The following document is an example of an external Class 3 QAPP. This is for a small limited study by an external (non-SC DHEC) party. Please see Page 18-19 of the SCDHEC Guidance Document for Preparing QAPPs for Environmental Monitoring Projects/Studies (Rev 1.1 Sept 2008) for more information.

Please note: It is essential prior to developing a QAPP that the EQC Office of Quality Assurance (OQA) is contacted to determine what Class the project will fall under.

Section A Project Management

A1 Title Page

Noname River Basin Study

Prepared by Alan Robinson
Town of Noname, SC
March 21, 2009

Comment: This is an example only.

Note that the Lab Director is included in the approval page.

Project Manager: Chris Mitchell
City Manager, Noname, SC

Lead Organization: Town Council of Noname, SC

Project Location: Noname River Basin

Project Manager: _____ Date:_____
Alan Robinson

SC DHEC BOW: _____ Date:_____
Carol Copeland, Watershed Manager

_____Date:_____
David Graves, Aquatic Biology Section Manager

Acme Labs Director _____Date:_____
Edith Williams, PhD

SCDHEC OA Office: _____Date:_____
Nydia Burdick, Manager

Comment: This is an updateable Table of Contents. To update: click on the table and hit F9. You may choose to update the pages or the entire table. In order to add items to this table, you must view the outline toolbar. Then highlight the item you wish to add and select Level 1, 2, or 3. Then you must update the table as above and choose update the entire table in order to see the new item.

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A3 Distribution List

Comment: All of the people listed in the Distribution List receive the QAP and <u>any updates/changes to the QAPP.</u> At the very least this list must include those people that signed the approval page and anyone involved in the project. In the case of a large group (for example the field investigators) the manager can be the only person listed, but the manager is responsible to ensure those working for him know what is in the QAPP. This can include that manager making copies and distributing them to the group.

Name	Title	Organization	Phone	Fax
Chris Mitchell	Project Manager	Noname SC	803-555-2222	803-555-2221
Alan Robinson	Field Manager	Noname SC	803-555-2222	803-555-2221
Bill Reid	Mayor	Noname, SC Mayor	803-555-2222	803-555-2221
Carol Copeland	Basin Manager	BOW	803-898-4203	803-898-4117
Nydia Burdick	QA Manager	OQA- Columbia	803-896-0862	803-896-0850
Edith Williams	Lab Director	Acme Labs	803-777-6292	803-777-1234
David Graves	Aquatic Biologist	BOW	803-898-4398	803-898-4200
Bill McDermott	Project Validator	BOW	803-898-4398	803-898-4200
Meredith Murphy	Water Manager	BOW	803-898-4222	803-898-4140

Table 1 Distribution List

A4 Project/Task Organization

Comment: Anyone in a major role in the project must be listed and their role defined. The person who maintains the QAPP must be identified.

Chris Mitchell is the Project Manager and will manage personnel in this study.

Alan Robinson will be the field manager and will collect samples and take them to the lab within holding times. Mr. Robinson is also responsible for developing and maintaining the QAPP.

Bill McDermott– is the Data Validator for this project.

Carol Copeland – Will provide expertise from the BOW Program.

Nydia Burdick – Will review and approve the QAPP.

Edith Williams – is the Lab Director for Acme Labs (Lab Cert Number SC00999). Under her authority samples will be analyzed and the results verified.

Patrick Grayson - The QA Officer for Acme Labs. Mr. Grayson will verify the lab data and insure that the analytical requirements of the QAPP are met. This includes ensuring that acceptance requirements in Section A7 are met.

Field Investigators- will survey the basin and determine possible sampling sites. As an aid to Mr. Robinson they will also collect samples. ***Comment: Notice that the individuals were not listed,***

only the field manager. If only one or two people are specifically collecting samples or performing field analyses, then it may be decided that a QAPP needs to go to them both. For this project there is a field manager, who may choose to give them a QAPP, parts of the QAPP that pertain to them, or verbally give instructions.

