERG and what the quality procedures are to perform these activities. While it is possible that these quality procedures are referenced in a separate QAPP, it is important that this QAPP recognize who will be using the data, how the data will be provided in formats that facilitate the end use of the data, and note procedures that will be in place to ensure the integrity of the data as they are transferred to the user.
1	2	References to the ERG QMP should be made as necessary. For example, if a more detailed list of standard duties and responsibilities of the individuals in Figure 2-1 is available in the QMP, it should be referenced in Element A.4. Otherwise, the list given in the QAPP under Element A.4 is very limited and doesn't cover all necessary quality-related tasks and responsibilities of these staff.
4	2	Section 2.3.1 indicates that there are two major sources of information: companies' responses to questionnaires and existing EPA data. No mention is made in the QAPP about what existing EPA data will be used or how it will be included in study databases. QA and data management details for these data should be included in the QAPP.
4	2	The QAPP states that the electronic questionnaire is in Microsoft® Excel format. Some explanation is needed as to why Excel was selected. In particular, if this selection was made in part for quality-related purposes, such as programming certain data entry fields to allow for only valid data to be entered by the respondent, then these types of notes should be made within the QAPP. In fact, if ERG is using various techniques to ensure that the databases only accept valid data, these techniques should be noted in the QAPP.
5	2	ERG plans to cut/paste data from electronically submitted questionnaires into the project database. A safer route to prevent any accidental cut/paste errors (as well as to provide documentation of exactly what was done) would be to write an import routine to transfer the data from the spreadsheets into the database.
5	2	ERG states that it will "perform QA" on the data, but no details are provided concerning the exact procedures to be followed to verify that the submitted data from the companies is accurately reflected in the project database. These procedures need to be documented in the QAPP.
6-8	2	Tables 2 and 3 refer to “data acceptance criteria.” However, for certain types of data (i.e., rows of the table), the information provided in the table are not criteria, but rather notes and questions. Each row of the table needs to feature specific criteria that the data will be judged against to determine if the data are acceptable for use on the project.

Table E-10. Detailed Review of the QAPP for Organization of Data from Hydraulic Fracturing Service Companies (Continued)

Page	Section	QAPP Comments Organization of Data from Hydraulic Fracturing Service Companies
6	2	The questionnaire and public comment acceptance criteria (Tables 2 and 3) do not define acceptance criteria or the corrective action procedure if specifications are not achieved. The criteria include qualitative terms such as "majority," "relevant," and "most accurate." The document should define these terms so that assessments are consistent.
8	2	Element A.8 indicates that ERG has an approved CBI Security Plan under this contract. It should be referenced in Element A.9 within the paragraph that discusses handling of CBI data
9	2	The Hydraulic Fracturing Project File Management Plan is referenced as the documentation of procedures on standard controls for project-related data, documents, and records. The paragraph continues by referring to the centralized record (i.e., Access database) of all data collected. It is unclear whether the Hydraulic Fracturing Project File Management Plan is the same as the project database that contains the questionnaire data (and if it is, it is unclear why this would be referred to as a project file management plan). Clarification needs to be made.
1	2.1	The distribution list includes ERG staff that is not included in Figure 2-1 such that their communication, reporting relationships and accountability within the program are defined.
1	2.1	The responsibilities of most ERG roles listed on the distribution list are not defined.
2	2.2	No schedule of milestones and deliverables are defined. There is no clear list of project reports and deliverables.
4	2.3	The QAPP states that ERG will perform QA on 5% of database entries to ensure accuracy; additional 5% QA reviews will be performed until no additional problems are detected. The frequency of QA review for hand-entered data is not sufficient. 100% of hand-entered data are typically reviewed or a random sampling method used such that the level of uncertainty can be defined.
5	2.3	No QA checks are described for public comments.
6	2.4	The section does not define the EPA category level for this project. The EPA hydraulic fracturing QMP states that all projects conducted for the study are Category I projects.
6	2.4	The amount of data review planned for hand-entered data is insufficient. It is standard and best practice for hand-entered data to be 100% verified or a random sampling method used such that the level of uncertainty can be defined.
6	2.4	Tables 2 and 3 do not define corrective action if the criteria are not met.
6	2.4	In Table 2, the specification for completeness is that a majority of the questions are answered by a respondent. Criteria for identifying 'majority' are not provided.
7	2.4	Section 2.4.2 (Public Comment) states that ERG will extract relevant data submitted with public comments as directed by EPA. Criteria for identifying 'relevant' are not provided.
8	2.4	Table 3 states that comparability will be assessed by determining which data are most accurate. This appears a subjective process.
8	2.4	Excluding outliers (listed in the specification for this criterion) may eliminate rare but critical high or low values.
8	2.5	Specific qualifications in reviewing and assessing hydraulic fracturing data are needed to determine if, for Table 2 (questionnaire), acceptance criteria are achieved for representativeness, reasonableness, and comparability.
8	2.5	Specific qualifications in reviewing and assessing hydraulic fracturing public comment data are needed to determine if, for Table 3 (public comments), acceptance criteria are achieved for comparability.
8	2.6	The project controlling documents are not defined.
8	2.6	There is no discussion of how the data collected in this project are related to the activities described in the QAPP prepared by Shaw Environmental on data collection.

Table E-10. Detailed Review of the QAPP for Organization of Data from Hydraulic Fracturing Service Companies (Continued)

Page	Section	QAPP Comments Organization of Data from Hydraulic Fracturing Service Companies
8	2.6	The data collected under this QAPP will be either TSCA CBI or general project data. The QAPP does not define how information to be handled as TSCA CBI will be labeled and handled/distributed such that it is maintained separate from general project files.
8	2.6	The QAPP text states that a draft Fracturing Project File Management Plan will document procedures for control of project-related data, documents, and records. This plan should be completed and approved prior to work on the project tasks and provided as an attachment to the QAPP.
8	2.6	The section indicates that data will be collected or accessed from other sources. The methods used to gather and assess secondary data for this task are not defined.
3	3	Under Element B.5, it states that ERG will include all relevant data and that EPA will determine data that should be removed from the project database. It would be preferable that instead of excluding or removing data from the database, data deemed to be non-relevant or unusable be flagged as such in the database so that they can be excluded from analyses. This would be a more transparent method of handling unusable data.
3	3	Element B.5 indicates that a technical checklist will be developed after the final version of the questionnaire is developed. At that point in time, a revised QAPP should be issued which includes both the final questionnaire and the technical checklist.
6	3	It would be beneficial to add "Reason for Inclusion" as a field in the case studies table.
2	3.1.3	The section does not identify who will perform each of the data handling activities defined in the section.
2	3.1.3	A file naming schema is not defined.
2	3.1.3	The process for receipt, log-in, and maintenance of public comments such that custody and integrity are maintained is not discussed.
3	3.1.4	The section does not identify who is responsible for data receipt QC activities.
3	3.1.4	The QAPP states that data removed from the database at the discretion of EPA will be documented in a memo to the project files. The decision to remove data from the database should be captured in a comment field in the database so that the database has a complete record of data handling and transparency.
3	3.1.4	The section describes how questionnaire data will be reviewed for completeness and consistency but does not describe the process or criteria for assessing representativeness, reasonableness, and comparability.
3	3.1.4	The method used to document the data review is not defined.
3	3.1.4	The QC procedures used to ensure that public comments are logged in, stored, uploaded, and evaluated consistent with the QAPP are not discussed. Section 3.2.1 indicates that public comments were received as hardcopy or e-mail.
5	3.2.1	The QAPP does not address how secondary data provided as attachments to the questionnaire will be handled and if/when it will be assessed using Table 2 or added to the database. Appendix A, *Hydraulic Fracturing Data Analysis Plan*, describes data handling and analysis that are not addressed in the body of the QAPP. This includes developing maps with locations of operations, vendors, and incoming water sources and comparison with other relevant mapping data. It also includes analysis of chemical formulation/mixture analysis, evaluating water specifications vs. water quality criteria, reviewing human health impacts of chemicals within fracturing fluids and reviewing the analytical methods used to determine concentrations of chemicals and identifying difference that may affect reported concentrations.
5	3.2.1	This section does not discuss or references criteria for the use of non-measurement data, intended use, and limitations.
5	3.2.2	The section does not identify who is responsible for data management at each stage of the data flow process.

