*Guidance*
*for*

# *Quality Assurance Project Plan*

*Development for*

*EPA Funded Cooperative Agreements with State and Tribal Agencies for the Conduct of FIFRA Pesticide Programs*

*Document Control No. EC-G-2000-067*
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## FORWARD

This guidance document is intended to help State and Tribal agencies with cooperative agreements under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to develop acceptable Quality Assurance Project Plans (QAPPs) for their programs, as required by Agency regulations and policies. It is intended to provide descriptions, suggestions and examples illustrating the component parts of a QAPP, the topic areas for discussion, and the level of detail that is expected in describing how a State or Tribal pesticide program would account for these elements. This guidance is intended to supplement, and to be used together with the Agency's generic documents "EPA Requirements for Quality Assurance Project Plans: QA/R-5", and "Guidance for Quality Assurance Project Plans: QA/G-5". The QA/R-5 and QA/G-5 documents are available on the Internet at: http://www.epa.gov/quality1/qa_docs.html.

This guidance is the second product developed by a joint EPA-State workgroup originally created in September 1998 during a Pesticide Regulatory Education Program (PREP) course given in Davis, California. Many of the state participants in the PREP course were not familiar with the latest developments in the Agency's requirements relating to quality assurance documentation for grant recipients, and urged the Agency to help develop additional guidance tailored specifically to the characteristics and needs of pesticide programs. The workgroup issued "Guidance for Quality Management Plan Development" (OECA Document Control Number EC-G-1999-024) in June 1999. The workgroup is co-chaired by the Office of Enforcement and Compliance Assurance (OECA) and the Office of Pesticide Programs (OPP), and includes representatives from EPA Regional Offices as well as State and Tribal pesticide lead agencies and State pesticide laboratories. The group members are listed in Appendix F.

Since there is great variation among States and Tribes in terms of pesticide program size and scope of responsibilities, no single example will be equally useful for all. This guidance document is emphatically not intended to be a literal model or to imply that EPA considers this the ideal State/Tribal QAPP language. Understanding that all agencies operate within certain budget, resource, and personnel constraints, this guidance is intended to illustrate a QAPP, but will have to be adapted to describe the actual organizational structure, responsibilities and resources of the agency developing a QAPP, and describe how the agency will meet the QAPP requirements.

The need for guidance tailored to pesticide programs deserves some explanation. The primary reason for the States' request for supplementary guidance is that the Agency's generic guidance documents, QA/R-5 and QA/G-5, are consistently phrased in terms of "projects" in ways which do not fit well with FIFRA program activities. The effect is that the Agency guidance implies that every data gathering activity is a finite "project" with a beginning, middle and end, and consequently, subject to advance planning, predictable schedules, and detailed specification of what data are to be gathered, what compounds are to be analyzed for, and the exact methods to be used throughout sampling, analysis and assessment procedures.

The reality of pesticide regulatory programs is quite different, in that most of the data gathering activities do not consist of planned projects in the usual sense, but rather are actions that arise in the context of on-going enforcement and compliance responsibilities, i.e., inspections or investigations. Collectively, State and Tribal pesticide agencies conduct over 40,000 inspections or investigations per year, resulting in the collection and analysis of close to 12,000 samples. The samples include both pesticide product formulations as well as a wide and unpredictable variety of environmental samples, ranging from soil, water and foliage to clothing and animal carcasses. The universe of pesticide products is a further complicating factor, since there are over six hundred active ingredients formulated into more than 20,000 registered products. In short, the level of program activity, the chemicals involved and the methods appropriate to sampling and analysis are largely contingent on factors not under State or Tribal program control. Under such circumstances, OPP and OECA believe that a State pesticide program should be able to produce a single QAPP that will cover its generic data gathering activities. Only very rarely would a pesticide data gathering activity be distinctly different enough (and large enough) compared to regular program responsibilities and activities to warrant a separate QAPP.

Finally, please note that the term "agency" is used throughout this document to identify all Pesticide State Lead Agencies (SLAs) and Tribal organizations that apply for cooperative agreement funds to conduct FIFRA programs.

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The program QAPP is a formal document describing in comprehensive detail the necessary quality assurance (QA), quality control (QC), and other technical activities that must be implemented to ensure that the results of all FIFRA program activities will satisfy stated performance criteria. The program QAPP must provide sufficient detail to demonstrate that:

- the program's regulatory, technical and quality objectives are identified and agreed upon;
- the intended measurements, data generation, or data acquisition methods are appropriate for achieving program objectives;
- assessment procedures are sufficient for confirming that data of the type and quality needed and expected are obtained; and
- any limitations on the use of the data can be identified and documented.

Most environmental data operations under the FIFRA Program require the coordinated efforts of many individuals, including program managers, inspectors, quality assurance managers, samplers, laboratory personnel and others. The program QAPP must integrate the contributions and requirements of everyone involved into a clear, concise statement of what is to be accomplished, how it will be done, and by whom. It must provide understandable instructions to those who must implement the program QAPP, such as division directors, section and program/project managers, supervisors, and staff. Staff might include, but not be limited to: inspectors, field sampling teams, analytical laboratory management, bench chemists and personnel, inspectors, hydrogeologists, enforcement staff, and data reviewers.

In order to be effective, the program QAPP must specify the level or degree of QA and QC activities needed for the particular environmental data operations. Because this will vary according to the purpose and type of work being done, it is often practical to use a graded approach in planning and carrying out the work. This means that the QA and QC activities applied to a program will be commensurate with:

- the purpose of the environmental data operation (e.g., monitoring, enforcement, worker health and safety, etc.),
- the type of work to be done (e.g., routine inspections, complaint investigations, worker health and safety assessments, groundwater monitoring, etc.), and

C the intended use of the results (e.g., enforcement, information, implementation of new technology, development of environmental regulation).

The program QAPP should be composed of standardized, recognizable elements covering each aspect of the program from planning, through implementation, to assessment. These elements are presented in that order and have been arranged for convenience into four general groups. The four groups of elements and their intent are summarized as follows:

A Program/Task Management - This group of QAPP elements covers the basic area of program management, including objectives, roles and responsibilities of the participants, etc. These elements ensure that the program has defined goals, that participants understand those goals, that use of the data in decision making is clear, that the approaches to be used and the planning requirements and outputs are specified.

B Data Generation and Acquisition - This group of QAPP elements covers all aspects of program data generation and describes procedures to ensure that appropriate methods for data collection or sampling; measurement, analysis and data generation; data handling; and QC activities are employed and are properly documented.

C Assessment and Oversight - This group of QAPP elements covers the activities for assessing the effectiveness of the implementation of the program and associated QA and QC activities. The purpose of assessment is to ensure that the Program QAPP is implemented as prescribed.

D Data Validation and Usability - This group of QAPP elements covers the QA activities that occur after the data collection or generation phase for the various program activities is completed. Implementation of these elements ensures that the data conform to the specified criteria, thus achieving program objectives.

All applicable elements must be addressed in the program QAPP. If an element is not applicable, this should be so stated in the QAPP. Documentation, such as state environmental regulations, approved Work Plans, laboratory Quality Assurance Plans, Standard Operating Procedures, Compendia of Methods, etc., may be included as appendices or referenced in response to a particular required QAPP element. This approach consolidates existing documentation and minimizes duplication or preparation of material already in place. It is the organization's responsibility to ensure that reference documents are available as needed. Information contained in a previously EPA approved Quality Management Plan may be referenced as needed, although it may be preferable to

reproduce the information to help ensure the completeness of the QAPP. The preparing organization should decide what may be the best approach to distributing information between the two documents. In some cases, a hybrid document may be permitted, but this should be discussed with the appropriate EPA Region's QA staff in advance. It is recommended, but not required, that the format outlined in this guidance be followed. It is also left to the discretion of the preparing agency whether one QAPP or multiple QAPPs would best describe the QA system being implemented under FIFRA grants.

The program QAPP should be consistent with the organization's approved Quality Management Plan (QMP). Material referenced that is contained in the QMP does not need to be included with the QAPP. The program QAPP should also address related QA planning documentation (e.g., Quality Management Plans or Quality Assurance Project Plans) required from suppliers of services (e.g., contractors, non-profits, local or municipal agencies, environmental laboratories, etc.) critical to the technical and quality objectives of specific program activities, projects or tasks.

This guidance is based on EPA documents QA/R-5 and QA/G-5 which should be used in conjunction with this document when developing a state's FIFRA program QAPP. This document is not intended to be a "boiler plate document," but instead is a collection of ideas and examples pulled together to give possible scenarios and direction for individual organizations to use in developing their QAPPs.

It is expected that other documents will be needed to support this document; standard operating procedures (SOPs) and the Laboratory's QA Plan. Most of the real detail will be in SOPs and will be very specific to the individual agencies (SLAs, laboratories, Regions). The process of integrating sampling, analysis and output is emphasized. They cannot and should not be separated.

## GROUP A: PROGRAM MANAGEMENT

The elements in this group (Table 1) address program management, including program statutory authority, if applicable, objectives, roles and responsibilities of the organization's personnel, etc. These elements document that the program has defined goals, that program personnel and support organizations (contractors, laboratories, local agencies, etc.) understand the goals and the approach to be used, and that the planning outputs have been documented.

**Table 1. Group A: Program Management Elements**

| | |
|---|---|
| A1 | Title and Approval Sheet |
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| A3 | Distribution List |
| A4 | Program Organization |
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| A6 | Program Description |
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### A1 - TITLE AND APPROVAL SHEET

The requirement in R-5 states: *"On the Title and Approval Sheet, list the title of the plan, the name of the organization(s) implementing the plan, and the names, titles, signatures of appropriate approving persons and their approval dates."*

This requirement is straightforward, except that this sheet should reflect managers with FIFRA program responsibility, rather than those with responsibility for a specific activity. Approving officials may include, but not be limited to:

- Organization's Program Manager (Division Director, Administrator, etc.),
- Organization's QA Manager,

- Organizations Grant Manager (for EPA's grant or financial agreement),
- EPA Regional Project Manager,
- EPA Regional QA Manager,
- Others, as needed (e.g., division, branch or section supervisors, field operations manager, laboratory managers, other state agency officials, local agency officials, etc.),

## A2 - TABLE OF CONTENTS

EPA R-5 guidance states: *"List the table of contents for the document, including sections, figures, tables, references, and appendices. Document control format may be required by the EPA Project Manager and QA Manager. When required, apply the document control format in the upper right-hand corner of each page following the Title and Approval Sheet."*

For the FIFRA program QAPP, this requirement is straightforward. It is recommended that a document control format (Figure 1) be used on each page following the Title and Approval Sheet to track the date and revision number for each section. Note that this is a suggested format. The organization may choose to track the document using a footnote, rather than a header, and may choose to include other information than that shown below

Section No. _____
Revision No. _____
Date _____
Page___ of ___

**Figure 1. Example Document Control Format**

## A3 - DISTRIBUTION LIST

EPA R-5 guidance states: *"List the individuals and their organizations who will receive copies of the approved QAPP and any subsequent revisions. Include all persons responsible for implementation (including managers), the QA managers, and representatives of all groups involved."*

The FIFRA program QAPP follows this requirement closely. List the individuals and their organizations, including all persons responsible for implementation (e.g., division, branch or section supervisor, organization QA managers, staff, and representatives of all other organizations who are covered by or must implement the program QAPP) who need copies of the approved program QAPP and any subsequent revisions,. Paper copies need

not be provided to individuals if equivalent electronic information systems can be used. Use of document control format (see above) facilitates document revisions since only the section that is changed needs to be redistributed, rather than the entire document. The organization should use its judgement concerning the distribution or redistribution of complete copies of the QAPP. Those individuals responsible for implementation of specific parts of the quality system should always have the most current information concerning their area of responsibility. Copies provided as a courtesy may not need frequent updates

## A4 - PROGRAM/TASK ORGANIZATION AND PLANNING DOCUMENTATION

### A4.1 - Program/Task Organization

EPA R-5 guidance states: *"Identify the individuals or organizations participating in the project and discuss their specific roles and responsibilities. Include the principal data users, the decision-makers, the QA manager, and all persons responsible for implementation. The project quality assurance manager **must be** independent of the unit generating the data. (This does not include being independent of senior officials, such as corporate managers or agency administrators, who are nominally, but not functionally, involved in data generation, data use, or decision-making.) Provide a concise **organization chart** showing the relationships and the lines of communication **among** all project participants. Include other data users who are outside of the organization generating the data, but for whom the data are nevertheless intended. The organization chart must also identify any subcontractor relationships relevant to environmental data operations."*

The FIFRA program QAPP should identify the key individuals and/or organizations responsible for implementing the overall program and/or separate program areas and discuss their specific roles and responsibilities. Include the principal data users, decision makers, and the program QA manager. If the FIFRA program involves, for example, a Department of Agriculture, a Department of the Environment, a Department of Health, an state environmental laboratory, etc., these should all be included and their interrelationship discussed in the text. On a functional basis, describe the organizational structure and identify staff responsible for implementation. Staff should be identified by name in the organizational chart, but need to only be identified by title and responsibility elsewhere in the QAPP. The organization should use its judgement in determining to what level the FIFRA program QAPP will identify specific personnel versus functional positions, however, a program QAPP which does not identify a QA Manager (or functional equivalent, see below) and the specific managers and their titles who are responsible for data generation activities will have more difficulty being approved by EPA. The program QA Manager should be independent of the unit generating the data. Because few state FIFRA programs have the resources for a full time QA person,

especially one outside of the laboratory, alternative arrangements may be necessary which still permit some degree of organizational independence. Note that having a laboratory QA manager is not sufficient unless the person performs QA duties for the entire FIFRA program, not just the laboratory. The following are a few examples of how this might be achieved.