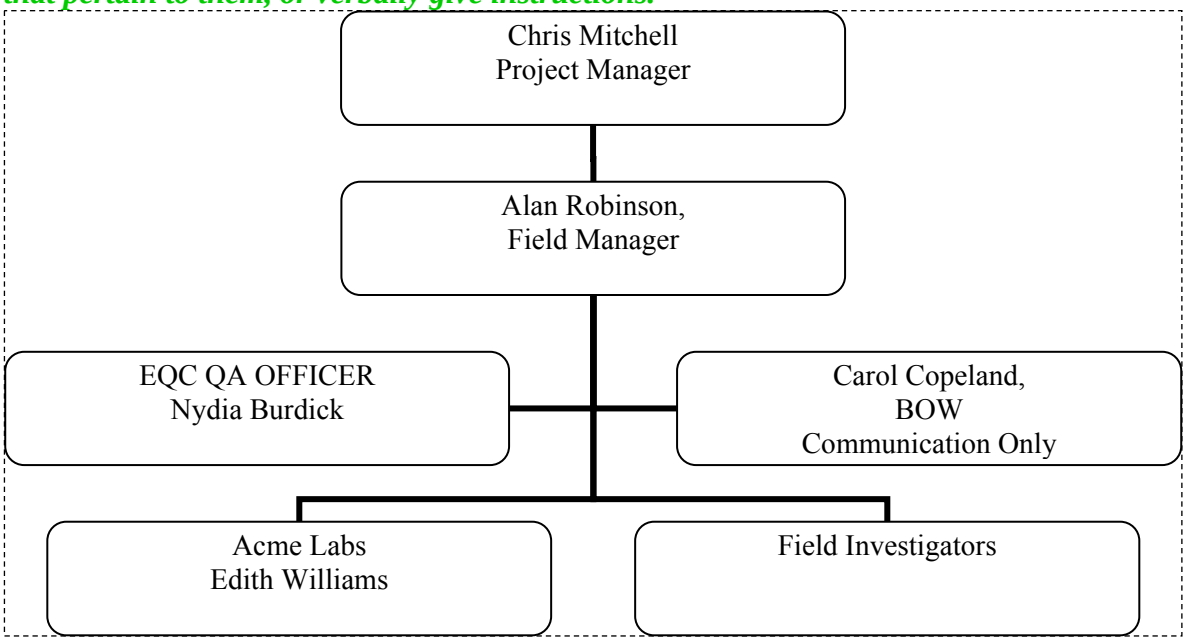

Figure 1 Project Organization Chart

Comment: Notice the position of the QA Office. This indicates that the QA Office assists but is independent of the project. The same is true for the SCDHEC Basin Manager. The SC DHEC Validator is not part of this Organizational chart, but would appear in the same place that the QA Office and Basin Manager is placed. He is independent of the Project, but determines if the data is of sufficient quality.

The QA Office determines that the QAPP is meets all the requirements of the QAPP Guide, checks to make sure that the Lab is Certified for all analyses that will be performed, that the methods that will be done are approved. The Basin Manager checks to make sure that what is being done is valid, that the methods chosen for analysis are appropriate to the project, and the project conforms to regulation.

In the case of a study by a town or a community, often the investigators are volunteers. This is fine, but they must be trained to collect samples and must not perform field analyses (pH, conductivity, DO etc) unless they are willing to be certified as a Laboratory by the SC DHEC Office of Environmental Laboratory Certification (Lab Cert).

Note: The chart above can easily be changed by clicking in the boxes. If more boxes are needed, refer to the help section of MS Word under organization charts.

A5. Problem Definition/Background

Explain why the study is being done, the historical background, the regulations involved, and what decisions or actions may come out of this study.

The Noname River Basin contains the longest free-flowing black water river in SC. The Basin stands as a unique asset to the State of South Carolina, due to its valuable ecological, economic, recreational, and cultural resources. The Noname River starts in Edgefield and Saluda Counties (South Fork) and Lexington County (North Fork) and merges into one stream body in Orangeburg County flowing through Dorchester, Colleton, and Charleston Counties before reaching the Atlantic Ocean. The most significant threat to water quality within the Noname River Basin is non-point source pollution. The Noname River Basin is on the 303(d) List for the following impairments, varying for different parts of the basin: pH, E. Coli bacteria, dissolved oxygen, and turbidity. In most cases, the exact source of the impairment remains unclear. Such identification would facilitate corrective actions, aiding in the implementation of the State's Anti-degradation Policy as part of S.C. Regulation 61-68. Attainment of State water quality standards will serve the interests of the State of South Carolina. The purpose of this project is to locate possible non-point sources of pollution and then determine the extent that each source contributes to the impairment of the water quality. Since the primary threat to this water system is from increased populations of E. Coli, the lab will analyze the samples for E. Coli. Furthermore, Best Management Practices (BMPs) will be put into place and a second study will be conducted soon afterwards. This second study will be a decision type study to determine if the BMPs made a difference.