Table E-10. Detailed Review of the QAPP for Organization of Data from Hydraulic Fracturing Service Companies (Continued)

Page	Section	QAPP Comments Organization of Data from Hydraulic Fracturing Service Companies
5	3.2.2	The amount of data review planned for hand-entered data is insufficient. It is standard and best practice for hand-entered data to be 100% verified.
5	3.2.2	It is not clear if data in the database will include an initial log-in identification number assigned to the original survey results.
5	3.2.2	The naming convention scheme is not described.
5	3.2.2	The data storage and database path and storage location are not defined.
5	3.2.2	Data handling equipment and procedures that will be used to process, compile, and analyze the data are not described.
5	3.2.2	Data reporting conventions, including the use of data qualifiers and units, are not discussed.
5	3.2.2	The database format is not described. The method of verifying entry into the database is not defined.
5	3.2.2	Data security and confidentiality are not described.
5	3.2.2	The data loading/entry process and hardware and software equipment for data/information handling and storage throughout the life cycle of the project are not described, including transformation and reduction (mathematical operations).
5	3.2.2	Procedures to ensure consistency, such as SOPs or checklists, are not referenced.
5	3.2.2	Specific computer hardware/software performance requirements and how configuration acceptability will be determined is not addressed.
1	4	Outside of its standard contract-level monthly progress reports, there is no description of how ERG will be reporting regularly to EPA on its progress to enter and verify/validate the data into the databases. If such progress will be communicated, it should be noted under Element C.2.
1	4.1	According to the text, QA oversight is limited to a QA review of project files to ensure that project staff has developed appropriate QC procedures and that deliverable review sheets have been completed.
1	4.1	No process is established to ensure that errors are reported in real time and not repeated (continuous improvement). The QAPP should define appropriate QC procedures that will be implemented consistently for the program. These QC procedures should receive management approval.
1	4.1	The documentation of issues requiring corrective action, implementation of corrective action, and verification that corrective action has been implemented effectively and incorporated at the program level, as appropriate, is not discussed.
1	4.2	The section does not specify who prepares the QA section of the monthly report.
1	4.2	The primary purpose of this section is to describe the frequency, content, and distribution of reports issued to keep management informed of the results of audits and assessments. The section does not describe how data quality issues will be reported to ERG management. The QAPP should be updated to describe the procedure used to communicate QA/QC issues to management.
1	5.1	This section references QA/QC procedures but does not describe data verification and validation vs. the QAPP criteria.
1	5.1	This section does not detail the procedures that will be used to verify accurate data entry into the database and does not indicate when and at what stages these reviews will be performed.
1	5.2	The QAPP does not define the methods used to assess the usability of questionnaire data to address project objectives.
1	5.2	The section does not identify mathematical or statistical procedures that will identify whether individual data values within existing data sets should be rejected, transformed, or otherwise qualified.
1	5.2	The QAPP states that ERG will describe data quality and limitations but does not define the methods or criteria that will be used make this assessment.

Table E-10. Detailed Review of the QAPP for Organization of Data from Hydraulic Fracturing Service Companies (Continued)

Page	Section	QAPP Comments Organization of Data from Hydraulic Fracturing Service Companies
1	5.2	The section indicates that primary data calculations and analyses will be documented for the project files. Any data transformations should be documented in a comments field in the database.
1	5.2	The section states that ERG will include an evaluation of data quality in all project deliverables. The text does not detail how data quality will be determined or who will perform this analysis.
	Survey Comments	There is no mention of how the nine hydraulic fracturing companies were selected or how the sample size was estimated.
	Survey Comments	The survey requests information on the location of sites where service was provided within the past year, and where service will be provided within the coming year. This period may not be sufficient for collecting enough information on all the processes and locations that may affect drinking water resources because the processes may vary by season and climate, and some significant human health effects may appear after more than one or two years of exposure to water contaminants.
	Survey Comments	The survey requests information on human health and environmental impacts. While hydraulic fracturing companies may harbor some information on such information, the information may be limited by year of publication or subject content. There is no mention of animal studies that may act as a surrogate for health effects of novel chemicals or chemicals that do not yet have established human studies.
	Survey Comments	The survey does not ask about the site selection process. While this information may be implied in the requested policies, practices and procedures used for hydraulic fracturing, there is no assurance that it is present or provided. Understanding the site selection mechanisms will help determine whether factors such as social equity, environmental responsibility, and land topography are consistently considered.
	Survey Comments	Information on the frequency of hydraulic fracturing drilling and fluid injections is needed. While this may be implied in the requested policies, practices and procedures used for hydraulic fracturing, it is not explicitly stated. Frequency of injection is vital in estimating the potential exposure of drinking water sources to the hydraulic fracturing fluid contaminants, and eventually, human exposure.
	Survey Comments	Information on the half life of the chemical constituents in the formulations and mixtures used for injection, whether biodegradable or not, extent of interaction with other constituent chemicals and with injection pressure are needed. The suggested factors help further determine the fate and transport of the chemicals used in the fracturing process, which affects contamination of surrounding soil, underground water, and leakage into other water sources. Furthermore, it is unknown whether new potentially adverse chemicals may form as a result of the high injection pressures and reactivity of the constituent chemicals.
	Survey Comments	Further information regarding the QA process used in fracturing is needed, including whether fluid samples are collected or chemical constituents are measured at different time points in the fracturing process, including the dumping sites, upstream if fracturing or disposing of the fluids near a river, or in surrounding wells if underground.
	Survey Comments	It is unclear if the volume of fluid recovered is assessed. Since between 15 and 80 percent of the column injected may be recovered, this information needs to be assessed directly from the hydraulic fracturing companies in order to determine how much fluid remains underground.
	Data Analysis Comments	Analytical components of SOPs need to be clarified as these documents contain abundant text and differ from one company to another.
	Data Analysis Comments	Need to specify some parameters that are relevant to drinking water quality including average drilling distance and average distance from water sources.