**I.** The organization may have one independent QA manager for the program.

**II.** The organization may use personnel from a different department or part of the program to provide independent oversight . For example, maybe there is an ex-inspector working in a non-data generating area who would be available, or a person from the Department of Health could be used.

**III.** The organization may use multiple qualified personnel within the same department as affected by the program. The different people would act as QA reviewers for parts of the program, for which they are not data generators. For example, the supervisor of a laboratory's formulations section could review data generated by the use/misuse section. A designated inspector could perform oversight of the laboratory, the laboratory QA manager could provide oversight of inspector sampling activities, etc.

Note that organizational independence does not include being independent of senior officials, such as senior managers or agency administrators, who are nominally, but not functionally, involved in data generation, data use, or decision making. All alternative arrangements must be documented and justified in the program QAPP and will be considered by the Regional QA Manager on a case by case basis. The individual responsible for maintaining the official, approved program QAPP should be identified.

Provide one or more concise organization charts showing the relationships and the lines of communication among all organizations or program personnel. Thus, one chart might show the relationship of the organization to its regulated community, its contractors and subcontractors, local and municipal agencies, analytical laboratories, etc., and the other show the structure of the organization itself with its division directors, branch chiefs, section supervisors, etc. The inclusion of data users who might utilize data generated by the program is optional, provided they are in an informational rather than a direct decision making role. Thus, environmental groups, members of the public, etc. do not have to be shown on the charts. An example of a program organization is shown in Figure 2.

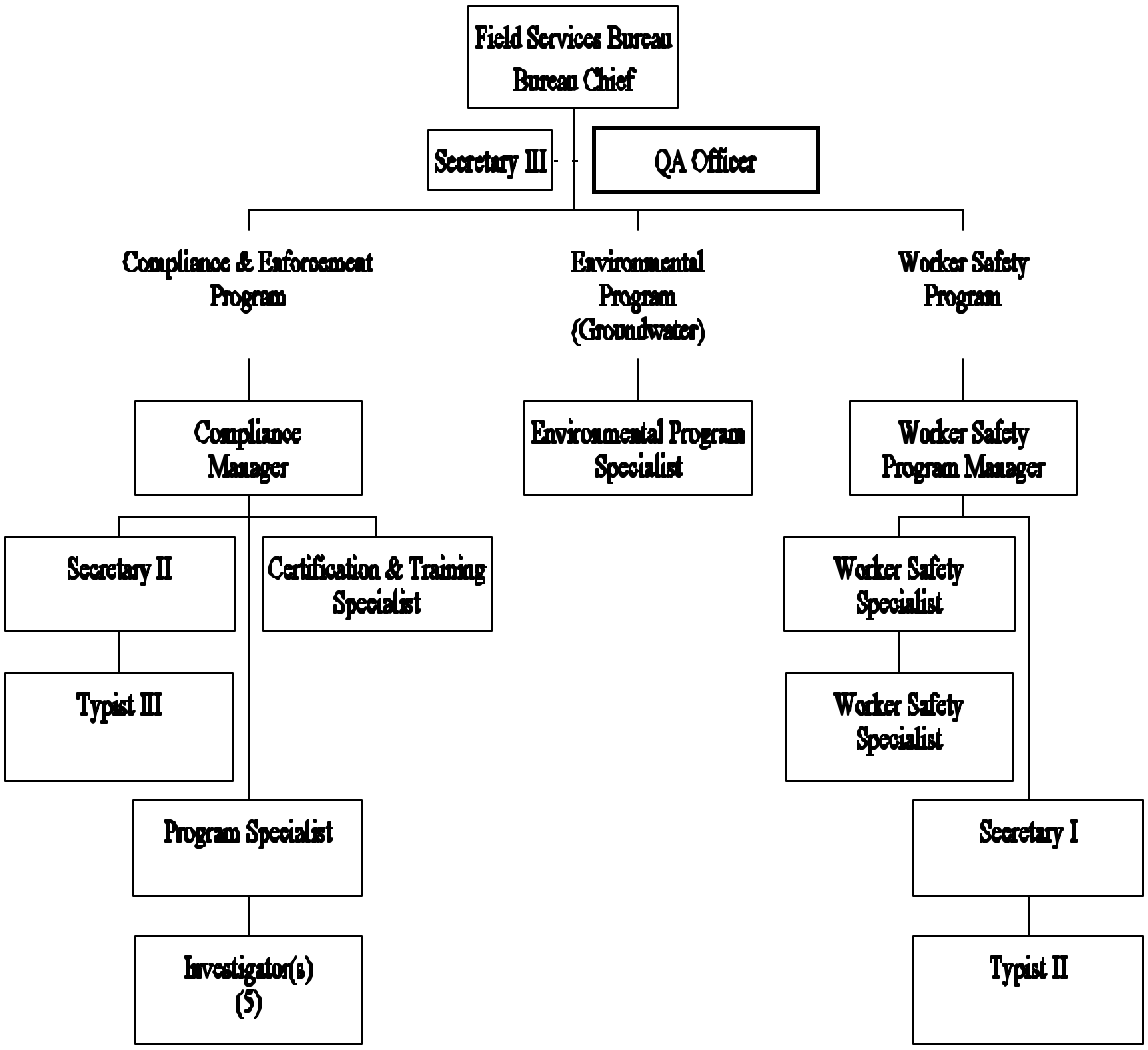


***Figure 2 Example of Field Services Bureau Organization***

### A4.2 - Planning Documentation

The FIFRA program QAPP should define requirements for QA documentation. Thus, if a QAPP, a work plan, a field sampling plan, a sampling and analysis plan, or some other planning document is to be required for a program activity, either one that is on-going or one that is on a one-time basis, this section should describe this requirement. If a sampling and analysis plan, a field sampling plan, an inspection report, or some other planning document must be prepared or a specific form filled out, this also should be described in this section. The program QAPP can include examples of any forms or SOPs for the preparation of these documents. The section should outline what information should be contained in work plans, field sampling plans, sampling and analysis plans or other planning documents and discuss how these documents relate to the QAPP. Usually these types of documents will be more site or project specific than the program QAPP and complementary to it, but since requirements for additional documentation may vary considerably from state to state or organization to organization, requirements should be described. Review and approval procedures should be documented as well as provisions for revision of the documents, if appropriate.

## A5 - PROGRAM DEFINITION/BACKGROUND

EPA QA/R-5 states: "*State the specific problem to be solved or decision to be made. Include sufficient background information to provide a historical and scientific perspective for this particular project*."

This section of the FIFRA program QAPP should make it clear that the general purpose of the program is to ensure compliance with and enforcement of pesticide regulations. The QAPP should also state the specific tasks and purposes of the program, which may reflect one or multiple areas of program responsibility. This section can paraphrase environmental regulations, define general or specific problems to be solved, describe typical decisions to be made, or an outcome to be achieved. The section should include sufficient background information to provide a historical, scientific, and regulatory perspective. This section should be fairly general in nature. Specific decisions to be made based on the data are better covered in the context of data quality objectives in Section A7 below.

## A6 - PROGRAM TASK DESCRIPTION

EPA QA/R-5 states: *"Provide a description of the work to be performed and the schedule for implementation. Provide maps or tables or state the geographic locations of field tasks. This discussion may not need to be lengthy or overly detailed, but it should give an overall picture of how the problem or question described in A5 will be resolved."*

It is rarely possible to schedule or predict compliance and enforcement activities under the FIFRA program, as envisioned by the EPA QA/R-5 document. This guidance document assumes that work under the FIFRA program includes: formulation investigations, use/misuse investigations, groundwater monitoring, worker health and safety investigations, and may include special projects, but this may vary, and each state should describe its own activities and programs. Special projects for the purposes of this guidance refers to research projects (for example, the testing of a new application technique or the effectiveness of a new pesticide), endangered species investigations, unique or infrequent inspection or investigative activities, or any other activity which is not of a recurring nature. Surface water is usually covered by a state's water program, but if it is also monitored under the FIFRA program, sections of the guidance should be modified accordingly.

Provide a summary of the types of work involving environmental measurements carried out under the program, whether routine on-going activities like monitoring, one-time events like a site investigation or a research project, review of data from permittees or other responsible parties, use of secondary data in modeling, etc. The nature and extent of the data to be generated should be described in general terms. Discussions of schedules can be deferred to Section B1.2. For recurring events (groundwater or surface water monitoring mainly) maps or tables can be provided here or in Section B or an appendix and referenced here. This discussion need not be lengthy or overly detailed, but should give an overall picture of how the information relates to decisions that the program must make. The information should have been discussed in A5; decisions should be discussed in A7.

## A7 - QUALITY OBJECTIVES AND CRITERIA FOR MEASUREMENT DATA

EPA QA/R-5 states: *"Discuss the quality objectives for the plan and the performance criteria to achieve those objectives. EPA requires the use of a systematic planning process to define these quality objectives and performance criteria."*

To support this requirement, EPA has developed a systematic planning process based on a graded approach for environmental decision making called the Data Quality Objectives (DQO) Process. The DQO Process is the Agency's preferred planning process and provides quality objectives and performance criteria based on the user's determination of tolerable error in the results. For details on the DQO Process and guidance on how and when it may be used, see the "Guidance for the Data Quality Objectives Process (QA/G-4) (EPA, August 2000)." This process has limited applicability to most FIFRA activities, since generally only Special Projects lend themselves to development of formal DQOs and defining of error limits, hypothesis testing, etc. The state's FIFRA program QAPP should discuss the DQO process that will be required for such projects or whether some alternative process will be used.

For other, more routine enforcement and monitoring situations, the program QAPP should discuss the decisions to be made by the program and the quality of the data/performance criteria required to achieve/support those decisions. This is typically done in terms of "if...then" statements. At the highest (enforcement) level the discussion should center on regulatory or action levels and the quality of data required to make decisions in situations where these levels are exceeded. In some cases, these regulatory criteria may be maximum contaminant levels (MCLs) defined under state or federal drinking water regulations. In other cases, the state may have defined its own regulations which should be reproduced here. Formulation criteria are defined on the labels and are based on the pesticide's original registration. If total maximum daily loads (TMDLs) have been defined for pesticides, these may be the regulatory threshold. It is recognized that in use/misuse situations, especially, EPA has generally not defined regulatory standards for FIFRA. Thus state decisions may be made based on either health concerns (e.g., worker protection), a violation of application requirements, or other criteria. The QAPP should discuss the criteria against which the data will be compared for decision making.

At the next level (e.g., monitoring) data may be required for informational purposes or possibly used to establish trends. The FIFRA program QAPP must relate these types of objectives to sampling and analysis activities. In many cases actual specific measurement quality objectives criteria (such as precision, accuracy, sensitivity, blank contamination, completeness) related to sampling and analysis activities may be defined in other documents such as a laboratory QA plan or field or laboratory SOPs. The whole subject of QC criteria or measurement quality objectives is covered in greater depth in Section B and does not need to be covered here; the focus here should be on the bigger picture defined by program objectives.

## A8 - SPECIAL TRAINING/CERTIFICATION

EPA QA/R-5 states: *" Identify and describe any specialized training or certification requirements needed by personnel in order to successfully complete the task. Discuss how such training will be provided and how the necessary skills will be assured and documented."*

The intent of the section should be fairly clear from the above statement. Some reference can be made here of any requirements such as EPA training. If any special analysis methods and/or equipment require operator training and in-house certification, this should also be mentioned. This section should be used to delineate special training or certification for personnel or facilities associated with the FIFRA program.