Emphasis will be placed on the major river systems that are close to the town of Noname. These systems include: the North Fork Noname and the main stem of the Noname River.

A6. Project/Task Description

Summarize what is to be done in the project, include the measurements that will be made (field and lab, approximate work schedules, detail where the study will take place-includes maps, and if there are any time or resource problems (personnel, weather, money—are examples).

As stated previously, the purpose of this proposed project is to identify problem areas as well as their probable sources and to bolster existing knowledge concerning the Noname River Basin's ambient water quality baseline. Visual surveys were conducted prior to the beginning of the Project to identify any illegal or un-permitted discharges, any agricultural area of concern, and any construction/land clearing within the those parts of the Noname River Basin located within 10 miles of Noname, SC. The Visual Survey and 303(d) List were used as a basis for targeting and establishing Sampling locations were determined according to the visual survey results and sampling locations. From this the Project team determined that 8 sites (see Figure 2) would be included in this portion of the study and that sites would be sampled monthly.

Figure 2 Map of Sampling Sites
(This would be the map where the sampling sites would be shown.) The map above is used as an illustration only.

The following table gives Project activities and their anticipated date of initiation and completion.

Activity	Name/Group	Anticipated date of initiation	Anticipated Date of Completion	Comments
Visual Reconnaissance	Alan Robinson and Field Investigators	2/1/2009	2/28/2009	
Site Determination	Alan Robinson and Field Investigators	2/1/2009	2/28/2009	
QAPP Approval	Nydia Burdick	3/9/2009	3/30/2009	**Comment: Notice this is a 3 week period of time.**
Project Training	Alan Robinson	3/1/2009	3/30/2009	
Sampling Begins	Noname Field Investigators	4/13/2009	8/30/2009	On Tuesday and Thursday of each week.
Lab Cert Audit of Acme Lab	SC DHEC Office of Environmental Laboratory Certification	6/1/2009	6/3/2009	Already scheduled
Data Verification	Alan Robinson	4/20/2009	9/15/2009	
Final Lab Report	Alan Robinson and Chris Mitchell	9/30/2009	10/31/2009	
Data Validation	Bill McDermott	As soon as Verification is complete	12/1/2009	

Table 2 Project Schedule

The dates shown in the table above are estimates only. Because rain events can impact the results of the data, it is important to associated rain data with the collected samples. Wet weather or rain events are defined as rainfall that exceeds 0.10 inches (as determined by local volunteers with fencepost rain gauges). Sampling events may be delayed in the cases of serious droughts or rain events.

A7 Data Quality Objectives (DQOs) and Data Quality Indicators (DQIs)

Comment: In this section the performance/measurement criteria must be listed. This is the discussion of how items like precision, comparability, accuracy and so on are important to the project, how they will be determined and what the requirements of the QAPP are for each. This is taken care of below stating that the acceptance criteria listed in the SOP is good. Sometimes, that is not the case and the requirements are list here. In addition the DQO process is to be inserted here (see page 25 of the QAPP Guide Rev 1.1 and below.

E. Coli samples will be collected using a sterile 120 ml IDEXX Bottle at the surface of the water. Normally these are collected at 0.3 meters, but the shallowness of some areas has caused the need for surface sampling. Samples will be brought on ice to the laboratory within 6 hours.

All Measurement Criteria of QC performed in the Laboratory will meet requirement as listed in the attached SOP for E. Coli determination by Quantitray (Appendix A).

Flexible DQOs and not the full formal DQO process is required for a Class 3 QAPP. What this means is that those portions of the DQO process that "fit" the project are discussed. If something does not apply to the project, then it is not needed in the QAPP. Since this project is primarily an investigative project the decision statement will not be needed (Section A7 pg 25-26 of the SCDHEC QAPP Guide, Rev. 1.1)

DQOs

1. State the problem- To improve the water quality of the Noname River the sources of pollution must be determined and, once identified, repaired.