Table E-11. Detailed Review of the QAPP for Statistical Assessment of Data from Hydraulic Fracturing Service Companies

Page	Section	QAPP Comments Statistical Assessment of Data from Hydraulic Fracturing Service Companies
	General	Assessment of representativeness: Further details are needed to understand how the authors plan to assess the national representativeness of the nine hydraulic fracturing companies that were surveyed.
	General	Statistical sample designs: • It is unclear how the authors will provide statistical support to meet EPA's objective to evaluate the potential impacts of hydraulic fracturing on drinking water resources since no specifics were provided. For example, what kind of information will be requested from the oil and gas companies and what criteria will be used to correlate the fracturing processes with drinking water quality? • It is unclear how the nine oil and gas companies will be selected as being representative of oil and gas operations that use hydraulic fracturing in the US.
	General	Revised sample weights and guidance: • More information is needed on how the sample weights for the oil and gas companies will be developed (based on wells, oil and gas companies, etc.?).
Section 2 3-4, 6	2	Project Objectives: The QAPP is ambiguous about the target population. It does not sufficiently address how the initial questionnaire provides adequate information for determining a suitable frame for the target population. No schedule of milestones (CBI may contain resources and budget not contained here).
Section 2 page 4	2.2.2	Eight key questions are defined, but it is not clear how they can be answered by the specific dataset. No specific project objectives are provided.
Section 2 page 6	2.3.1	**Assessment of representativeness:** It is not clear how results from nine respondents plus third-party sources can be used to assess representativeness.
Section 2 page 6	2.3.3	**Revised sample weights:** This section describes sample weights and guidance but it is not clear how they will be used and how they are related to answering the key questions.
Section 2 page 6	2.3.4	**Population estimates:** This section provides statistical jargon about population estimates, but it lacks detail on how the estimates will be derived and how they will be used.
Section 2 page 7	2.4	The section on assessment of representativeness indicates that the basis for the assessment is to be a comparison of the response data to available Web sites or industry sources. The risk of relying on this strategy for assessment is that the available information from Web sites or industry sources could be biased.
Section 2 page 7	2.4.1	**Assessment of representativeness:** It is not clear how representativeness can be assessed when the initial sample size is not based on a statistically sound experimental design. It is also not clear how this information will be used in analysis of the results.
Section 2 page 8	2.4.2	**Statistical sample designs:** This section implies that a follow-up survey might be administered, but it lacks detail.
Section 2 page 9	2.4.4	**Population estimates:** This section is virtually a repeat of Section 2.3.4 with no additional detail.
Section 5 page 1	5.1	**Data Review, Verification, and Validation:** This section is very general and it is not clear how that data will be verified and validated.
Section 5 page 1	5.1	The QAPP does not specify specific criteria for outlier determination.
Section 5 page 1	5.2	The QAPP does not specify criteria for the decision that questionnaire data would be representative of the target population.
Section 6 page 1	6.0	**References:** The reference list is very limited and includes an EPA fact sheet about the hydraulic fracturing study. It would be useful to include references relevant to statistical analysis of survey data.

Table E-12. Detailed Review of the QAPP for Surface Water Transport Modeling of Discharge of Treated Waste Water

Page	Section	QAPP Comments/Questions Surface Water Transport Modeling of Discharge of Treated Waste Water
4	A4	Project organization: The description of roles and responsibilities is not detailed for QAPP purposes. Team members described as "TBD" appear to be responsible for significant parts of the work. The link between the QA Manager and the team (many of whom are un-named) is not clear.
5-6	A5	Problem Definition and Background: • This section is generic with unsubstantiated statements about potential water quality issues. • It is not clear what process was used to identify the water quality concerns that are stated. It would be useful if tables were provided to illustrate the potential levels of contaminants that are mentioned (e.g., radioactive materials, chloride, and bromide). • The reason the project includes a model are listed; however, it's not specifically stated why modeling is the best approach especially considering the approach assumes that an effect due to hydraulic fracturing will be found. There is no clear "null" hypothesis (i.e., an effect is assumed). • The focus of the modeling study is to identify "problematic conditions" but no definition or end-points are provided for these conditions. • Fate and transport properties of the specific water quality variables are not discussed and there is no mention of how the project will differentiate hydraulic fracturing impacts from other activities within a watershed that might release similar constituents. • The intensity of drilling activities within a watershed is not mentioned, nor is there any discussion of potential migration pathways between surface water and groundwater. • The QAPP mentions that "HF flowback and production water disposal methods vary across the U.S." (page 6) but it does not provide any quantitative information or discuss how the variability of disposal methods would be modeled or validated. • There is no discussion about the types of decisions that will be made and who the decision makers are. • Uncertainties/conflicts that will be resolved are discussed but how they will be interpreted is not clear (e.g., if an effect is found, what does that mean? How will the info be used?).
7-13	A6	Project/Task Description: • This section is very general. There is no real clear-cut delineation of tasks. • The first section on "data requirements" (page 7) is focused on three river systems in Pennsylvania but no rationale is given for how this area was selected. Coordination with the case study sites would help to avoid redundancies in data compilation. • The second section is on "model selection" and is also very general. The QAPP states that the choice of model that will be used in scenario analysis is dependent on the scenario conceptual model for specific sites. While the components included in the scenario conceptual model (e.g., location of hydraulic fracturing chemical discharges, flow rate, etc.) are defined, it is not clear how this information will be used in model selection nor how any scenarios might lead to selecting one model over another. • The QAPP lists WASP, QUAL2K, RMA4, and "others" as being under consideration by EPA. The models listed (by name) are all accepted models and are widely used; however, by not listing the "others" potentially under consideration or the process by which they will be evaluated, it is difficult to determine exactly what work will be done.