For example:
Personnel that are acting as QA managers for the program or for a specific activity, but who are from different departments within the organization, might have to successfully complete

a QA training course(s) given by a recognized organization or expert in the field prior to performing their QA responsibilities.

Other possible training that might be required:

AOAC training seminars on quality systems,
Training or seminars provided at EPA's annual quality meeting,
Training in ISO 9000 or 14000 or other systems provided by consultants, professional societies, or educational institutions.
Training on computer software, models, and databases.

In addition, both the field and laboratory operations may also need training/certification requirements.

Personnel may require training before using new equipment or performing new methods. This may be provided by in-house instructors, instrument vendors, consultants, professional societies, or educational institutions. EPA also provides training occasionally such as through its PREP training courses. The FIFRA program QAPP should discuss how proficiency will be demonstrated (receipt of a certificate, analysis of a performance sample, etc.).

Investigators or field sampling technicians should be appropriately trained in sample collection and handling. EPA has annual investigator training courses. An Investigator within the organization may train other investigators in a discipline. Groundwater sampling training may be available from the Environmental Department of the state, private consultants, educational institutions, or other sources. Again, the plan should discuss how proficiency will be demonstrated.

When hiring new personnel for FIFRA activities, the program QAPP should outline minimum requirements for the position. For example if the person is hired as a sample custodian, it might be required that they have health and safety training in hazardous materials handling, a minimum computer proficiency, and some prior laboratory experience.

Outside facilities may need to be certified in the work that they are performing for your organization.

This section should also discuss how training records are maintained. If all of the training requirements are covered in the state's Quality Management Plan, the material can be referenced or reproduced here.

## A9 - DOCUMENTS AND RECORDS

EPA QA/R-5 states: *"Describe the process and responsibilities for ensuring that the most current approved version of the QAPP is available. Itemize the information and records which must be included in the data report package and specify the desired reporting format for hard copy and electronic forms, when used. Records can include raw data, field logs, instrument printouts, and results of calibration and QC checks. Identify any other records and documents applicable to the program/project/task, such as audit reports, interim progress reports, and final reports, that will be produced. Specify the level of detail of the field sampling and/or laboratory analysis narrative needed to provide a complete description of any difficulties encountered during sampling or analysis. The narrative refers to an annotated summary of the analytical work performed by a laboratory that describes in narrative form what activities were performed and identifies any problems encountered. This information is important to the data user when interpreting the data received. Specify or reference all applicable requirements for the final disposition of records and documents, including location and length of retention period."*

This section must be looked at in the context of the information that will be provided for all the different aspects of the state's FIFRA program. For each of the different areas within the program (herein defined as groundwater monitoring, formulations, use/misuse, worker health and safety, and special projects, but this will depend on the scope of the state's activities), this section should describe the paperwork and electronic requirements. If appropriate, it should also include examples of forms or reports which must be submitted to the Department, not just those used internally by the state in its own data collection activities.

For groundwater monitoring, this might include information to be recorded in field notebooks or examples of data recording forms such as purging logs or well sampling logs.

For formulations this might be collection reports or inspection reports.

For use/misuse it might be the information required to document an incident or a case, examples of special forms to be filled out during interviews, records to be reviewed, etc. It might also include field notebook information or sampling sheets to be completed if samples are collected to strengthen a case. A chain of custody form should also be included as an example.

For worker health and safety it might include copies of interview forms, or questionnaires to be completed, or forms used to document the collection of clothing or other evidence.

For special projects it might be special forms used to collect data for the project.

For laboratory work it might be quality control summary forms, examples of control charts, example laboratory reports, internal chain of custody forms, etc. The Program QAPP should

define the contents of all reporting packages and specify the reporting format for hard copy and any electronic forms.

Describe the process and responsibilities for ensuring that appropriate program personnel have the most current approved version of this or related Program QAPPs, including version control, updates, distribution, and disposition.

Itemize the information and records which must be included in reporting data to decision makers under the program. This would include examples or a description of any special reporting forms used by the program which would be used by inspectors, samplers, permittees, responsible parties, municipalities or local agencies, or other organizations to report data to the program organization after results have been summarized or processed. Reporting requirements might include raw data, data from other sources such as data bases or literature, field logs, sample preparation and analysis logs, instrument printouts, model input and output files, and results of calibration and QC checks. On the other hand, this material may be used by inspectors and laboratory personnel only (as described above) and would not be reported in interim progress reports or final reports which might go to decision makers.

Specify or reference all applicable requirements for the final disposition of records and documents, including location and length of retention period.

## B. DATA GENERATION AND ACQUISITION

The elements in this group (Table 2) address all aspects of data generation and acquisition to ensure that appropriate methods for sampling, measurement and analysis, data collection or generation, data handling, and QC activities are employed and documented. The following QAPP elements describe the requirements related to the actual methods or methodology to be used for the:

- collection, handling, and analysis of samples;
- data obtained from other sources (e.g., contained in a computer data base from previous sampling activities, compiled from surveys, taken from the literature); and
- the management (i.e., compiling, handling) of the data.

The methods described in these elements should have been summarized earlier in element A6. The purpose here is to provide detailed information on the methods. If the designated methods are well documented and are readily available to all program participants, citations are adequate; otherwise, copies of the methods and/or SOPs should accompany the QAPP either in the text or as attachments.

**Table 2. Group B: Data Generation and Acquisition Elements**

| | |
|---|---|
| B1 | Sampling Process Design (Experimental Design) |
| B2 | Sampling Methods |
| B3 | Sample Handling and Custody |
| B4 | Analytical Methods |
| B5 | Quality Control |
| B6 | Instrument/Equipment Testing, Inspection, and Maintenance |
| B7 | Instrument/Equipment Calibration and Frequency |
| B8 | Inspection/Acceptance of Supplies and Consumables |
| B9 | Non-direct Measurements |
| B10 | Data Management |

## B1. SAMPLING PROCESS DESIGN (EXPERIMENTAL DESIGN)

EPA QA/R-5 states: *Describe the experimental data generation or data collection design for the project, including as appropriate: the types and numbers of samples required, the design of the sampling network, the sampling locations and frequencies, sample matrices, measurement parameters of interest, and rationale for the design.*

### B1.1 Purpose/Background

This section should describe data collection activities to be conducted under the state's FIFRA program. For most states, this will describe activities conducted by the state's Department of Agriculture, but other agencies, for example a Department of Environmental Protection or Department of Health, or a separate state laboratory organization may also be involved. There also may be state contracts, pesticide management plans, or other agreements in place with municipal, county, or local governments; with private contractors; or with state or private laboratories. Discussions must cover all major FIFRA activities (or more as appropriate) as described previously in Section A.

This section should describe all the relevant components of the sampling design; define the key samples to be collected; indicate the number and type of samples expected; and describe where, when, and how samples are to be taken. The level of detail should be sufficient that a person knowledgeable in this area could understand how and why the samples will be collected. This element outlines procedures that a state program will follow to ensure that the "right" samples will be taken, handled, and preserved in a defensible manner consistent with method, enforcement, or monitoring requirements. In some cases this work may be carried out by contractors. In that case the QAPP should describe how the contract is structured to ensure FIFRA, QA, and organization requirements are met through statements of work, contract oversight, etc.

Areas to be covered in Section B1 include the following:

- a description of the type of samples to be collected,
- a rationale for where and how different types of samples are collected,
- the sampling assumptions,
- the procedures for locating, scheduling, and selecting environmental samples,
- a classification of measurements as critical or noncritical, and
- the validation of any nonstandard sampling/measurement methods.

Elements B1.2 through B1.7 address these subjects.

## B1.2 Scheduled Program Activities

This element should describe how start and completion dates for different program activities are established. It is expected that these might differ considerably depending on the nature of the sampling activity. Major differences will be evident depending on whether short term events (e.g., a response to a complaint), long term events (e.g., groundwater monitoring), or project events (where a project has an identified beginning and end) are being discussed. The subsections below describe examples of the type of information that should be provided concerning planning and scheduling of major FIFRA program or project areas. It is recognized that state programs differ and not all programs may apply to all states. Where responsibility for a program is shared with another organization (for example with an environmental agency or a contractor), the roles of both entities in the planning process should be discussed. For enforcement and compliance events, there often is a "trigger" event that initiates a schedule of activities. The appropriate sections should discuss trigger events and the sequence of events which typically follow.

### B1.2.1 Groundwater Monitoring

Groundwater monitoring generally takes place on a recurring basis although this may not always be true. This section should describe the steps involved in scheduling an event, differentiating, if appropriate, between one time events and on-going events taking place at regular intervals. Groundwater monitoring programs mandated by EPA regulations may have the benefit of a long lead-time for planning, since regulations often have a substantial lag time between the date of rule publication and required implementation. On the other hand, the discovery of a localized contamination problem may lead to a need for monitoring within a much shorter time-frame. It is recognized that responsibilities for monitoring groundwater vary from state to state. In some cases it may be an inspector in the Department of Agriculture, in others it may be a water quality specialist in the environmental program. This section should reflect how the program is implemented within the state, and it is expected that the steps taken may vary considerably. An example of a relatively short-term schedule and factors which may need to be considered is given below. The QAPP should be as comprehensive as possible in describing what is required since it defines requirements for the program. Alternatively, much of this may be covered in an SOP which can be included as an appendix and referenced here.

Step 1: Sampler defines objectives for the study. These will include establishing criteria to be used in evaluating the results (water standards, health based levels, etc.) and the decisions which will be made based on the data.

Step 2: Sampler prepares required planning document, and has it reviewed and approved. This might be a sampling plan, a preprinted form, a proposal sheet, or some other

planning document. The QAPP should describe what information is required and include a copy of any document used routinely. This might include establishing criteria for well selection, identifying the wells to be monitored, discussing whether appropriate wells exist or new ones must be drilled, describing the pesticides of interest, discussing sampling procedures, defining what sampling equipment is needed, describing how much time is needed to conduct the event, and calculating what resources are necessary to perform the sampling.

Step3: If it does not happen automatically as part of the document review process, sampler submits information on project scope and resource needs to the appropriate manager(s). Manager approves sampling event.

Step 4: Sampler contacts well owners, verifies well information, confirms site specifics, etc.

Step 5: Sampler identifies analytical needs and lines up the analytical support required. Note that this may include having the laboratory confirm that it has the ability to perform the analysis, has the appropriate standards available, has performed a detection limit study, and has QC criteria established. This may need to take place earlier during the planning document stage depending on lead time. A time line is established and confirmed with all appropriate individuals (sampling team, equipment storage, analytical laboratory, travel desk, well owners, etc.).

Step 6: Sampler proceeds to reserve equipment and laboratory space, lines up sampling support, and ensures that laboratory can handle the samples (for example, confirm schedule, timing, number and types of samples laboratory can expect).

Step 7: Well owner is notified, site data, sampling date, and sampling schedule are confirmed. Sampler picks up equipment, checks equipment calibration and condition, and deploys to field.

Step 8: Sampler collects the samples, prepares appropriate chain of custody and laboratory submittal documents, and either transports or ships the samples to the laboratory.

Step 9: Samples are accepted by the laboratory sample custodian, logged in, preserved (if not preserved in the field), and either processed or put into appropriate holding area.

Step 10: Sampler receives results from the laboratory and evaluates results. After reviewing quality control data and resolving any data quality problems, the sampler compares the data to preestablished criteria (water quality standards, for example) and makes a recommendation to management concerning decisions to be made (or makes them him or herself if appropriate). If appropriate, the well owner or other involved agencies are notified of the results.

Step 11: Sampler documents activities and decisions in a final report or on the appropriate form and places the information in a file. Data are archived in hard copy and/or electronic format. Information is entered into a database, as appropriate.

If a monitoring program is set up, the schedule, the sites to be monitored and details on the wells (depth to groundwater, screening intervals, etc.), the method of sample collection, the target pesticides, and the methods to be used for the analysis could all be summarized in a table. The overall purpose of the monitoring program and the decisions to be made, etc. (see above) would be described in the appropriate venue.

### B1.2.2 Formulations

This section should discuss how the collection of formulation samples is planned and scheduled. Because these samples are more likely to be the result of inspections or one-time events, a schedule such as discussed above may not be feasible or appropriate unless certain inspectors survey a specific geographical area or type of formulator (for example, an agricultural formulator the first week, a commercial establishment the second week, etc.) on a regular basis. However, the procedures to be followed from initiation to final report could be described.