2. Identify the decision- N/A

3. Identify inputs to the study - E.Coli enumeration by Colilert/Quantitray

4. Define the Study Boundaries- Noname River and tributaries 10 miles north and 10 miles south of Noname, SC

5. Limits on Decision Error- Although this is an investigative type study, limiting error are important. Because of the nature of analyzing bacterial populations precision measurements will not be determined. Accuracy will assured by the use of a GPS unit to locate the exact site, icing the samples and getting them to the lab quickly to ensure the best recovery of the organisms. Furthermore the Lab SOP calls for running positives and negatives weekly on the Colilert media. Representativeness is a great concern and the experiment design and the visual reconnaissance should ensure that the non-points sources are identified properly. Comparability is important in this study because this study will be compared with historical data and future studies to this study and historical data. In order to ensure that the items compared are comparable, the same sampling and analytical methods are being employed as have been used in the past. The future study will also

employ these same methods. Completeness is important, but not all samples are critical. It is estimated that up to 25% of the data could be lost and the study would not be impacted. While sensitivity is not usually discussed when determining bacterial counts, the shortened holding times, icing the samples and running Colilert should help to protect the bacteria.

6. Analytical approach/Decision rule – NA

7. Optimize the design for obtaining the data- It is believed that 8 sites collected twice a week over a 4 month period, producing approximately 240 samples will be enough to determine the approximate location of the non point sources.

A8 Training

This section requires the identification of any specialized training or certification requirements; how the training will be provided; who is responsible for ensuring all are trained and where the documentation for the training is stored. For this QAPP, this portion needs to be a discussion of how sampling personnel will have the training to collect the samples properly. The Laboratory that will be used for any analysis (field or laboratory) must be certified. The training programs at certified labs have already been reviewed by the SC Office of Environmental Laboratory Certification and does not need to be included here for a Class 3 QAPP. <u>However, the Laboratories Certification Number issued by the SC DHEC Office of Environmental Certification MUST be included here.</u>

Specialized training for this project will include GPS measurements and collecting samples for E. Coli analysis. Mr. Robinson will train local volunteers (AKA Field Investigators) to determine possible E. Coli sources, collecting samples validly, and using a GPS to verify sampling site location. Training records will be kept in the City files under this project's folder.

Acme Laboratory is certified by SC DHEC Lab Cert. for performing E.Coli analysis by Quantitray. Their Certification Number is SC00999.

A9 Documentation and Records

Here give how project staff will receive the most current version of the QAPP, what the project manager wants to see in the data package coming from the lab; a list of all documents generated by the project; and finally a storage and archival plan for the project records.

Mr. Robinson is responsible for writing, maintaining and distributing the QAPP. The QAPP will be hand carried to Noname, SC Staff. Other persons on the Distribution List will receive the most updated QAPP via U.S. Mail.

Data Report package:
The data report package from the lab will include the following items:

1. The Data in a printed Excel Spreadsheets and also on CD. Each Spreadsheet submitted will give the data for 1 Site but for the entire sampling period.

2. A MS Word file on each site (both hardcopy and on CD) will give a narrative for each sample collected detailing any problems with the chain of custody, sampling, analysis, and QC.

Other records generated by this project:

Item	Produced by:	Hardcopy/Electronic
Field Logs*	Field Staff	Hardcopy
Chain of Custody+	Field Staff	Hardcopy
Micro Analysis Sample records+	Lab	Both
Micro Incubator Temp charts+	Lab	Hardcopy
Micro initial media checks with positive and negative organisms+	Lab	Hardcopy
Micro sterility checks on media and bottles etc	Lab	Hardcopy
Quantitray leak checks	Lab	Hardcopy
Reports+ *	Lab	Both
Lab QC records+	Lab	Both
Internal Audit reports+	Lab	Both
Training Records*	Field	Both
Training Records +	Lab	Both
Corrective Action Reports*	Field	Hardcopy
Corrective Action Reports+	Lab	Electronic
Sample Narrative+	Lab (includes COC comments from field)	Both

Table 3 Project Documents and Archive

*These records will be filed in the Noname, SC town files for 2 years. Archived to Noname, SC Record warehouse for 5 years and then destroyed.