Table E-12. Detailed Review of the QAPP for Surface Water Transport Modeling of Discharge of Treated Waste Water (Continued)

Page	Section	QAPP Comments/Questions Surface Water Transport Modeling of Discharge of Treated Waste Water
		• The timeline for the project is short but at the time of QAPP development, the model selection process was not completed. The type of model affects the input data requirements which should be defined in the QAPP. The modeling exercise could also be linked to the case studies, rather than being a generic hypothetical scenario. • For the generic model, on the other hand, several reasons are given for selecting the empirical/statistical models pioneered by Holley and Jirka (1986) and Jobson (1996): they are based on U.S. rivers, use tracer data that do not require travel time and dispersion coefficient assumptions, and they are complementary to the codes listed as contenders for use in scenario analysis. • The selection of test watersheds (page 8) is vague and does not seem to be connected to the "data requirements" section on the previous page. The key watershed characteristics are not elucidated rather than be "prioritized by the amount of available data"; there is no discussion of the types of data that will be needed for watershed selection and how the model will be linked to hydraulic fracturing activities within a watershed. Also linkages between groundwater and surface water are not mentioned. • The section on "funding" (page 9) seems out of place. • The section on "expected products" (page 9) is vague and it is not clear how the listed outcome "Assessment of conditions that make surface water discharge of treated HF waste problematic" will be met through this project.
14-16	A7	Quality Objectives and Criteria: • This section is very general and does not relate to specific project activities. • There is no definition of DQOs, performance criteria, or model acceptance criteria as recommended in EPA/240/R-02/007 (e.g., acceptable level of uncertainty associated with model prediction, relative to decision error). • The section on "model uncertainty" lacks adequate detail. • The study states that data to validate the model will be drawn from published, peer-reviewed papers or federal- and state agency-accepted data/reports and that it is of sufficient quality. However, publication of data does not establish either quality or whether the data are appropriate for the current use. • The quality of the data for the current purpose must be determined. • Methods to assess data quality (screening criteria) are not defined.

Table E-12. Detailed Review of the QAPP for Surface Water Transport Modeling of Discharge of Treated Waste Water (Continued)

Page	Section	QAPP Comments/Questions Surface Water Transport Modeling of Discharge of Treated Waste Water
17-20	A9	Documents and Records: • This section is very general and does not appear consistent with the other QAPPs. It might make more sense to have a uniform approach across the hydraulic fracturing study. • The types of reports are stated, but not described. • The possibility of changes to the QAPP in particular, with the version labeling scheme, is discussed, but the process for approval is not. • Model science formulation report and peer review reports are not discussed nor are their directories listed. • Aside from a rigorous description of the data/model storage and retention processes, this section did not provide any detailed information regarding the reports that would be derived from the work: data assessment reports, model science formulation report, peer review reports, model assessment reports, interim progress reports, code standards, code auditing and testing, interim project progress, model calibration and evaluation. In addition, the description of configuration management, change control process, and the model(s) user manual(s) were not included in this section.
22	B7	Sampling and Measurement Requirements: • Section B7 does not document the procedures for calibrating the model (EPA/240/R-02/007). • Goodness of fit for the empirical model is said to be determined by "visual observation" of breakthrough curves through "professional judgment." This statement provides no real quantitative information about the factors that will determine whether the fit is, in actuality, "good" or not. The use of a qualitative method without established acceptance criteria to evaluate a model's effectiveness does not instill confidence in the conclusions drawn from the model; whether these conclusions are valid or invalid, the selection of this method leaves the possibility of a bias in the interpretation of the "professional," especially in an experiment whose design is assuming an effect. • Models that required calibration were only briefly mentioned in the section. These models, however, were said to be calibrated using quantitative methods (i.e., least squares), which is more rigorous than the qualitative methods described above. • Data used for calibration were briefly mentioned and a citation was provided, but no further information was included. • Frequency, details of the procedure, and resources and responsibilities of calibration were not discussed. • Types of output generated by model calibration were not discussed, nor were acceptance criteria or the methods of comparison. • Sensitivity analysis was not discussed. • Corrective action to be taken if criteria are not met was not discussed.
22	B9	Non-direct measurements: • This section provides a list of potential data sources and it may overlap with other activities that are being conducted under EPA's study. • There is no information provided on how the quality associated with these data will be documented and their relevance in addressing project objectives (EPA/240/R-02/007). • Methods for determining the underlying quality of data are not described; it is assumed the vetting process by the data generators is of sufficient quality for the purposes of this project. Unless the vetting process is investigated and determined to be appropriately rigorous, this is not a prudent assumption. • Related to the previous point, the QAPP fails to mention the potential for field- or lab-specific deviations in sampling and analytical methods or the steps that will be taken to reconcile these potential differences and assure the data can be used in conjunction with each other.

Table E-12. Detailed Review of the QAPP for Surface Water Transport Modeling of Discharge of Treated Waste Water (Continued)

Page	Section	QAPP Comments/Questions Surface Water Transport Modeling of Discharge of Treated Waste Water
		• No mention is made of the acceptance criteria of the non-direct data other than a generalized statement of the data being "of sufficient quality for [the] project".
24-25	B10	Data Management: • This section is similar to A9. It mentions that some of the data will be manually entered into spreadsheets and spot-checked. Since this is primarily a monitoring project, it isn't clear why there would be a need for manual data entry. • No requirements for the QA for model inputs are described. • According to EPA/240/R-02/007, this section should: Document the data management process from data acquisition through transmission and processing, and to final use; document the components of the process to generate model outputs; and highlight the QA procedures associated with the configuration of the hardware and software utilized by the model. These elements are not adequately addressed in the current document.
26-27	C1	Assessments and Response Actions: • This section contains text that is more appropriate for section A6 (Project/Task Description). • The use of sensitivity analysis and uncertainty analysis is important for modeling, but there is inadequate detail on how this would be performed. • The reference to the variability of hydraulic conductivity and porosity (page 17) is somewhat irrelevant since the project appears to focus on surface water modeling, where these parameters are less significant than for groundwater transport models. • According to EPA/240/R-02/007, this section of the QAPP should contain information to address the following questions: o Are more studies needed? o How good does my confidence have to be to move forward? o What do I need to know to be able to show this model is sound? However, the assessment text is general and does not describe assessments appropriate for modeling activities (e.g., model theory and algorithm evaluation assessments, assessments of the effect of variability within a population and uncertainty of model structure and parameter values on model outputs, the sensitivity of model outputs to a particular model and model inputs used, data quality assessments, model verification tests by statistical comparisons of model outputs with field or laboratory data, internal and external peer reviews, and hardware/software configuration testing). EPA/240/R-02/007 defines several quantitative and qualitative assessments appropriate for modeling activities and data but none of these are described in the QAPP. • The QAPP restates that model performance analysis will be conducted using the seven USGS tracer tests that were mentioned earlier. It also states that the goal of the performance analysis is to determine "how well does the model represents actual conditions in the field." Detailed explanations of how these analyses will be completed and what methods will be used (other than "professional judgment") are not available in this or any other section of the QAPP.
29	References	References: It is somewhat surprising that the most recent of the two cited references is 1996. The project team would benefit from a more thorough review of this topic.