### B1.2.3 Use/Misuse Investigations

Misuse investigations are generally the result of citizen complaints or field observations made by inspectors; thus they are rarely scheduled very far in advance. Nonetheless, this section should discuss the sequence of events leading up to and after the sampling event. An example scenario might be:

Step 1: Pesticide program agency hot line receives a call. Incident is assigned to an inspector by his supervisor.

Step 2: Inspector assembles sampling equipment, chain of custody forms, incident report paperwork, sampling containers, ice chests, etc. and notifies laboratory to expect samples of a particular matrix for a specific pesticide if this information is known.

Step 3: Inspector proceeds to field, meets with complainant and collects sample(s). Inspector collects other relevant information to build his/her case. It must also be considered whether other pollutant sources exist and whether they should be sampled. Applicator records, weather conditions at the time of the incident such as temperature and wind direction, frost, precipitation; adjacent relevant sites and their pesticide application history; and interviews with relevant individuals might all be required. Sample(s) are transported or shipped to the laboratory.

Step 4: Incident report is prepared and filed appropriately.

Step 5: Analytical results are returned from the laboratory, inspector looks for detections of target pesticide and assess the information in the context of the other gathered information.

Step 6: Inspector consults with other professionals, managers, attorneys and then recommends or takes appropriate action or notifies manager. This might include, but would not be limited to, a voluntary compliance agreement, legal action, or development of a response/remediation plan by the responsible party.

Step 7: A letter , report, order, etc. is prepared for concurrence by inspector's manager, department, attorney, other agencies, and the responsible party as appropriate.

Step 8: Follow-up as necessary to complete case activities, i.e., oversight of responsible party activities, additional inspections to ensure corrections are implemented, further legal action taken, etc..

Step 9: A final case review is conducted, the case is closed, and relevant materials are filed appropriately.

If an organization has special procedures for emergency situations such as a criminal investigation, an imminent danger to life or the environment, etc. which may preclude preparation of normal documentation until after the event, the system to handle review and approval of the action and the subsequent documentation should be described.

Use investigations are to some degree specified in cooperative agreements with EPA and are part of the routine activities of the department. Thus, they usually can be scheduled well in advance. A typical schedule might be:

Step 1: Inspector contacts party to be observed and establishes a day when pesticide application is to occur.

Step 2: Inspector assembles sampling equipment, chain of custody forms, paperwork, sampling containers, ice chests, etc..

Step 3: Inspector proceeds to field for observation, sample collection if the situation warrants (e.g., if it appears a misuse situation has occurred), and transports/ships sample(s) to the laboratory.

Step 4: Analytical results received from laboratory, inspector evaluates data and takes any required action.

### B1.2.4 Worker Health and Safety Investigations

Worker health and safety investigations address compliance with EPA's Worker Protection Standard regulations (40 CFR Part 170). These investigations can be conducted as the result of complaints or as a part of routine inspections. If they are the result of complaints, a scenario comparable to a misuse investigation might be expected (see Misuse B1.2.3). If a routine inspection is being conducted, a schedule similar to that under a use inspection (see Use B1.2.3) would be followed.

### B1.2.5 Special Projects

Occasionally, a Department of Agriculture or FIFRA implementing Agency may need to or desire to conduct some type of special project. This might be an activity that is covered under a state or federal regulation, such as Endangered Species Protection, or it might be the result of special grant or other funding from EPA, the state, or other sources. For example, the impact of a pesticide on a specific habitat, a research project on the effectiveness of a new application method, or an integrated pest management technique, or demonstration project all might be considered special (i.e., non-routine and non-recurring) projects. This section should discuss, from a generic perspective, the schedule of events which might need to take place from project inception to project conclusion, recognizing that these projects may be of different lengths and complexity. The discussion might include when certain planning documents such as work plans, QA plans, sampling plans, laboratory validation studies, participant permission, approval by or coordination with different agencies, etc. are required. Finally, the QAPP should define what would be expected to be the most significant milestones during the project itself.

## B1.3 Rationale for the Design

The objectives for an environmental study or data collection should be formulated in the planning stage of any investigation. These objectives should be defined as soon as possible, but may need to be modified or redefined as an activity progresses based on new information

that becomes available. The requirements and the rationale for the design for the collection of data may be developed in different ways. If the activity will be of sufficiently long term or of sufficiently large scope, then the quantitative outputs of the DQO Process (see EPA guidance or the discussion in Part A of the QAPP) can be used. However, the DQO process may not be needed for many FIFRA activities, especially if they do not involve environmental measurements. It is recommended that the DQO process be used, but in many cases, an abbreviated DQO process may be appropriate. Sampling design is highly dependent on the key characteristic being investigated and the media to be sampled. For example, if the purpose of the study is to estimate an overall average contamination at a site or location, the characteristic (or parameter) of interest might be the mean level of contamination. The relationship of this parameter to any decision that has to be made from the data collected is obtained from Steps 2 and 3 of the DQO Process (see Figure 3). In other cases, objectives may need to evolve and planning should reflect this.

It is expected that many state activities and investigations will be based on nonrandom sampling. For example, in many misuse investigations sampling may be strictly judgmental. If policies have been developed to guide samplers and inspector in using a non-random sample design, they should be described here. Some examples might be, specific health concerns, budget limitations, a desire to have a prespecified number of wells down gradient of a pesticide application, etc. DQOs are ideally based on quantitative criteria, but EPA and few states have established specific regulatory levels, especially in the misuse area; and no levels have been established for the large number of insecticides, herbicides, rodenticides, and other chemicals regulated under FIFRA (over 600 active ingredients). Thus, sample collection decisions (except for special projects), will need to support the types of subjective decisions often made under the program; the discussions in the section below should reflect this.

The potential range of values for the parameter of interest should be considered during development of the data collection methodology and can be greatly influenced by knowledge of potential ranges in expected concentrations. For example, the number of composite samples needed per unit area is directly related to the variability in potential contaminant levels expected in that area.

The choice between a probability-based (statistical) data collection design or a nonrandom (judgmental) data collection methodology depends on the ultimate use of the data being collected. This information is specified in Steps 5 and 6 of the DQO Process. For activities which lend themselves readily to use of the DQO process, adherence to the data collection design chosen in Step 7 of the DQO Process will directly affect the magnitude of potential decision error rates (relating false rejection and false acceptance of data) established in Step 6. Any procedures for coping with unanticipated data collection design changes also should be briefly discussed. Random sampling might be appropriate where a large area is under

investigation and the distribution of a pesticide is unknown. The QAPP should define when such random sampling is appropriate.

The QAPP should also describe procedures for an evolutionary program. For example, if there is a suggestion that there is non-point source impairment of an aquifer with an objective to minimize or mitigate the presence of the pesticide in the aquifer and prevent further introduction of pesticides, but there is insufficient information available initially on hydrology, soils, cropping, pesticide usage, etc. to make a definite decision (i.e., set up an "if...then" scenario), then the rationale for the design may need to evolve. The QAPP should describe what types of initial objectives/steps are appropriate and how subsequent steps will be factored in, reviewed and approved.

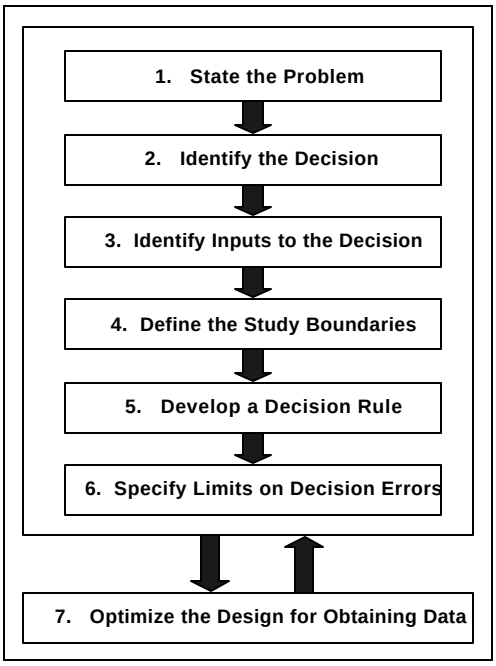


**Figure 3. The DQO Process**

### B1.3.1 Groundwater Monitoring

In most cases, the sites for groundwater monitoring will already be well established for most state programs. If they are not, using the DQO process to determine what sites should be monitored and at what frequency may be appropriate and helpful. Assuming that both locations and analytes are already known, this section of the QAPP should, possibly in tabular form, identify each location and provide a rationale for its selection, discuss the reason specific analytes were selected, and discuss the rationale behind the timing of the sampling events and the sampling frequency. If the analytes, frequency and timing of

sampling, or the number of samples to be collected are expected to change over time, the QAPP should discuss the mechanism by which these changes are to be made.

### B1.3.2 Formulations

Formulation sampling is more likely to be judgmental in nature. The QAPP should discuss the decision process leading to the collection of different samples. For example, formulators are chosen on a random basis with a frequency dictated by past history of compliance or pool chemicals are targeted in July because that is the month that most of these chemicals are sold. Thus, if a rationale cannot be provided for each location/pesticide formulation that is sampled, this section should document the strategy or decision process that will be used.

### B1.3.3 Use/Misuse Investigations

Use/misuse samples are generally samples of opportunity (i.e., samples collected as the result of a subjective judgement by the inspector in the field), samples that are planned in advance (use investigations), or collected as the result of complaints (misuse investigations). Thus, this section should describe the rationale for deciding when samples might be collected in the field and when they would not be collected. The rationale for selecting specific types of samples in the field should be described. Reference to or including language from state SOPs, the NEIC Sampling Guide, the EPA Pesticide Inspectors Manual, or other EPA/state approved reference source may be appropriate.

If a compliance plan is developed by a responsible party that includes a sampling component as the result of an investigation into his or her use/misuse of pesticides, the oversight of the implementation of the plan should also be described. This is especially true if there is a component of confirmation sampling.

### B1.3.4 Worker Health and Safety Investigations

Worker Health and Safety Investigation samples are generally samples of opportunity (i.e., samples collected as the result of a subjective judgment by the inspector in the field), samples that are planned in advance, or collected as the result of complaints. Thus, this section should describe the rationale for deciding when samples might be collected in the field and when they would not be collected. The rationale for selecting specific types of samples in the field should be described.

### B1.3.5 Special Projects

Depending on how these projects are handled, this section should state that, if such a project is sponsored by the Department or carried out in conjunction with another organization, then

information on rationales for sampling locations, analytes, frequency, etc. will be provided in the planning documents related to the project. The QAPP should make clear what these are, what they should contain, and how they are reviewed and approved. If existing QA documents from other organizations are to be used in lieu of development of a separate project specific document, these documents must include information on rationales which are agreeable to the pesticide program agency. It is for these types of projects that the use of EPA's DQO process would probably be most appropriate.

### B1.4 Sampling Methodology and Rationale

The planning process usually recommends a specific data collection method (Step 7 of the DQO Process), but the effectiveness of this methodology rests firmly on assumptions made to establish the data collection design. Typical assumptions include the homogeneity of the medium to be sampled (for example, sludge, fine silt, or wastewater effluent), the independence in the collection of individual samples (for example, four separate samples rather than four aliquots derived from a single sample), and the stability of the conditions during sample collection (for example, the effects of a rainstorm during collection of wastewater from an industrial plant). The assumptions used to select sampling methodology should have been considered during the DQO Process. In many cases, default approaches based on existing SOPs will dictate the approach. In addition to defining the methodology, this section should summarize approaches to any contingency plans developed to account for exceptions to the proposed sampling plan. These might identify who must be consulted and the types of changes that might need to be reviewed or approved prior to implementation versus the types of changes requiring only documentation. An important part of the contingency plan is documenting the procedures to be adopted in reporting deviations or anomalies observed after data collection has been completed. Wherever possible, alternatives should be developed prior to the event. If SOPs exist for this type of decision making they should be included in an appendix and referenced or described here in outline form. Examples of situations requiring a contingency might include an extreme lack of homogeneity within a physical sample or the presence of analytes that were not mentioned in the original sampling plan. Chapter 1 of EPA QA/G-9 (Guidance for Data Quality Assessment, Practical Methods for Data Analysis, QA00 Update, July, 2000) also provides an overview of sampling plans and the assumptions needed for their implementation.