+ These records will be filed at Acme Labs for 2 years, and then archived for 8 more years. Electronic records are backed up nightly. At the end of the project all files will be backed up separately (on DVDs) and stored with the hard copies.

Section B Measurement/Data Acquisition

B1 – B7 Sampling and Analysis Design and Requirements

This section combines B1-B7 in Section B. The difficulty with this sometimes, is that items can be omitted. Below is this example projects B1-b, however, it has been separated in to each item required by the QAPP Guide. Each requirement is written in green type. A QAPP submitted to the Office of Quality Assurance does not have to annotated in this way. (This was just simply to make it easier to see the requirements.) However, all requirements must be met. Please refer to the QAPP Guide for more information. Each page of the QAPP that the items refer to is given in parenthesis as in "(25").

1) A schedule detailing project sampling activities (32)

Sampling will begin 4/13/09 and will end on 8/30/2009. Samples will be collected each Tuesday and Thursday of each week. All rain events will be measured and documented using a simple manual rain gauge.

2) A description and justification for design strategy indicating the area, volume or time period to be represented by a sample. The type and total number of samples expected or needed.

In February 2009, Noname, SC Field Investigators performed visual reconnaissance of the Project's Geographical Area. This reconnaissance included a walk of the River to sight out possible non-point sources (NPS). Items that were of interest included facilities, poultry enclosures, dog pens, etc.

In addition, the Investigators listed out items they have noticed during routine sampling that may have implication for stream impairment. As result of these activities the following sites were chosen for this study. From this survey, 8 possible sources of impairment were noted. For each source sampling sites were designated above the source, at the source, and below the source. For those sites that are close (within 50 yards) to already established SC DHEC sites, the established site will be used. As previously stated, the samples will be collected twice a week- on Tuesday and Thursday. A single water sample will be collected from each site.

A single duplicate sample will be collected at one location each sampling event. The duplicate location will rotate through the sites so that a duplicate is collected at each site at least once. Duplicates will be taken by collecting a sample in a 290 ml IDEXX bottle and aliquoting into two containers. Samples will be well shaken and then aliquoted aseptically into two 100 ml sterile bottles. Because of the nature of bacterial samples the precision data is for informational purposes only. All samples will be transported to the laboratory within 6 hours in order to meet required holding times.

3) Sampling locations are specified as well as how the sites will be identified.

The sites at the sampling source were named using sequential numbers 1-8. The Sites located at established DHEC sites will also receive a number, but will be identified with SC DHEC numbers in the report. These are also given in the Table in Appendix B. The upstream sites will be named with the number used at the source site plus the letter U (for upstream). Likewise the downstream

sites had the letter "D" added. Thus the site at source 7 would be named 7, upstream is 7U, and downstream is 7D. Samples will be identified with the site name and the sampling date. Because the Water Quality Standards are given according to how the water body is used, the usage will be noted and will be included in the final report. Appendix B includes a list of all the sites, a map of the area with the sites shown, the GPS locations of each site, and the suspected non-point sources itemized for each site.

4) A discussion of what to do if sampling sites become inaccessible. If a sampling site becomes inaccessible, then sampling at that site will be delayed. If the inaccessibility will last for more than two weeks, a new nearby site will be located. This site must be sampled along with the original sample (when the site become accessible) for the rest of the project. If no site can be located, the remaining sites will be included in the study without the inaccessible site.

5) Identification of project activities schedules such as each sampling event, times samples should be sent to the laboratory etc. Each sampling event will occur on Tuesday and Thursday of each week between April 13th and August 30th. For each event the following will take place:

Item	When	Staff	Duration	Comments
Dumping rainwater from the rain gauges	24± 1 hours before samples are collected.	Field Investigators	Less than 1 minute per site. About 45 minutes for 2 field investigators with each visiting half the sites.	Date and time documented in the Field Investigators logbook
Filling out the COC	Just before collecting the sample	Field Investigator	5 Minutes	
Reading rain gauge	24 hours after the rain gauge at each site was dumped	Field Investigator	1 minute	Documented on the COC.
Collecting Samples	24 hours after the rain gauge at each site was dumped	Field Investigator	10 minutes per site. The route is broken in half- with each investigator taking half the sites. The .route will take approximately 1.5 hours to complete after the first sample is collected.	COC documentation
Return to town	After the last site collected and placed in cooler.	Field Investigator	30 minutes	
Meet Field Manager at office and relinquish samples to him	Immediately upon arrival at the Town Hall.	Field Investigator and Field Manager	10 minutes	COC must be signed correctly to maintain custody chain.
Field Manager drives samples to the Lab	Immediately upon receiving the samples	Field Manager	30 minutes	Total time at this point is roughly 2.75 hours after the first sample was collected.
Field Manager relinquishes samples to Acme Labs	Immediately upon arrival at the lab	Field Manager and Acme Sample Custodian	5 minutes	COC must be signed correctly to maintain custody chain.