Table E-13. Detailed Review of the QAPP for Well File Review Focusing on Well Design and Construction, and Hydraulic Fracturing Planning and Operation

Page	Section	QAPP Comments Well File Review Focusing on Well Design and Construction, and Hydraulic Fracturing Planning and Operation
2	A1	The Contract No., task order or project number, and prepared by information is missing. The title and approval sheet in general is fairly vague. The approval block only includes EPA personnel. There is no approval from the three subcontractors.
6	A4	Vaguely defines roles and responsibilities for EPA staff. Roles for the subcontractors are briefly described, but if this is an umbrella QAPP, their roles should be more specific.
9	A5	No schedule is referenced or defined including deliverables. There is a mention of a final report in 2012 and a follow on in 2014, but there are no other details on the report. An overall project timeline (schedule) should be referenced.
9	A6	The project objectives are not defined; rather, the section lists questions that are being asked to answer the objectives. The objective of this QAPP is to determine what, if any, potential contamination of underground sources of drinking water (USDWs) has occurred in the creation of wells using hydraulic fracturing. The QAPPs developed by ERG, Westat, and Cadmus are mentioned but references are not cited. Based on the documents posted on the EPA Web site, it does not appear that the Cadmus QAPP has been finalized.
9	A.6.1	**Objectives of the well file review:** Twelve "objectives" are listed, but it is not clear how they can be answered by the specific dataset. Objective 11 (if time permits, the well locations will be mapped…) seems inconsistent with the other objectives and Section A.6.2.1 states that GIS mapping is being conducted through a separated contracted effort.
10	A.6.2	**Data Review Methodology:** This section defines who will be responsible for subsets of the information and how it will be organized, but it does not provide information on how the data will be analyzed.
13	A.6.2	There appear to be some discrepancies between the Section A.6.2 text describing the data to be abstracted from the well files and the documentation of the spreadsheet files to be used for entering data (shown in Appendix 3). For example, the first sentence of the second paragraph of Section A.6.2.2.2 states that holes with a bottom hold location within 300 ft of the surface location will be considered vertical; however, Appendix 3 shows the "Vertical" field of the spreadsheet will be set to "Yes" if the "bottom hole within 5% of surface location".
18	A.7	**Quality Objectives and Criteria:** The quality objectives that are defined relate to the completeness of the records. Acceptance criteria are itemized in Table A.5, but no information is provided on how the team plans to deal with data that do not meet acceptance criteria. The definitions of "accuracy" (page 19, "agreement between technical experts"), "precision" ("correct entry of data"), and "bias" (re-examining a random subset of data) are inconsistent with typical scientific use of these terms as defined in EPA guidance documents. Methods to account for the inherent bias of the dataset (<1% of hydraulically fractured wells) are not presented.
17	A7	The accuracy goal for data entry is defined as 100% but only 10% of the data entries will be reviewed. A statistical sampling design should be used to define the amount of data review required to achieve the objective. The precision goal for data entry is defined at 100% agreement on duplicate data entries in spreadsheets and databases but the QAPP does not define the frequency and procedure for duplicate entries.
19	A7	The data precision bullet makes reference to using "duplicate data entry or similar procedures" for determining if data were correctly entered into spreadsheets and databases. There is no mention in the QAPP that any type of double-data entry will occur when reviewers enter their data into spreadsheets, nor is there any mention that data will be hand-entered into the database.

Table E-13. Detailed Review of the QAPP for Well File Review Focusing on Well Design and Construction, and Hydraulic Fracturing Planning and Operation (Continued)

Page	Section	QAPP Comments Well File Review Focusing on Well Design and Construction, and Hydraulic Fracturing Planning and Operation
19	A7	The "Bias" bullet should contain a statement that for this QAPP: "bias" is being defined as "data interpretation differences by different reviewers" instead of the usual use of "bias" in sample collection and analysis QAPPs (i.e., "measurement bias").
20	A8	• The text states that reviewers have many years of experience. The QAPP should specify how experience will be documented. Reference to Table A3 would identify the technical expertise required. • The text does not define the specific qualifications required for GIS experience and review of GIS data. • The procedures used to ensure that personnel understand the requirements of CBI and that training is documented should be defined.
20	A9	• The section does not define the controlling project documents or the QAPPs prepared by ERG, Westat and Cadmus. • Most data errors and project issues arise when data, responsibilities, or project steps are handed off to other people or organizations. The document does not describe if and how the data collection QAPP is linked to the QMP, modeling QAPP, analytical chemistry QAPP, and case study QAPPs. • Need to expand on CBI procedures and how CBI documents and records will be stored/protected.
22	B.4	**Analytical Methods:** This section provides a list of data queries that are essentially counting the number of wells that were reported for each criterion. No information is provided on statistical analyses of the data.
23	B5	The sole QA/QC activity identified is a 10% review of data entries conducted by a second, independent reviewer. The type and quality of data being managed under this QAPP warrants a more rigorous approach. For example, there should be 100% review of critical, hand-entered data. If data errors reach a predetermined threshold, the cause of the errors should be investigated, the level of QC review increased, and other related data reviewed to identify similar data errors.
24	B9	Table A.5 defines well data acceptance criteria but does not indicate if data will be flagged based on usability.
24	B10	All information presented in Sections B3 and B4 should be moved to B10. Those sections address the use and management of the information. By moving this text, it will help to address the following: • Naming format used to save data files (give examples) • Where ERG will store the original data received from the oil and gas operators; who will receive the Cadmus GIS data and where it will be stored. • How and where data compilation and manipulation will be documented. • Methods to maintain electronic data version control. • Method to maintain the integrity of the source data file. • File naming conventions such that version control is maintained. • Change control. SOPs, checklists or forms should be cited or developed to ensure that the data handling and review process is consistent throughout the project life cycle.
24	C1	Only one audit is listed (Technical Systems Audit; TSA) for the activities described in the QAPP. No schedule is defined. The text does not describe the TSA focus, where the TSA will be performed, or the use of a SOP or checklist to define the elements of the audit. The EPA NRMRL QMP specifies that for Category 1 projects an audit of data quality (ADQ) should be conducted on 50% of the data sets. The current QAPP does not include any independent QA data audits.

Table E-13. Detailed Review of the QAPP for Well File Review Focusing on Well Design and Construction, and Hydraulic Fracturing Planning and Operation (Continued)

Page	Section	QAPP Comments Well File Review Focusing on Well Design and Construction, and Hydraulic Fracturing Planning and Operation
25	D1	The amount of data to be reviewed by the data reviewer is defined in Section 2.10 at 10% but the frequency of reviews and when they will occur in the data flow process are not defined. For example, will manually entered data be verified before the data are uploaded to a database or manipulated or will data processing continue independent of the data review process?
25	D2	Section A7 states that data which is obviously inconsistent will be precluded from analysis. This section should define mathematical or statistical procedures (such as outlier analyses or goodness-of-fit tests) that will identify whether individual data values within existing data sets should be rejected, transformed, or otherwise qualified before any statistical analysis. The QAPP does not define the features of the data management system that will verify the accurate entry of values for important data parameters into this database, along with any data reduction procedures (for example, averages of replicate measurements). Further, the QAPP does not define when the activities will occur.
26	D3	The short discussion of the database does not indicate the documentation that will be developed to support the database (i.e., Entity Relationship Diagram, Data Dictionary, etc). The section does not address how results will be evaluated to determine if the criteria were satisfied. In addition, the section does not address how user requirements are met, or how limitations on the data will be assessed.
42	Appendix 2	**Description of how 350 wells were chosen:** The algorithm for selecting the wells and the manner in which it "balanced geographic diversity and random selection" is not described in this appendix. The use of 350 randomly selected wells to draw conclusions about what is happening at 25,000 wells could result in a high degree of uncertainty in the results, and selection bias could be a concern. If the referenced algorithm is reasonable, and if the operators are able to provide most of the requested information about most of the requested wells, then the dataset will be "representative". The conclusions drawn from these data will be more suited to being described as an initial investigation into the issues described, based wells selected using the method in Appendix 2, rather than a comprehensive review, from which the EPA could draw strong conclusions about what is happening at most wells.
43	Appendix 3	**Database:** This section describes a database that is being developed under a separate contract (ERG). It is not clear who the user-audience is for the database or how it will be used in the context of the hydraulic fracturing study.
58	Appendix 4	**Form:** The form provided in this section will provide a paper trail of issues related to inputting data into the database, but it does not provide information on how these issues will be tracked within the database.