### B1.5 Procedures for Selecting Environmental Sample Locations

Choosing sampling locations will depend on: the practicality and feasibility of acquiring the samples, the key analyte(s) on which decisions are to be made, and resource constraints such as the costs of sample collection, transportation, and analysis.

This element of the QAPP should also describe the frequency of sampling, the specific sample media to be sampled, and sampling equipment. When decisions on the number and location of samples will be made in the field, the QAPP should describe whether these decisions will be based on field observations or field screening data. The QAPP should describe what location data are to be collected, stored, transmitted, and the methodology used to record this information (field notebook, incident forms, field report, etc.). It is recommended that each report include the following for each sample point:

- Coordinates (such as from a GPS (Global Positioning System)) or descriptive information on a location (based on reference points, addresses, landmarks, and maps),
- Contingencies to describe permissible decisions where prescribed locations are inaccessible,
- Discussions for documenting possible location bias and its assessment, and
- Procedures for reporting deviations from the sampling plan or other planning document.

When appropriate, a map of the sample locations should be provided and location map coordinates supplied.

### B1.5.1 Groundwater Monitoring

In most cases, sites for groundwater monitoring will already be established, although extension of existing monitoring operations or the adding of new, previously unmonitored areas is always a possibility. A reference to the tables previously provided in Section B1.3.1 would be sufficient to identify locations, although a map could be provided if one was not provided earlier. The more detailed the locations, the better (e.g., use global positioning system (GPS) coordinates if available). Where new locations are to be identified, the QAPP should describe the criteria and the process that will be used to do this. Ideally, this will be the result of something like the DQO process, but more practical considerations may dictate these decisions. For example, use of existing wells may be more convenient and feasible than constructing a new one, or economic and political factors may be more important. The QAPP should discuss provisions for deciding and documenting how the choice of the new location(s) will or will not meet overall monitoring objectives. If the location(s) were not chosen as a result of something like the DQO process, there should be provisions for discussions of location bias and how this will be factored into any decisions to be made.

The QAPP should define what criteria might be taken into consideration in the selection of existing groundwater wells or in the development of new wells. Factors to be considered might include (but are not limited to): location, spatial design, suitability of the well, owner access issues, physical access issues, depth of the well, distribution of the wells, aquifer identification or aquifer penetrated, location and length of screened intervals, well construction materials and details, distance from agricultural cropping and pesticide use

area, precipitation and irrigation, type of well (irrigation, drinking water, etc.), groundwater flow rate and direction, soils, etc. It is also recommended that guidelines be provided for when an existing well might be used and when drilling a new well might be appropriate.

### B1.5.2 Formulations

Formulation sampling is usually straightforward with respect to the location and selection of the actual samples in the field. Assuming a rationale has already been provided for the choice of product to be sampled in one of the documents discussed in Section A9, it should be sufficient to reference Appendices containing the NEIC Sampling Guide, the EPA Inspectors Manual, state SOPs, or other appropriate, approved source. This section should also discuss the protocol for splitting samples with the owner/operator/retailer.

### B1.5.3 Use/Misuse Investigations

Use/Misuse sampling is usually straightforward with respect to the location and selection of the actual samples in the field. Assuming a rationale has already been provided for the investigation, in one of the documents discussed in Section A9it should be sufficient to reference Appendices containing the NEIC Sampling Guide, the EPA Inspectors Manual, state SOPs, or other appropriate approved source concerning the rationale for the selection of sample locations in the field. However, this section should, at a minimum, discuss:,

- contingencies for cases where locations are inaccessible or the optimal sample cannot be collected (for example, it rains before the inspector arrives; the grass has been cut, etc.),
- location bias and its assessment, and
- procedures for reporting deviations from the two sampling guides or previously prepared sampling documents (e.g., went to collect soils but also collected wipe samples).

### B1.5.4 Worker Health and Safety Investigations

These samples may vary considerably in their source. In some cases they may be comparable to misuse samples (a wipe sample or a soil sample for example). In other cases it may be a unique sample (for example worker's clothing). This section should discuss how this program is carried out from a sample collection perspective. It might discuss what types of samples are typically collected under this program and how they are handled. Differences between this program and the types of samples collected under other types of investigation should be made clear in the discussion.

### B1.5.5 Special Projects

Depending on how these projects are handled, this section should state that when special projects are carried out by the Department, discussions and rationales pertaining to the location and selection of environmental samples will be provided in the planning documents related to the project. The sampling plan should also contain provisions for:

- procedures for finding prescribed sample locations,
- contingencies for cases where prescribed locations are inaccessible,
- location bias and its assessment, and
- procedures for reporting deviations from the sampling plan.
-

### B1.6 Classification of Measurements as Critical or Noncritical

The QAPP should discuss the classification of measurements as critical (i.e., required to achieve program objectives or limits on decision errors, Step 6 of the DQO Process) or noncritical (for informational purposes only or needed to provide background information). Critical measurements will undergo closer scrutiny during data gathering and review processes and will have first claim on limited budget resources. It is also possible to include the expected number of samples to be tested by each procedure and the acceptance criteria for QC checks (as described in element B5, "Quality Control Requirements"). It is recognized that the current version of EPA's QA/R-5 QAPP requirements document no longer uses the "critical" vs. "non-critical" distinction in terms of objectives (although the EPA's QA/G-5 QAPP guidance document retains this distinction). The organization preparing the document is advised to consult these two documents to determine which approach is most consistent with its FIFRA program. This guidance has adopted an approach consistent with that described in QA/G-5.

#### B1.6.1 Groundwater Monitoring

Certain measurements in groundwater monitoring may be considered noncritical, for example, pH, conductivity, and turbidity measurements may be less critical if they are only used to determine if a well is ready to be sampled. On the other hand, these may be crucial parameters in determining whether it is appropriate to sample the well in an unbiased manner, so they may be critical. Possibly the wells are being monitored for multiple purposes, for example, water quality as well as the presence of pesticides. From a FIFRA program perspective, the water quality measurements may not be critical (even though they are critical from another program's perspective). Thus, the QAPP should provide perspective on how decisions are made, when the data may have more than one use or may be used by more than one agency. If samples are collected regularly (e.g., quarterly), it may be possible that all samples would not be critical; guidance should be provided in this

regard. This might also apply if there are multiple wells connected to a common aquifer, or where a plume is being tracked and the samples on the leading edge of the plume are more critical than those which already demonstrate contamination.

This section would probably benefit from some specific examples. One scenario might be a sampler tasked with characterizing the impairment of an aquifer. There are 46 wells in the immediate area. Do you sample them all? Since this is dependent on decisions to be made and resources, the QAPP might state how budgets, time, staff, equipment availability, etc., are used in making a decision whether all wells are to be sampled or whether some minimum number can be sampled and how that minimum number would be determined. If 24 wells represented the number of wells needed to characterize the aquifer, how would a minimum number like 13 affect decision making? When could a step-wise approach be used (i.e., 10 wells are sampled, results assessed and then 10 more added)? Several examples such as this would help department personnel understand how to ensure sufficient data will be obtained to support decisions.

In another situation, it might be necessary to refine the number of pesticide analyses to be conducted on the sample. The QAPP could provide examples of the criteria to be used to make these decisions. For example, pesticide toxicity, gallons or pounds used in the last year in the area, proximity of the application area to critical habitat or drinking water supplies, depth to groundwater and the water solubility of the pesticide, possible metabolites (i.e., are they more likely to appear than the parent compound or could they impact the environment more severely?), etc., all are factors; how does a program make decisions on what to look for? Possibly well measurements such as pH, dissolved oxygen, conductivity, and turbidity may play a role in determining what analytes should be chosen.

### B1.6.2 Formulations

It would appear that all samples collected under the formulations program are critical since each sample is a unique sample. Although the primary focus is on whether the product is being "held for distribution or sale," it is possible that collection of pesticides having a direct impact on human health (for example, a chemical used on food crops) might be considered more critical than one used in other situations (for example, a rat bait).

### B1.6.3 Use/Misuse Investigations

It would appear that all samples collected under the use/misuse program are critical since most samples are unique, however, collection of pesticides having a direct impact on human health (for example, a chemical used on food crops) may be considered more critical than one used in other situations (for example, exposure of a structure to spray drift). It is recognized that some states may wish to focus strictly on whether the pesticide was used

improperly (contrary to label requirements), and not focus on sub-issues. Regardless, it may be beneficial for the QAPP to describe how critical and non-critical samples or analytes are identified and when the collection of either type of sample is warranted or not warranted.

### B1.6.4 Worker Health and Safety Investigations

Most samples collected in worker health and safety investigations are likely to be considered critical, the QAPP should discuss if this is the case and what might be considered exceptions. There may be a primary chemical of interest, as well as secondary chemical.

### B1.6.5 Special Projects

The critical or non-critical nature of specific samples should be discussed in the QAPP, Sampling Plan or other planning document written for the special project.

## B1.7 Validation of Any Nonstandard Methods

It is anticipated that for most FIFRA related sampling events either conventional sampling procedures (e.g., groundwater sampling procedures, soil sampling procedures, etc.) as described in the NEIC Sampling Guide, the EPA Pesticide Inspector's Manual, SOPs, or other EPA/state approved guides or reference documents will be followed. However, if nonstandard sampling methods, sample matrices, or other unusual situations are a possibility such as for a special study, the QAPP should describe requirements for method validation studies to confirm the performance of the method for the particular matrix. The purpose of this validation information is to assess the potential impact on the representativeness of the data generated. For example, if qualitative data are needed from a modified method, rigorous validation may not be necessary. Such validation studies may include round-robin studies performed by EPA or by other organizations. If previous validation studies are not available, some level of single-user validation study or ruggedness study should be performed and included as part of the final report. The QAPP should have provisions for an independent QA review of the new procedure or application of an established procedure to a new matrix/analyte. The QAPP should clearly define validation study information required for approval. Although the validation procedure should be discussed in this section, it can also be discussed in Section B2 for nonstandard sampling methods and in section B4 for nonstandard analytical methods, and referenced here. If the protocol is discussed here, any nonstandard methods should be identified in this section.

# B2. SAMPLING METHODS REQUIREMENTS

EPA QA/R-5 states: *"Describe the procedures for collecting samples and identify the sampling methods and equipment, including any implementation requirements, sample preservation requirements, decontamination procedures, and materials needed for projects involving physical sampling. Describe specific performance requirements for the method. For each sampling method, identify any support facilities needed. The discussion should also address what to do when a failure in the sampling or measurement system occurs, who is responsible or corrective action, and how the effectiveness of the corrective action shall be determined and documented.*

*Describe the process for the preparation and decontamination of sampling equipment including the disposal of decontamination by-products; the selection and preparation of sample containers, sample volumes, and preservation methods; maximum holding times to sample extraction and/or analysis."*

## B2.1 Purpose/Background

Environmental samples should reflect the target population and parameters of interest. As with all other considerations involving environmental measurements, sampling methods should be chosen with respect to the intended application of the data. Just as methods of analysis vary in accordance with activity needs, sampling methods can also vary according to these requirements. Different sampling methods have different operational characteristics, such as cost, difficulty, and necessary equipment. In addition, the sampling method can materially affect the representativeness, comparability, bias, and precision of the final analytical result.

Several approaches can be taken in preparation of this section of the QAPP. Most situations requiring sampling should have been previously described. Requirements for the documentation of sampling events may include everything from single page forms which must be filled out to full fledged Sampling and Analysis Plans which require QA Officer or EPA approval. The sampling section should discuss when the various types of documentation are required, what approvals are necessary, and what information is needed. In many cases, State SOPs, the NEIC Sampling Guide, the EPA Pesticide Inspector's Manual, or some other established source of methods can be referenced. All documents (within reason, appending books is not practical) used in sampling should be included as appendices to the QAPP. Completed activity specific sampling plans or sampling forms would not be included with the QAPP, but examples of blank forms or a typical sampling plan should be provided for guidance purposes. The QAPP should describe what information is required in a sampling plan if a form is not used.

## B2.2 Describe Sample Collection, Preparation, and Decontamination Procedures

### B2.2.1 Sample Collection

### B2.2.1.1 Sample Method Selection

This section should discuss the procedures by which appropriate sampling methods are selected. For each parameter within each sampling situation (groundwater, formulations, use/misuse, worker health and safety investigations, and special projects), the QAPP should identify appropriate sampling methods from applicable EPA regulations, compendia of methods (e.g., the NEIC Sampling Guide, the EPA Pesticide Inspector's Manual, AAPCO guidance, state developed methods/SOPs, or other sources of methods). If different methods must be used for enforcement purposes versus routine monitoring, this should be made clear. If EPA-approved procedures are available, they will usually be selected, but this is a state decision. When EPA-approved procedures are not available or are not used, standard procedures from other organizations and disciplines will need to be cited. A complete description of all methods (EPA and non-EPA) should be provided in the QAPP; this is most easily accomplished by including sampling SOPs in an appendix.