Table 4 Sampling and COC Events

7) Identify sources of variability and how this variability is reconciled with project information.

A source of variability for this study includes rainfall. This is addressed below in the discussion about rain gauges. In order to be able to the best direct comparisons of the samples, rain event samples will be associated with the samples. Another source of variability is the nature of bacterial analysis. Bacteria are well known not to easily be distributed evenly through a sample even when the samples are well shaken. Thus there will be some precision samples collected just to obtain an idea of the error in comparing one bacterial sample to another (see above discussion on duplicates). No conclusions will be drawn from that data.

8) SOPs for sampling must be either attached or included in this section. The QAPP must be clear in how each sample type/matrix will be collected—including how many of each matrix.

Sample Collection SOP:

A single water sample will be collected twice a week at each site.

All sample collection, field analysis, handling, preservation, and Chain of Custody (COC) will be done as follows:

1. The sample will be collected in mid-river by either using a boat or wading.
2. The sample will collected upstream of the sampler.
3. The COC is filled out just prior to sample collection.

9) Indicate what sample containers should be used and what sample volumes should be collected.

10) Indicate whether sampling equipment and samples should be cleaned and/or decontaminated, identifying how this is done. If there are by-products (rinsates for instance—from rinsing the sampling equipment-) discuss the disposal of those by products. (This is dealt with below by saying that the IDEXX bottles are disposable and sterile).

11) Indicate how samples are to be homogenized, composited, split, or filtered if applicable.

4. A 120 ml sterile disposable IDEXX bottle (or for duplicates a 240 ml bottle) will be used and the samples will be collected under the water surface in an aseptic manner by unscrewing the lid underwater.
5. Once the bottle is filled, the sample lid will immediately be replaced. The sample is then aliquoted into a new 120 ml sterile IDEXX bottle which is filled to the 100 ml line. For duplicates, the 240 ml bottle will be shaken vigorously 25 times and then aliquoted into 2 100 ml sterile IDEXX bottles. Both are filled to the 100 ml line.
6. The sample information is written on the bottle. This includes
    a. Site
    b. Date and Time of collection
    c. Initial of the sample collector
7. The time the sample was collected is written on the COC.

12) Identify whether the samples should be preserved. If preserved indicate how preservation should be carried out (and with what). In this case the preservative is ICE.

13) Indicate holding times and how samples will be physically handled.

8. Samples will be placed in iced in coolers immediately. The temperature blank in the cooler must be ≤ 10ºC upon arrival of the samples in the lab.
9. Samples will be brought to the lab within 6 hours of collection by Mr. Robinson.
10. Once the COC is signed, and the samples are relinquished to the laboratory, then the cooler is opened and the laboratory blank is read. This temperature is documented on the COC.
11. The samples are logged into LIMs (Laboratory Information Service), along with the reading of the temperature blank. The samples are bar-coded and then taken to the Microbiology Lab along with the COC.
12. The samples will be analyzed as soon as they are brought into the Microbiology lab, with a maximum delay of 2 hours.

13) If field analysis is being done, indicate how the instruments will be deployed and operated to avoid contamination and ensure collection of the valid data. Since there is no field analysis being doing, this is N/A for this project.

14) If continuous monitoring is use as part of the project, indicate the averaging time and how instruments should store and maintain raw data, or data averages. This is N/A for this project.

15) What support facilities or equipment is needed?
This is N/A for this project.