Table E-14. Detailed Review of the QAPP for Supplemental Well File Review

Page	Section	QAPP Comments Supplemental Well File Review
6	A5	• This section does not describe the GIS and FracFocus tasks. • A schedule of deliverables is not provided. • The final products are not described.
6	A6	Section does not include a definition (or listing) of the elements of the worksheet relevant to this task.
	A6	The process for "recording data" is not well defined. There is no discussion of acceptance criteria for secondary data use.
7	A6	"Complaints" are listed as a task to be reviewed, but there is no description of the task other than "review". It is not clear if a report is to be generated or how the data are to be recorded.
8	A7	DWOs are not defined; the text suggests that quality elements will be "considered", but does not define acceptance criteria. The accuracy goal is defined as 100% but procedures for meeting the accuracy goal involve review of 10% of the files (only). It is not clear how 100% accuracy will be achieved by this method.
10	A8	Competence and CBI clearance are the only training documented for this task.
11	A9	This section does not include any discussion of secondary data considerations. It should include information about the approach for identifying, selecting and obtaining existing information for use on the project.
12	B3	A description of how to handle data from surveys and other sources (naming conventions, storage procedures, and file maintenance) is not provided in this document and could be included here.
13	B9	Acceptance criteria are not defined.

Table E-15. Detailed Review of the QAPP for Environmental Justice Analysis

Page	Section	QAPP Comments Environmental Justice Analysis
6	1.2	The section does not include a clear problem or objective statement. Three questions are posed for examination. There is no discussion of why the secondary data that will be collected during the project are relevant for consideration for the current project. No background is provided on how existing data will be collected and maintained.
7	1.3	Data from nine hydraulic fracturing service companies will be used to represent well sites per county. The QAPP states that "Though this data is measured in well sites per county, and thus is not at a particularly high resolution, it is the most representative data available of the location of hydraulically fractured wells." The use of an inadequate data set cannot be justified as the basis of the conclusions that the study is attempting to make. The data analysis is ultimately based on observations of GIS plots. Statistical analyses such as correlation analysis or principle component analysis should be performed.
8	1.3.2	In the third bullet under disparity index, the formula should be changed to the following for the reasons cited above: Disparity Index = (number of well sites) x (% "vulnerable" – regional average of % "vulnerable". Region should then be defined as the counties in which the natural gas is located and available for extraction.
9	1.4	Acceptance criteria are not defined for demographic, hydraulic fracturing, and GIS mapping data. Although presented in tables, the data specifications are sometimes defined as questions rather than criteria. The completeness specification should define the percent of population for which data are available. No criteria are defined for data accuracy. Data uncertainty is mentioned by minimum criteria not established.
11	1.5	The qualifications needed to perform the analyses and use of GIS mapping tools should be defined.
11	1.6	The section does not describe the documents or files that will be generated during the project and how they will be kept during the project such that version control is maintained. The methods used to obtain the secondary data should be defined (e.g., downloaded from Web sites, provided as hard copy reports).
12	2.1	This section does not define QC procedures, but rather refers to the screening criteria described in Section 1.4.
12	2.2	No additional discussion is provided on the limitations of the data or acceptance criteria.
13	2.3	The section does not define where hard copy or electronic records will be saved or named to maintain version control. It does not describe hardware and software used for data or information handling and storage throughout the life cycle of the project, i.e., from secondary (existing) data sources, to the office's data or model system.
13	3.1	The QAPP does not discuss the frequency of data quality audits, who will conduct them, what they will entail, and how results will be reported, corrective action identified, and verification performed. With the exception of frequency, the same observations apply to the technical systems audit.
14	3.2	The Reports to Management section does not discuss the communication of audit issues to management.
14	4.1	The section does not describe how data will be assessed to determine if it is fit for use. (e.g., an assessment of data reasonableness would be appropriate for the study so that anomalous data could be removed from the data set).
14	4.2	The reconciliation process reverts to Section 1.4 acceptance criteria table. As previously noted, true acceptance criteria are not defined for the data.

Table E-16. Detailed Review of the QAPP for Health and Toxicity

Page	Section	QAPP Comments Health and Toxicity
1	Signature Page	Organization of the first two signatures is not identified.
2	Table of Contents	Sections are not numbered.
7	4.2 Reference documents (section 2 of the SQAP)	This section is described in the IEEE guidance as "a complete list of documents referenced elsewhere in the text of the SQAP." • Several documents that are referenced in the remainder of the SQAP are not listed in this section: • "Agency guidance" for records collection, maintenance and retention is referred to in Section 12 but no reference is listed here. • The NCEA QMP is referenced in Section 3 – Roles and Responsibilities (pg 11) but not listed here. • The "Git software version control system" is referenced on page 14 (Software Configuration Management Plan) but the reference is not listed here.
8	4.3.1 Organization	• It is not clear how the organizational chart on pg 8 relates to the project organization. This chart does not directly relate to the staff listed in the roles and responsibilities section (there is some overlap but it is not complete). The organizational chart does not support the roles and responsibilities text. • Distinct roles for three QA positions are described in the roles and responsibilities section; the NCEA DQA, the ORD DQA and the Program QA Director. However, the organizational chart identifies the "Director of QA (DQA)" only. It is not clear if this box is intended to show the NCEA DQA, the ORD DQA or the Program QA director. • The organizational chart shows a reporting relationship from the Director of QA to the Deputy Center Director which is in conflict with the text description of reporting and accountability.
9	4.3.2 Tasks	Tasks are listed, but not described. All other required items are addressed in this section.
10	4.3.3 Roles and responsibilities	Roles are defined and linked to tasks, but do not link to org chart. The text indicates a role for a Hydraulic Fracturing Program QA Manager (reviews documents submitted by NCEA QAM) but the element is not described or defined and it is not shown on the organizational chart.
11	4.3.4 Quality assurance estimated resources	This section is described in the IEEE guidance as "the estimate of resources and the costs to be expended on quality assurance and quality control tasks." This is addressed as a general practice but not specific to this project. This may be adequate but difficult to track.
4.4 Documentation(section 4 of the SQAP)		
NA	4.4.1 Purpose	This section is not included as a subsection in the plan. However, the required elements are provided in the subsections of Section 4.4.2. Adding this section would improve the overall context of the task and clarity of the document.
NA	4.4.2 Minimum documentation requirements	(see subsections below)
12	4.4.2.1 Software requirements description (SRD)	Requirements are addressed.