### B2.2.1.2 Equipment

List all equipment which must be taken to the field to support the different methods. Different media and sampling methods will require different sampling equipment. It should be clear what equipment is required for the expected types of sampling anticipated under the program. This section should discuss what equipment may be available, its working condition, and how unavailable equipment may be borrowed or procured.

### B2.2.1.3 Sampling Method Requirements

The QAPP should discuss sampling method requirements or reference SOPs in the Appendix. All methods were developed for specific applications in terms of the medium and analyte to be sampled, the conditions under which it is appropriate to use the method, and situations were the use of the method may be inappropriate. Deviations from a method's intended use may affect method performance. Thus, a bailer is not appropriate for a fast moving stream. Certain types of pumps may not work for a 50 foot aquifer where they would work fine if groundwater was at 10 feet, etc. For most FIFRA situations, the state sampling SOPs, the NEIC Sampling Guide, the EPA Pesticide Inspector's Manual, or other sources should define the conditions where a method should and should not be used. If not, the QAPP should describe requirements for the documentation of the following:

- Description of the types of sampling locations and media appropriate to the method,
- Analytes for which the method is appropriate,
- Limitations of the sampling method/collection procedure,
- Calibration of the equipment if necessary,

- Checking of the equipment to ensure it will work under the weather or other conditions anticipated at the site,
- Description of modifications to the equipment or method which can be made to handle unusual situations or conditions,
- Description of properly operating equipment,
- Description of a properly collected sample,
- Description of the storage container to be used,
- Preservation or special handling requirements for normal and unusual conditions (for example, extremely alkaline or acid water, water with high carbonate, foliage with high dust levels, etc.),
- Procedures taken to ensure representativeness, and
- Compositing or subsampling to reduce the representative field sample into a representative laboratory sample.

If there is more than one acceptable sampling method applicable for a particular situation, it may be necessary to choose one from among them. The QAPP should discuss how a sample would be chosen to ensure that:

- the sample accurately represents the portion of the environment to be characterized,
- the sample is of sufficient volume to support the planned chemical analysis, and
- the sample remains stable during shipping and handling.

### B2.2.2 Sample Preparation

Some samples/methods may require field preparation steps. The most obvious example is the compositing or filtering of samples or where a non-homogeneous sample is collected such as soil tissue, insects, foliage, or crop material. If not covered in readily referenced SOPs, procedures for sample homogenization of non-aqueous matrices as a technique for assuring sample representativeness should be described.

### B2.2.3 Decontamination

If not covered by an SOP, describe the department's decontamination procedures and materials. Decontamination is primarily applicable to grab samples collected with non-disposable equipment or where dedicated equipment (such as in a groundwater well) has to be removed to be repaired, calibrated or adjusted. Thus a well with dedicated pumps, or use of disposable equipment would remove the need for decontamination. Nonetheless, it is expected that some FIFRA sampling might involve the reuse of sampling equipment. Since the inspector or sampler must consider the appropriateness of the decontamination

procedures for the sampling event at hand, there should be defined procedures in the QAPP covering these situations. The procedures described here or in the SOPs should reflect the sample. For example, if a pesticide is present in the environmental matrix at the 1% level as in a formulation sample, it is probably unnecessary to clean sampling equipment to parts-per-billion (ppb) levels. Conversely, if ppb-level detection is required (such as might be the case in a use/misuse investigation), rigorous decontamination or the use of disposable equipment is required. The description of the disposal of decontamination by-products should be consistent with applicable rules, regulations and policies that would pertain to a particular situation, such as the regulations of State and local governments, OSHA and EPA.

### B2.3 Identify Support Facilities for Sampling Methods

This section should discuss support facilities for the sampling aspects of an investigation. For example, where equipment is stored, who is responsible for it, where sampling containers are obtained, when and how equipment is returned, how access is obtained to the facility, whether cross contamination during storage is a possible problem, whether the conditions used for storage are appropriate (e.g., equipment that is cold sensitive is stored in a warehouse and needs to be warmed up before use), etc..

### B2.4 Describe Sampling/Measurement System Failure Response and Corrective Action Process

This section should address issues of responsibility for the quality of the sampling effort, the methods for making changes and corrections in the field, the criteria for deciding on a new sample location, and how these changes will be documented. This section should describe what will be done if there are serious flaws with the implementation of the sampling methodology and how these flaws will be corrected. For example, if part of the complete set of samples is found to be unobtainable in the field or are not usable once analyzed, the QAPP should describe how replacement samples will be obtained and how these new samples will be integrated into the existing sampling scheme and data set. It should also be stated who is responsible for decisions and implementation of corrective action and who is responsible for follow-up to ensure the actions have rectified the problem.

### B2.5 Describe Sampling Equipment, Preservation, and Holding Time Requirements

This section includes the requirements needed to prevent sample contamination (disposable samplers or samplers capable of appropriate decontamination), the physical volume of the material to be collected (the size of composite samples, core material, or the volume of water needed for analysis), the protection of physical specimens to prevent contamination from outside sources, the temperature preservation requirements, and the permissible holding times to ensure against degradation of sample integrity. Most of this information

should be contained in the state SOPs, the NEIC Sampling Guide, the EPA Pesticide Inspector's Manual, or other source so the appropriate appendices can be referenced. However, some of these requirements may need to be developed on a sampling event specific basis and this section should describe how this will be done (for example a holding time study).

The sampling containers which need to be used should be listed either in this section or in a clearly identifiable part of the appendix. This should include both the size of the container (i.e., 500 mL bottle, 8 oz. jar, 1 qt. zip lock bag, etc.), and also the material (glass, plastic, Teflon, etc.).

## B2.6 References

Publications useful in assisting the development of sampling methods include:

**Pesticides**

U.S. Environmental Protection Agency. N.d. *National Enforcement Investigations Center Sampling Guide*. NP:np.

U.S. Environmental Protection Agency. N.d. *EPA Pesticide Inspector's Manual.* NP:np.

**Solid and Hazardous Waste Sampling**

U.S. Environmental Protection Agency. 1986. *Test Methods for Evaluating Solid Waste.* Chapter 9. 3rd ed. NP:np.

U.S. Environmental Protection Agency. 1985. *Characterization of Hazardous Waste Sites - A Methods Manual.* Vol. I, "Site Investigations". EPA-600/4-84-075. Environmental Monitoring Systems Laboratory, Las Vegas, NV.

U.S. Environmental Protection Agency. 1984. *Characterization of Hazardous Waste Sites - A Methods Manual.* Vol. II, "Available Sampling Methods." EPA-600/4-84-076. Environmental Monitoring Systems Laboratory, Las Vegas, NV.

U.S. Environmental Protection Agency. 1987. *A Compendium of Superfund Field Operations Methods*. NTIS PB88-181557. EPA/540/P-87/001. NP,Washington, DC.

**Ambient Air Sampling**

U.S. Environmental Protection Agency. 1994. *Quality Assurance Handbook for Air Pollution Measurement Systems.* Vol. I, Principles. Section 1.4.8 and Appendix M.5.6. EPA 600/9-76-005. NP:np.

U.S. Environmental Protection Agency. 1994. *Quality Assurance Handbook for Air Pollution Measurement Systems.* Vol. II, Sections 2.0.1 and 2.0.2 and "Individual Methods." EPA 600/R-94-038b. NP:np.

U.S. Environmental Protection Agency. 1984. *Compendium of Methods for the Determination of Toxic Organic Compounds in Ambient Air*. EPA/600-4-84-41. *Supplement:* EPA-600-4-87-006, September 1986. Environmental Monitoring Systems Laboratory, Research Triangle Park, NC.

**Source Testing (Air)**

U.S. Environmental Protection Agency. 1994. *Quality Assurance Handbook for Air Pollution Measurement Systems.* Vol. III, Section 3.0 and "Individual Methods." EPA 600/R-94-038c. NP:np.

**Water/Ground Water**

U.S. Environmental Protection Agency. 1987. *Handbook: Ground Water.* EPA/625/6-87/016. NP, Cincinnati, OH.

U.S. Environmental Protection Agency. 1986. *RCRA Ground Water Monitoring Technical Enforcement Guidance Document.* NP, Washington, DC.

U.S. Environmental Protection Agency. 1985. *Standard Methods for the Examination of Water and Wastewater*. 16th ed. NP, Washington, DC.

**Acid Precipitation**

U.S. Environmental Protection Agency. 1994. *Quality Assurance Handbook for Air Pollution Measurement Systems.* Vol. V. EPA 600/94-038e. NP:np.

**Meteorological Measurements**

U.S. Environmental Protection Agency. 1989. *Quality Assurance Handbook for Air Pollution Measurement Systems.* Vol. IV. EPA 600/4-90-003. NP:np.

**Radioactive Materials and Mixed Waste**

U.S. Department of Energy. 1989. *Radioactive-Hazardous Mixed Waste Sampling and Analysis: Addendum to SW-846.* NP:np.

**Soils and Sediments**

U.S. Environmental Protection Agency. 1985. *Sediment Sampling Quality Assurance User's Guide*. NTIS PB85-233542. EPA/600/4-85/048. Environmental Monitoring Systems Laboratory, Las Vegas, NV.

U.S. Environmental Protection Agency. 1989. *Soil Sampling Quality Assurance User's Guide.* EPA/600/8-89/046. Environmental Monitoring Systems Laboratory, Las Vegas, NV.

Barth, D.S., and T.H. Starks. 1985. *Sediment Sampling Quality Assurance User's Guide.* EPA/600-4-85/048. Prepared for Environmental Monitoring and Support Laboratory. NP, Las Vegas, NV.

**Statistics, Geostatistics, and Sampling Theory**

Myers, J.C. 1997. *Geostatistical Error Measurement.* Van Nostrand Reinhold, New York.

Pitard, F.F. 1989. *Pierre Gy's Sampling Theory and Sampling Practice.* Vol I and II. CRC Press, Boca Raton, FL.

**Miscellaneous**

American Chemical Society Joint Board/Council Committee on Environmental Improvement. 1990. *Practical Guide for Environmental Sampling and Analysis*. Section II, "Environmental Analysis." NP, Washington, DC.

ASTM Committee D-34. 1986. *Standard Practices for Sampling Wastes from Pipes and Other Point Discharges.* Document No. D34.01-001R7. NP:np.

Keith, L. 1990. *EPA's Sampling and Analysis Methods Database Manual*. Radian Corp, Austin, TX.

Keith, L. 1991. *Environmental Sampling and Analysis: A Practical Guide*. Lewis Publishers, Inc., Chelsea, MI.

## B3. SAMPLE HANDLING AND CUSTODY REQUIREMENTS

EPA QA/R-5 states: *"Describe the requirements for sample handling and custody in the field, laboratory, and transport, taking into account the nature of the samples, the maximum allowable sample holding times before extraction or analysis, and available shipping options and schedules for projects involving physical sampling. Sample handling includes packaging, shipment form the site, and storage at the laboratory. Examples of sample labels, custody forms, and sample custody logs should be included."*

### B3.1 Purpose/Background

This section of the QAPP should describe all procedures that are necessary for ensuring that:

(1) samples are collected, transferred, stored, and analyzed by authorized personnel;

(2) sample integrity is maintained during all phases of sample handling and analyses; and

(3) an accurate written record is maintained of sample handling and treatment from the time of its collection through laboratory procedures to disposal.

Proper sample custody minimizes accidents by assigning responsibility for all stages of sample handling and ensures that problems will be detected and documented if they occur. A sample is in custody if it is in actual physical possession or it is in a secured area that is restricted to authorized personnel. The level of custody necessary is dependent upon the data's purpose. While enforcement actions necessitate stringent custody procedures, custody in other types of situations (e.g., routine monitoring) may be primarily concerned only with the tracking of sample collection, handling, and analysis.

Sample custody procedures are necessary to prove that the sample data correspond to the sample collected, if data are intended to be legally defensible in court as evidence. In a number of situations, a complete, detailed, unbroken chain of custody will allow the documentation and data to substitute for the physical evidence of the samples (which can be hazardous, toxic or perishable) in a civil courtroom. Some statutes or criminal violations may still necessitate that the physical evidence of sample containers be presented along with the custody and data documentation.