16) Address actions to be taken when problems occur and identify the individual responsible for corrective action and how this should be documented.
17) Specify what information is critical and what is for informational purposes only. (This will some times be that information is critical—here we've allowed a loss of 25% of the samples).
It is important to obtain at least 75% valid data from this project. If this is not achieved at the end of the expected sampling date, then the sampling will be extended in order to obtain 75% valid data. If problems occur with broken samples or invalid samples due to temperature on receipt, the hold time was exceeded or other problems, the lab will notify Mr. Robinson who will determine any needed corrective action and if resampling is needed. This corrective action and the result of these actions will be documented on a project corrective action form and stored in the project file at Noname, SC town files.

18) Indicate how sample information should be documented. See Table 4 for COC information. Besides the COC and the bottle, each sample is logged in the Field Investigators Field Log book along with the reading from the rain gauge. Samples are logged into the Lab LIMs system. Individual analyses on the Micro samples are logged in a Micro workbook for the Colilert analyses. This book also includes the QC for each sample batch.

19) Describe chain of custody (COC) procedures and include the form that will be used to track custody. See table 4 for COC procedures and Appendix B for the COC form.

20) Identify by number, date and regulatory citation all analytical SOPs (field and lab) that should be followed If an EPA method is referenced in the SOP, it must also be given here. Specify turnaround times (the time it takes to analyze a sample). Provide method validation information and SOPs for nonstandard methods. (Comment—since this is a relatively simple procedure for measuring rain, the validation portion can be skipped. If this was a truly non-standard method—like measuring caffeine in streams—then not only would the SOP have to be included, but proof that the method works.)

Rainfall Determination SOP:

A QRST Fencepost Rain Gauge will be attached to a removable post at all the sites. This plastic rain gauge is readable to 0.01 inches or 0.1 mm of rain. These are emptied 24 hours prior to sampling. The rainfall for the previous 24 hours is determined just before the sample is collected and recorded on the chain of custody. Wet weather or rain events are defined as rainfall that exceeds 0.10 inches.

Analytical Methods:

The samples will be analyzed by Colilert using Quantitray for enumeration. The SOP is in Appendix C of this QAPP. The SOP includes checks on the media, bottles and the QC for the analysis. Corrective actions in the laboratory for analyses that are out of control (failed QC etc) are handled by the Microbiology Section Manager. The QA Officer is notified via email of QC failures that cause sample invalidation.

Analyte	Method*	PQL	Lab	Turnaround Time
E. Coli by Quantitray	Colilert	1 CFU/100 ml	Acme	1 week
Rainfall	Rain Gauge	0.01 inches or 0.1 mm	Field Investigators	Prior to sampling

Table 5 Analytical Methods and Requirements

*The Colilert Method is an EPA approved method. The Lab SOP is attached. The rainfall SOP is directly from the manufacturer's information and the entire SOP is given above.

21) Identify all equipment or instrumentation that is needed. See the individual SOPs above and attached SOP Section 5.

22) Specify any specific method performance criteria. . See the individual SOPs above, Table 5, and attached SOP Section 8.

23***) Identify procedures to follow in the Lab when failures occur and identify the individual responsible for corrective action. (Comment- this may be in the Lab QA/QC plan which can be attached but there must be a referral to the exact section or page. Alternatively this can be a simple statement—see below).***

The Micro Lab Supervisor is responsible for any analytical problems for failures. These problems, correct actions and results of the corrective actions are logged in an electronic Corrective Action Log.

24) Identify sample disposal procedures. The Colilert method uses the entire sample.

25) Identify the QC activities which should be used and the frequency they are run.
Field – There is 1 duplicate sample at one site per event. The site at which the duplicate is collected is rotated. There are no control limits for Precision due to the nature of the analysis. Precision will be calculated as follows:

$$RPD = \frac{CFU1 - CFU2}{Average\ of\ CFU1\ \&\ 2} \quad x \quad 100\%$$

Lab – See attached SOP Section 8. The QC in the lab is mainly run positive and negative controls on the media.

26) Information about lab and field instrumentation and equipment needing inspection testing and maintenance.
Field Equipment N/A
Lab equipment and instrumentation- See Section 5 and 8 of the attached SOP.

27) Identify instruments that need calibration, how often, where the calibration is documented and how deficiencies are handled and documented. N/A for this project.

B9 Data Acquisition Requirements (Non-Direct Measurements) – only if applicable for a Class 4 QAPP.
Comments: Any data that is not directly produced by this project are non-direct measurements—this includes modeling. Include what you are using and justify its inclusion. The data used must be of known quality.