Table E-16. Detailed Review of the QAPP for Health and Toxicity (Continued)

Page	Section	QAPP Comments Health and Toxicity
12	4.4.2.2 Software design description (SDD)	Requirements are addressed. It was noted that the size of the project does not warrant a separate SDD plan.
13	4.4.2.3 Verification and validation plans	The description of the verification process does not assign responsibility for developing the TDD and/or BDD. Reference to "application developer" is assumed to mean the *NCEA HF software developer*. "Application developer" is not an established project role. This could be clarified.
14	4.4.2.4 Verification results report and validation results report	Addressed.
14	4.4.2.5 User documentation	This section is incomplete; the text states that documentation "*will be"* produced but the IEEE guidance indicates that these elements are a part of the SQAP. The requirements are not addressed in this document.
14	4.4.2.6 Software configuration management plan (SCMP)	• Procedures reference the "Git software version control system" as the guidance for software configuration management but this system is neither described nor referenced in the document. This SQAP does not adequately address the SCMP. • No schedule of events is provided. • The section states that change contention will be avoided by directing "specific people to work on specific parts of code" but does not identify who is responsible for the directing and how adequacy is assessed. • "Coders" are identified as the parties responsible for fixing issues, but this is not an established role and it is not clear 1) who will perform this function; 2) where the direction will come from; or 3) how an assessment is conducted. • Documenting release and delivery of the product is not addressed although other parts of the document indicate that the product is being used internally and will not be released. If this element is not required, it could be noted here.
4.5 Standards, practices, conventions, and metrics(section 5 of the SQAP)		
NA	4.5.1 Purpose	This section was not included in the document. Methods for monitoring and assurance of conformance with identified standards, practices and conventions are not described.
15	4.5.2 Content	Selected software quality assurance product and process metrics are not addressed.
4.6 Software reviews(section 6 of the SQAP)		
NA	4.6.1 Purpose	This section lists reviews, but does not state how the reviews will be conducted.
NA	4.6.2 Minimum requirements	The introduction to this section notes that the small size and limited scope of the project dictate an abbreviated software review process. Only three of the 10 listed minimum requirements are addressed. Elements that were omitted are noted below with an "NA" for page number.
18	4.6.2.1 Software specifications review (SSR)	Not addressed.

Table E-16. Detailed Review of the QAPP for Health and Toxicity (Continued)

Page	Section	QAPP Comments Health and Toxicity
NA	4.6.2.2 Architecture design review (ADR)	Not addressed.
NA	4.6.2.3 Detailed design review (DDR)	Not addressed.
18	4.6.2.4 Verification and validation plan review	Addressed.
18	4.6.2.5 Functional audit	Addressed.
18	4.6.2.6 Physical audit	Addressed.
NA	4.6.2.7 In-process audits	Not addressed.
NA	4.6.2.8 Managerial reviews	Not addressed.
NA	4.6.2.9 Software configuration management plan review (SCMPR)	Not addressed.
NA	4.6.2.10 Post-implementation review	Not addressed.
NA	4.6.3 Other reviews and audits	No other reviews or audits are noted.
18	4.7 Test (section 7 of the SQAP)	This section is addressed; the SQAP indicates that due to the size and scope of the project, no additional tests (outside the Verification and Validation Plan) are required.
18 (and 20)	4.8 Problem reporting and corrective action (section 8 of the SQAP)	This project is shown to have a 3 week duration (page 9) but problem reporting and corrective actions are to be reported quarterly. The schedule for reporting does not align appropriately with the project schedule. The assessment and response section included on page 20 may be more appropriate in this section.

Table E-16. Detailed Review of the QAPP for Health and Toxicity (Continued)

Page	Section	QAPP Comments Health and Toxicity
19	4.9 Tools, techniques, and methodologies (section 9 of the SQAP)	This section is short, but likely adequate given the small size and scope of the project.
19	4.10 Media control (section 10 of the SQAP)	Addressed.
19	4.11 Supplier control (section 11 of the SQAP)	Addressed.
19	4.12 Records collection, maintenance, and retention (section 12 of the SQAP)	Current agency practices for records collection, maintenance and retention are referred to but not described or referenced.
19	4.13 Training (section 13 of the SQAP)	This section does not meet minimum requirements for identifying necessary training.
20	4.14 Risk management (section 14 of the SQAP)	This section identifies system failure (catastrophic data loss and periodic inaccessibility of the agency network) as the only potential area of risk for the project. Mitigation of risk is not described in this document, but transferred to the Office of Science and Information Management (OSIM). No reference to the OSIM risk management system is provided.
21	4.15 Glossary (section 15 of the SQAP)	Section is adequate for intended use.
25	4.16 SQAP change procedure and history (section 16 of the SQAP)	A change history is included; however, this SQAP is the 00 revision and was approved on the date of the last noted revision. It appears that the change history documents the internal edit and review process which is not necessary.

Table E-17. Detailed Review of the QAPP for Modeling Impact of Hydraulic Fracturing on Water Resources Based on Acquisition Scenarios

Page	Section	QAPP Comments Modeling Impact of Hydraulic Fracturing on Water Resources Based on Acquisition Scenarios
1	A1	The effective date is not specifically designated on the cover or approval sheet. It might be implied that the effective date is February 6, 2012 for Version 1.0.
3	A2	Figures and tables are not included in the table of contents.
6-9	A5-A6	• The future scenarios are not clearly defined, but that is due to the fact that the input for these will be developed as part of the project. • It is not clear how the models will be used to determine impacts related to water withdrawals associated with hydraulic fracturing. • Uncertainties/conflicts that will be resolved are discussed but not exactly clear how they will be interpreted (e.g., if an impact is found, what does that mean? How will an impact be determined?). • Discussion of why modeling is an appropriate approach or why the selected model is best is not included in this section.
9-20	A6	A6 is named Project/Task Description in the QAPP; tasks are included in response to EPA's Performance Work Statement (PWS) provided to the contractor performing the work. Sections of the performance work statement are included within each subtask followed by a description of the work to be performed to address each PWS task. There is no definition of how an impact will be determined, nor is there any discussion/assessment of the existing models' ability to meet the stated project objectives.
20-28	A6-A7	The primary objective of this project is to determine the potential impacts (or relative impacts) to stream flow and groundwater recharge as a result of hydraulic fracturing (water withdrawals); however, there is no discussion of how an impact will be quantified, especially in light of the uncertainty inherent in model input parameters and simplifying assumptions required for numerical representation watershed characteristics. The use of models to assess relative differences between scenarios is a common approach, but reliance on relative/qualitative model calibration and no quantitative uncertainty analysis cast doubt upon the ability of the project as currently formulated to meet the stated objectives.
29	A9	• The types of reports are included with project schedule but the information to be included in the reports is not described. • The possibility of changes to the QAPP, in particular with the version labeling scheme, is discussed, but the process of approval is not. • Model science formulation report, peer review reports are not discussed. • This section did not provide any detailed information regarding the reports that would be derived from the work: data assessment reports, model science formulation report, peer review reports, model assessment reports, interim progress reports, code standards, code auditing and testing, interim project progress, model calibration and evaluation. In addition, the description of configuration management, change control process, and the model(s) user manual(s) were not included in this section. • New code development is not included for this project; therefore, documentation associated with code development is not required for this project.
32	B10	Procedures for assuring resource management are not discussed.
32-33	C1	• Plans for model performance assessment are discussed in this section; the discussion of model calibration acceptance criteria in A7 is limited. • The QAPP does not describe procedures for sensitivity analysis. • Plans for uncertainty assessment are discussed in A7; the uncertainty analysis will be qualitative in nature. There is no discussion of assessing the models' ability to resolve