These protocols may be described in a SOP included in an appendix or described in the QAPP itself. Although the NEIC Sampling Guide and the EPA Pesticide Inspector's Manual discuss Chain of Custody, it is a generic discussion and does not describe a specific organization's procedures, which the QAPP should directly or indirectly (i.e., an appendix)

discuss. Regardless of the where and how the topic is addressed, an outline of the scope of sample custody requirements--starting from the planning of sample collection, field sampling, sample analysis to sample disposal--should also be included. This discussion should further stress the completion of sample custody procedures, which include the transfer of sample custody from field personnel to the laboratory. Since the laboratory is often a separate entity or organization (or more than one organization) from the sample collector or inspector, sample custody within the analytical laboratory during sample preparation and analysis, and data storage will more likely be described in either the laboratory quality assurance plan or its SOPs. This information, from all laboratories used by the FIFRA program, should be included in an appendix and referenced here.

### B3.2 Sample Custody and Sample Shipping Procedures

The SOP or QAPP should discuss the sample custody procedure at a level commensurate with the intended use of the data. Information on preservation and holding times, if provided elsewhere, can be referenced. This discussion should:

- List the names and responsibilities of all sample custodians in the field and laboratories,
- Give a description and example of the sample numbering system,
- Define acceptable conditions and plans for maintaining sample integrity in the field prior to and during shipment to the laboratory (e.g., proper temperature, containers, and preservatives),
- Give examples of forms and labels used to maintain sample custody and document sample handling in the field and during shipping. An example of a sample log sheet is given in Figure 4; an example sample label is given in Figure 5,
- Describe the shipping containers to be used to send the samples to the laboratory (ice chest, custom box, etc.),
- Describe the method of sealing the shipping containers, including use of chain-of-custody seals, if appropriate. An example of a seal is given in Figure 6,
- Describe procedures that will be used to maintain the chain of custody and document sample handling during transfer from the field to the laboratory and/or among contractors. An example of a chain-of-custody record is given in Figure 7,
- Describe how the shipping container will be sent to the laboratory, for example, overnight courier, hand carry, bus, etc,

- Provide for the archiving of all shipping documents and associated paperwork,
- Discuss procedures that will ensure sample security at all times,
- Describe procedures for within-laboratory chain-of-custody together with verification of the printed name, signature, and initials of the personnel responsible for custody of samples, extracting and analyzing the samples at the laboratory,
- Include provisions for documenting the disposal or consumption of samples. A chain-of-custody checklist is included in Appendix C to aid in managing this element.

Minor documentation of chain-of-custody procedures is generally applicable when:

- Samples are generated and immediately tested within a facility or site; and
- Continuous rather than discrete or integrated samples are subjected to real- or near real-time analysis (e.g., continuous monitoring).

The discussion should be as specific as possible about the details of sample storage, transportation, and delivery to the receiving analytical facility.

## B3.3 Sample Preservation and Storage

This section should describe storage requirements for samples once they have been collected. This should include short term storage in the field, preservation requirements related to storage, and long term storage requirements (note preservation should have been covered under B2.5). This information is best presented in a table which includes the sample matrix, target pesticides or analyses, container, preservation requirements, storage requirements, and the maximum holding time permitted by the method. Storage requirements might also address the issue of secure storage or limited access storage for samples with potential legal implications. If procedures are in place to determine preservation and storage time requirements for new types of samples or matrices or to determine the stability of samples which must be held longer than their normal holding time (for example, due to an enforcement situation), this should be discussed here. This section should also discuss the final disposition of samples. In many cases, this information may be contained in the laboratory's QA Plan, which can be referenced, as appropriate.

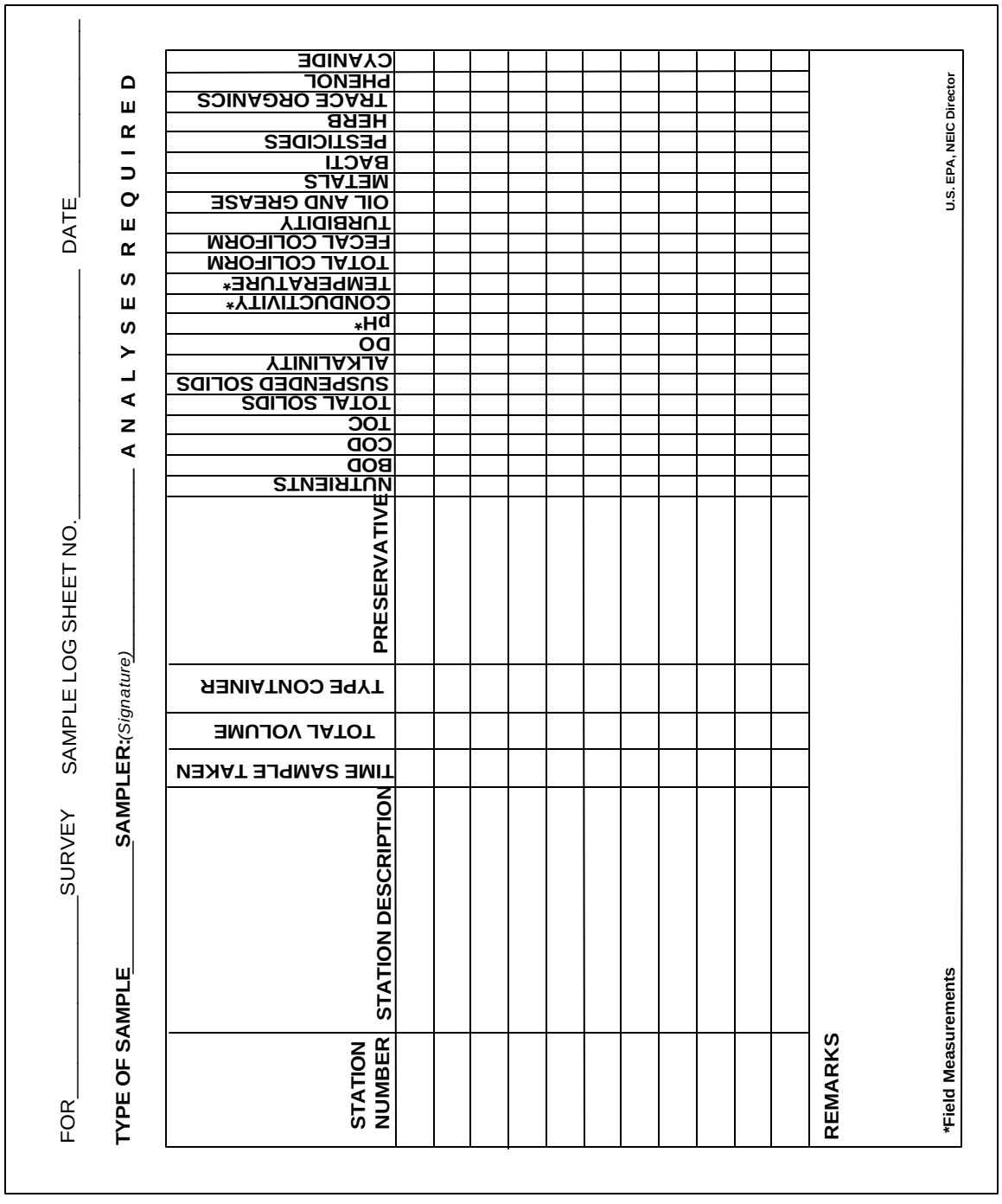


**Figure 4. An Example of a Sample Log Sheet**

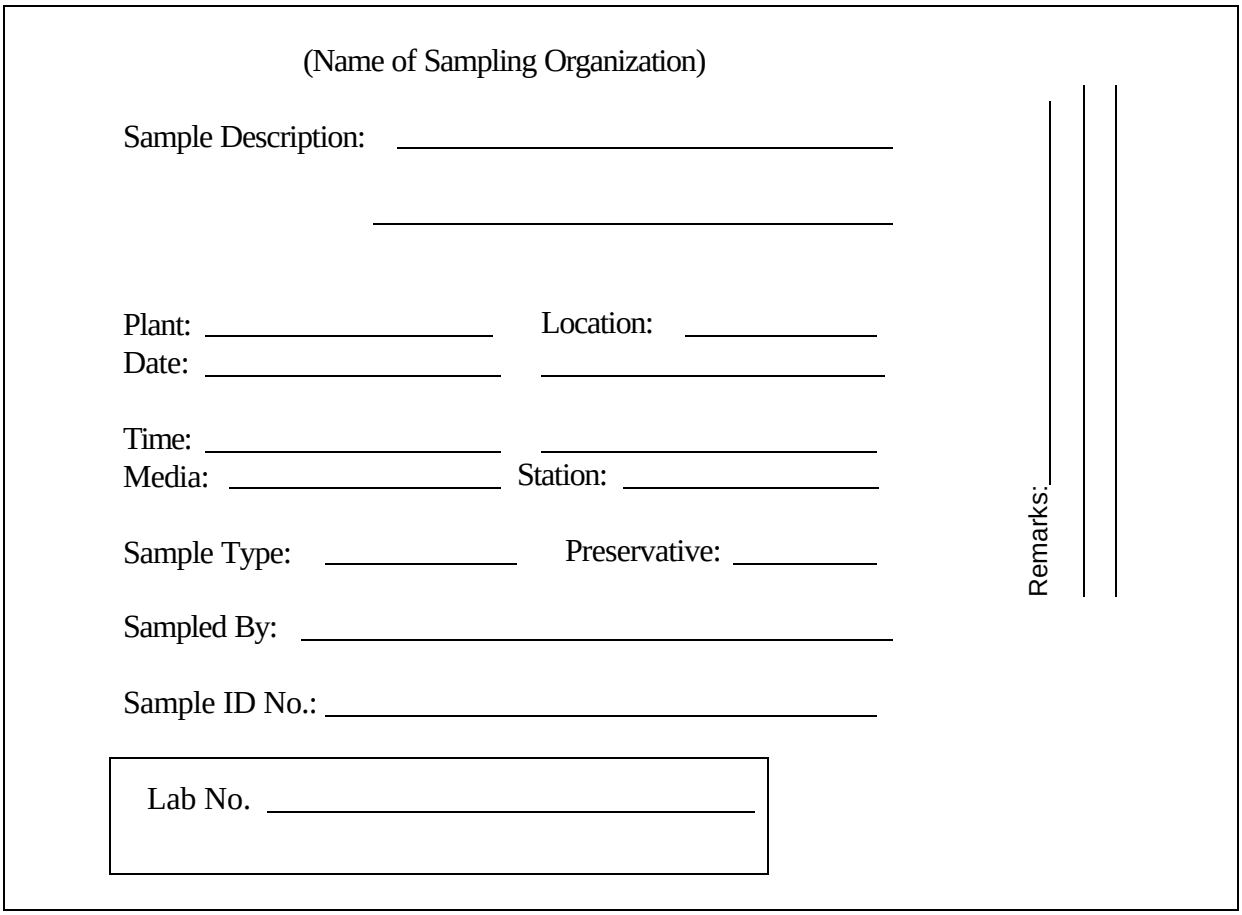


**Figure 5. An Example of a Sample Label**

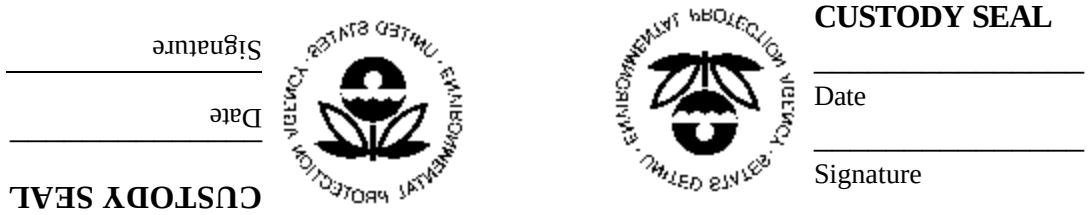


**Figure 6. An Example of a Custody Seal**

| | | | | **SAMPLERS** *(Signature)* | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| STATION NUMBER | STATION LOCATION | DATE | TIME | SAMPLE TYPE | | | SEQ NO. | NO. OF CONTAINERS | ANALYSIS REQUIRED | | |
| | | | | WATER | | AIR | | | | | |
| | | | | Comp | Grabx | | | | | | |
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| Relinquished by: *(Signature)* | | | | Received by: *(Signature)* | | | | | DATE/TIME | | |
| Relinquished by: *(Signature)* | | | | Received by: *(Signature)* | | | | | DATE/TIME | | |
| Relinquished by: *(Signature)* | | | | Received by: *(Signature)* | | | | | DATE/TIME | | |
| Received by: *(Signature)* | | | | Received by Mobile Laboratory for field analysis: *(Signature)* | | | | | DATE/TIME | | |
| Received by: *(Signature)* | | DATE/TIME | | Received for Laboratory by: | | | | | DATE/TIME | | |
| Method of Shipment: | | | | | | | | | | | |
| Distribution: Original - Accompany Shipment<br>1 Copy - Survey Coordinator Field Files | | | | | | | | | | | |