There are no non-direct measurements in this project.

B10 Data Management
Not required for a Class 3 QAPP.

Section C Assessment and Oversight

C1 Assessment and Response Actions

Type	Frequency & expected Date	Organization Responsible	Individual who is notified of deficiencies	Time frame of notification	Person responsible for Corrective Action	Corrective Action effectiveness documented where?	Individuals receiving Corrective Action Response
External Certification Audit	Due 5/2009, every 3 yrs	SC DHEC Lab Cert	Edith Williams	Within 90 days	Patrick Grayson	Laboratory Electronic Corrective Action file	Carol Smith (DHEC) and Edith Williams
External Proficiency Test	Due 7/2009, one per yr for WP	A2LA certified provider	Patrick Grayson and Carol Smith (DHEC)	Within 30 days of study close	Section Manager	Laboratory Electronic Corrective Action file	Patrick Grayson
Internal Audit	Mid project, 6/2009	Acme, P. Grayson	Section Manager	1 week after audit	Section Manager and analyst	Laboratory Electronic Corrective Action file	Patrick Grayson
Internal Audit-field	Beginning and mid project-5/1 and 7/1	P Grayson	Allen Robinson	Immediately	Allen Robinson	Corrective Action file folder	Chris Mitchell
Check of Cert Status	End and beginning of project	Chris Mitchell	Allen Robinson	Immediately	Allen Robinson	Corrective Action file folder	Chris Mitchell.

Table 5: Project Assessments and Corrective Actions

C2 Reports to Management

Not required for a Class 3 QAPP.

Section D Data Validation and Usability

D1 Data Review, Verification and Validation

Comments: This section details the criteria that are used to accept, reject or flag data. Note in this study that all non acceptable criteria will result in data being rejected. In other projects data may be flagged with a letter or number to indicate what was wrong with the data. See page 89 of the QAPP Guide for examples of commonly used flags.

Item	Criteria	If this criteria is not met, is the sample rejected or flagged?	Flag that will be used (if applicable)	Comments
Sample Temperature	Sample temperature blank is above 10ºC	Rejected	NA	
Colilert Color change	Sample turns an odd color when Colilert added	Rejected	NA	
Sample smell	There is a bleach or other chemical odor	Rejected	NA	
Hold Time	Sample arrives at the lab more than 6 hours after collection	Rejected	NA	
Sample Damage	Sample bottle is leaking or otherwise damaged	Rejected	NA	
Analysis Time	Sample is not set up with Colilert until more than 8 hours after collection	Rejected	NA	
Analysis Time	Sample is read after 28 hours of incubation	Rejected	NA	

Table 6 Data Criteria

D2 Validation and Verification Methods

The process for verifying and validating the data is as follows:

Comments: This is just an example. The way staff will verify must be discussed and agreed upon. The way validation will be done must be worked out with the Validator. A reasonable discussion or list of steps showing how verification and validation will be done is all that is needed here. <u>It is NOT advised that staff who are producing data be selected as the data validator.</u>

Verification:

Verification is done as per the ACME Laboratory Manuals:
A second analyst will check the analysis records and use the Colilert MPN tables to determine if the correct result was reported by the original analyst. The Project Manager will be responsible for ensuring that for every sample sent to the laboratory, a result was received. This check will

ensure that the sample data is complete. The Project Manager will also note if the goal of 75% data validity was achieved. If not, they will determine the number of samples required to achieve 75% valid data. Those samples will be collected by extending the sampling period at all sites. Mr. Robinson will notify staff on the distribution list that sampling will be extended and for how long. Verification will also include an overlook of field data to make sure documentation was complete. Any problems will be noted in an email to Mr. McDermott who will validate the data.

Validation:

Mr. McDermott will note the problems seen by the verifier. He will then examine the data and ensure that sample results match what was expected at the site--for example: that the upstream sites have lower concentrations of the analytes than at the source or downstream from the source. He will compare the data against historical data and determine if the data agrees with the project data. After these assessments, the Validator researches the data and/or documentation that are inconsistent. This is done by contacting Lab and Field Personnel to try and correct and/or explain inconsistencies. After all of the Validation steps have been completed, the Validator submits a report to the Project Manager who will include this report as appendix to the final report.