Table E-17. Detailed Review of the QAPP for Modeling Impact of Hydraulic Fracturing on Water Resources Based on Acquisition Scenarios (Continued)

Page	Section	QAPP Comments Modeling Impact of Hydraulic Fracturing on Water Resources Based on Acquisition Scenarios
		an impact associated with water withdrawals for hydraulic fracturing relative to the impact of input parameter uncertainty on model predictions/results. • Plans for data quality assessment are not discussed in this section. Earlier in the QAPP, it states that data are only as coming from sources of sufficient quality for the purposes of this project. This does not address the need to assess the accuracy, quality, and traceability of model input and output.
33	D1	Deviations from approved QAPP and the response actions to correct the deviations are not discussed in this section Potential data uncertainties and model limitations are not discussed in this section.
33	D1	Criteria to review and validate input data are listed in A7 and B9; criteria to review or validate model outputs are discussed in the QAPP (see Sections A7 and D2). These procedures should be cross-referenced here.
34	D2	No specific verification and validation methods are discussed in detail. The section simply states that spot checks and ongoing assessment of model components and their output relative to DQOs will be performed. Assessments of validation issues will be discussed between technical and QA representatives from the project team. The authority for resolving validation issues will be the QA Officer for EPA ORD.
34	D3	This section does not describe how data usability will be assessed vs. the study objectives, or describe how uncertainty and limitations will be identified and reported. It states that the value of the information generated by this project will be determined by evaluating data quality and by comparing methods/results with published data, and that data quality issues will be discussed in the journal articles.

Table E-18. Detailed Review of the QAPP for Hydraulic Fracturing Scenario Modeling

Page	Section	QAPP Comments Hydraulic Fracturing Scenario Modeling
3	A2	The tables, figures, and appendix not included in the table of contents.
5-6	A4	An organizational chart is included but only includes four LBNL staff with two points of contact from the EPA (QA Manager and EPA Project Manager for HF Failure Scenarios).
6-13	A5	Diagrams are not to scale (and this is not indicated) and the overburden is depicted as smaller than it actually would be. This is not a huge problem in the QAPP because the diagram is merely being used as a general explanatory tool, but a diagram like this could unfairly influence the public's perception of the document, especially if similar diagrams are used in the final report. Other than stating that the project is in support of the EPA's efforts to report to Congress on the effect of hydraulic fracturing on drinking water, the QAPP provides no discussion on decisions that will be made and/or who would make them
18-22	A7	• Data are stated to have been evaluated by another EPA project and include a citation; however, no mention of the DQOs of the cited project is made in this QAPP. • The authors state that the data will be properly evaluated for use in this project; however, the process of data evaluation and the acceptance criteria that will be applied are not clearly stated. • The authors list "contaminant-laden deeper water rising to potable water aquifers through fractures faults, imperfectly completed wellbores, and compromised abandoned wells" as a potential part of their analysis of groundwater contamination. This statement is vague and, unless elucidated, could potentially result in the disregard for the nature (i.e., physical and chemical properties) of the contaminants.
23-24	A9	• The QAPP states that interim progress reports will be submitted to EPA. No mention is made of data assessment reports. This may be because the data have already been evaluated by EPA; however, not including data assessment reports as a document derived from this work could imply that data evaluation reports will not be generated. Because the details of data evaluation were not provided in the QAPP, it might be prudent to write a data evaluation report. • Code auditing/testing reports are not planned. While extensive documentation has verified and validated the use of these codes in contaminant transport scenarios, it might be prudent to include results from test problems as part of the preliminary report to ensure transparency. • Model evaluation records are not specifically mentioned in this section; however, the LBNL plans to do a sensitivity analysis to demonstrate variability and uncertainty. Including the results of this analysis in the preliminary report might help increase transparency.
25	B9	This section does not discuss how secondary data from another EPA project, EPA, and scientific literature will be assessed for use. The screening criteria and process to verify that data collected for another purpose are suitable to meet the project objectives are not described.
25-26	B10	Specific procedures on data project management are not included in this section. The current section states that data will be checked, line by line, for accuracy and Section A9 provides a brief overview of data storage requirements; however, this information does not describe record keeping procedures, document control systems, or audits trails. The failure to include this information could lead to inconsistent or improper record keeping.

Table E-18. Detailed Review of the QAPP for Hydraulic Fracturing Scenario Modeling (Continued)

Page	Section	QAPP Comments Hydraulic Fracturing Scenario Modeling
26	C1	This section does not describe assessment procedures that will be used to verify the accuracy of the modeling activities. It references the use of a peer review process but does not provide details or reference a SOP. EPA QA/G-5M G*uidance for Quality Assurance Project Plans for Modeling (EPA, 2002b)* includes extensive guidance on assessments that are appropriate for modeling activities. The scope of authority of assessor (EPA QA Manager) to recommend or direct changes (as the result of the TSA) is not discussed in this section. The procedure for making changes to the QAPP is discussed in Section A9; however, it cannot be assumed that the same scope of authority can be applied to the TSA results. This information should be explicitly stated prior to the TSA audit to avoid conflicts.
26	C2	The section does not describe the reporting process for software tests, model performance evaluations, data quality assessments, quality problems and the results of assessment activities to management. In addition, it does not define the corrective action process.
27	D1	The three criteria by which input data are accepted are defined as (1) were the data collected using accepted standard methods, (2) according to "approved procedures," and (3) under QA Program. The document does not define "approved procedures" and how an assessment of a QA Program is determined. EPA QA/G-5 states that the criteria used to review and validate the model results should be stated to ensure objectivity and consistency.
27	D2	The methods used to validation model results and procedures to maintain integrity of data are not described.
27	D3	This section does not describe how data usability will be assessed vs. the study objectives, or describe how uncertainty and limitations will be identified and reported. It states that reports will describe and justify any deviations from the QAPP and data limitations of data output.