**Figure 7. An Example of a Chain-of-Custody Record**

## B4. ANALYTICAL METHODS REQUIREMENTS

EPA QA/R-5 states: *" Identify the analytical methods and equipment required, including sub-sampling or extraction methods, laboratory decontamination procedures and materials, waste disposal requirements (if any), and any specific performance requirements for the method. Address what to do when a failure in the analytical system occurs, who is responsible for corrective action and how the effectiveness of the corrective action shall be determined and documented. Specify the laboratory turnaround time needed, if important to the project schedule.*

*List any method performance standards. For non-standard method applications, such as for unusual sample matrices and situations, appropriate method performance study information is needed to confirm the performance of the method for the particular matrix. If previous performance studies are not available, they must be developed during the project and included as part of the project results."*

Analytical support for the FIFRA program may come from a variety of different sources, all of which should be discussed in the sections on analytical methods. These include measurements made in the field by the inspector, measurements made by a state Agricultural Laboratory, analyses performed by a private laboratory, or analyses performed by another state agency laboratory (e.g., a Department of Health or Environmental Laboratory). The analyses to be performed by all these laboratories to support the FIFRA program should be discussed in this section, or else copies of the relevant laboratory quality assurance plans and/or SOPs included with the QAPP as appendices. If included in appendices, the information in this section can be very limited. If this approach is not taken, then this section will become very detailed covering all the analyses in sufficient prescriptive detail so that the quality of data will be known. Otherwise, this section should describe the SLA's policy and some of the key information which should be contained in the SLA's QAPP, regardless of what organization performs the work. This section of the guidance is written on the assumption that most analyses will be performed by a state agriculture laboratory or else a contract lab.

This section, and the three that follow: B5 on Quality Control Requirements; B6 on Instrument/Equipment Testing, Inspection, and Maintenance Requirements; and B7 on Instrument Calibration and Frequency relate to program support activities. In many cases, the information will be found in laboratory SOPs or other documents, with possible summary tables in the laboratory's quality assurance plan, all of which should be referenced or included in the appendices. If this approach is taken, these sections may be brief.

## B4.1 Selection of Analytical Methods

The choice of analytical methods will be influenced by performance criteria, Data Quality Objectives, possible regulatory criteria, the matrix, and the analytes to be measured. Ideally decisions concerning methods should be made jointly by the data user and the laboratory, since the user knows what analytes are of interest and what decisions will be made with the data, but it is the laboratory that is familiar with options concerning different methods. With the use of any one of a number of methods possible, the program QAPP should include the laboratory's quality assurance plan. The latter should cite and include information on all analytical procedures it might use to support different FIFRA programs (e.g., groundwater analyses, formulation analyses, use/misuse investigations, surface water analyses, etc.).

Traditionally, monitoring methods and requirements to demonstrate compliance are specified in the applicable regulations (for example in 40 CFR 136 for the Clean Water Act) and/or permits, but this is often not the case with FIFRA. These methods may be found in EPA sources (such as SW-846, 40 CFR 136, Drinking Water Methods, etc.), AOAC methods, in methods developed by the state, or even in methods developed by the manufacturer. This section of the QAPP should describe how methods are chosen for different applications and what factors are prioritized in these decisions. The approach taken toward using modified or unpublished methods should also be discussed (see also the discussion below). It should be noted that the EPA Office of Pesticide Programs is planning to make methods available on its Internet site during the 2000-2001 time frame.

Laboratory contamination from the processing of hazardous materials such as toxic or radioactive samples for analysis and their ultimate disposal should be considered during the planning stages for selection of analysis methods. Safe handling requirements for samples in the laboratory with appropriate decontamination and waste disposal procedures should also be described, although these may be contained in the laboratory's quality assurance plan .

## B4.2 Validation of Any Nonstandard Methods

In many environmental areas, this historical approach of using well established validated methods is being replaced by the Performance-Based Measurement System (PBMS). PBMS is a process in which data quality needs, mandates, or limitations of a program or project are specified and serve as a criterion for selecting appropriate methods. The regulated body selects the most cost-effective methods that meet the criteria specified in the PBMS. Under the PBMS framework, the performance of the method employed is emphasized rather than the specific technique or procedure used in the analysis. Equally stressed in this system is the requirement that the performance of the method be

documented and certified by the laboratory that appropriate QA/QC procedures have been conducted to verify the performance. PBMS applies to physical and chemical techniques of analysis performed in the field as well as in the laboratory. PBMS does not apply to method-defined parameters.

Most Agricultural laboratories already have a defacto PBMS system in place since unusual matrices and atypical chemicals are more often the norm rather than the exception. The laboratory's approach to method development or validation for these non-routine situations should be documented in the program QAPP as well as in the laboratory's quality assurance plan. The protocol for validation of the method which might include, but not be limited to, optimizing extraction and instrument conditions, determination of detection limits, establishment of the linear calibration range, determination of typical recoveries, and establishment of quality control (QC) criteria (precision and accuracy). The QAPP should include a discussion of the review and approval process for the method that accompanies the study itself.

Most recognized methods include a component of round-robin studies performed by EPA or by other organizations. Ideally, new methods will also include this, but it is recognized that this is often not possible given time and budget constraints. However, some level of single-user validation study or ruggedness study should be performed and at least be available at the laboratory if it is not included with the final report. The laboratory's quality assurance plan should have provisions for an independent QA review of the new procedure or application of an established procedure to a new matrix/analyte. The program QAPP should clearly define validation study information required for approval and it is recommended that the user, as well as the laboratory agree when a method is ready for use.

### B4.3 Analytical Method References

Greenberg, A.E., L.S. Clescer, and A. D. Eaton, eds. 1992. *Standard Methods for the Examination of Water and Wastewater. 18th ed.* American Public Health Association. Water Environment Federation, np.

U.S. Environmental Protection Agency. 1982 . *Methods for Organic Chemical Analysis of Municipal and Industrial Wastewater*. EPA/600/4-82-057. Office of Research and Development, U.S. EPA, Cincinnati, OH.

U.S. Environmental Protection Agency. 1988 . *Methods for the Determination of Organic Compounds in Drinking Water*. EPA/600/4-88/039. Office of Research and Development, U.S. EPA, Cincinnati, OH.

U.S. Environmental Protection Agency. 1990 . *Methods for the Determination of Organic Compounds in Drinking Water, Supplement I.* EPA/600/4-90/020. Office of Research and Development, U.S. EPA, Cincinnati, OH.

U.S. Environmental Protection Agency. 1992 . *Methods for the Determination of Nonconventional Pesticides in Municipal and Industrial Wastewater.* Volume I. EPA-821-R-92-002-A. Office of Water/Engineering and Analysis Division, U.S. EPA, Washington, D.C..

U.S. Environmental Protection Agency. 1992 . *Methods for the Determination of Organic Compounds in Drinking Water, Supplement II.* EPA/600/R-92-129. Office of Research and Development, U.S. EPA, Cincinnati, OH.

U.S. Environmental Protection Agency. 1993 . *Methods for the Determination of Nonconventional Pesticides in Municipal and Industrial Wastewater.* Volume II. EPA-821-R-93-010-B. Office of Water/Engineering and Analysis Division, U.S. EPA, Washington, D.C..

U.S. Environmental Protection Agency. 1995 . *Methods for the Determination of Organic Compounds in Drinking Water, Supplement III.* EPA/600/R-95/131. Office of Research and Development, U.S. EPA, Cincinnati, OH.

U.S. Environmental Protection Agency. N.d. *Test Methods for Evaluating Solid Waste.* Chapter 2, "Choosing the Correct Procedure." NP:np.

U.S. Environmental Protection Agency. 1996. *Quality Control: Variability in Protocols.* EPA/600/9-91/034. Risk Reduction Engineering Laboratory, U.S. EPA, Cincinnati, OH.

U.S. Environmental Protection Agency. *Test Methods for Evaluating Solid Waste*. 3rd ed. Volume One, Section B, Chapter 4, "Organic Analytes." Office of Solid Waste, U.S. EPA, Washington, D.C..

## B4.4 Subsampling

If subsampling is required by the sampler or field inspector, the procedures should be described in relevant SOPs. If sampling will be performed by the laboratory it should be documented in laboratory SOPs included with the laboratory's QA Plan. Because subsampling may involve more than one stage, it is imperative that the procedures be documented fully so that the results of the analysis can be evaluated properly.

## B4.5 Preparation of the Samples

Preparation procedures should be described and standard methods cited and used where possible. Step-by-step operating procedures for the preparation of the samples should be listed in other relevant SOPs. The sampling containers, methods of preservation, holding times, holding conditions, etc., should be described if sample preparation changes the nature of the sample. For example, if a sample extract is generated, its storage and holding time should be specified since this information is not contained in the sampling guidance previously cited.

## B5. QUALITY CONTROL (QC) REQUIREMENTS

EPA QA/R-5 states: *" Identify QC activities needed for each sampling, analysis, or measurement technique. For each required QA activity, list the associated method or procedure, acceptance criteria, and corrective action. QC activities for the field and the laboratory include, but are not limited to, the use of blanks, duplicates, matrix spikes, laboratory control samples, surrogates, or second column confirmation. State the frequency of analysis for each type of QC activity, and the spike compounds sources and levels. State or reference the required control limits for each QC activity and corrective action required when control limits are exceeded and how the effectiveness of the corrective action shall be determined and documented."*

QC is "the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer." QC is both corrective and proactive in establishing techniques to prevent the generation of unacceptable data, and so the policy for corrective action should be outlined. This element will rely on information developed in Section A7, "Quality Objectives and Criteria for Measurement Data," which establishes measurement performance criteria. QC criteria can be summarized in tables in the FIFRA QAPP or the laboratory's quality assurance plan and should be in laboratory's SOPs. Some of the elements which should be covered are described below.

### B5.1 Quality Control Procedures

This section describes any QC checks not defined in other QAPP elements and should reference other sections that contain this information where possible. Ideally, a summary table will be presented in the QAPP for most of the common methods used under the organization's FIFRA program. A comparable table would be found in the laboratory quality assurance plan, and detailed information found in method specific SOPs. Most of the QC acceptance limits of EPA methods are based on the results of interlaboratory studies, however, many agricultural laboratories use AOAC (Association of Analytical Chemists) or procedures developed in-house. Because of improvements in measurement methodology and continual improvement efforts in individual laboratories, these method acceptance limits may not be stringent enough or applicable to some situations (for

example, formulation analyses). In some cases, acceptance limits are based on intralaboratory studies (which often result in narrower acceptance limits than those based on interlaboratory limits), and consultation with an expert may be necessary.

Table 2 lists QC checks often included in analytical method SOPs. This list is for example purposes only. The approach taken by each laboratory for each method should be decided by each state pesticide program and/or its laboratory based on program objectives and resources available. Typically, at a minimum, each laboratory method would include a 3 point calibration step (except for formulations where a 1 point may be acceptable), a matrix spike, a duplicate analysis, and a laboratory or method blank. The frequency with which these or other QC checks will be run, and the associated acceptance criteria and corrective actions to take if criteria are exceeded should be described in this section or else in the laboratory's SOPs or QA Plan. These should be included as an appendix to the overall pesticide program QAPP.

**Table 2: Analytical QC Checks**

| QC Check | Information Provided |
|---|---|
| Blanks | |
| field blank | transport and field handling bias and laboratory analytical system |
| reagent blank | contaminated reagent |
| rinsate blank | contaminated equipment and laboratory analytical system |
| method or matrix blank | response of entire laboratory analytical system |
| Spikes | |
| matrix spike | analytical (preparation + analysis) bias and matrix effects |
| matrix spike replicate/duplicate | analytical bias and precision |
| instrument spike | instrumental bias |
| surrogate spike | analytical bias and matrix effects, extraction efficiency |
| blank spike (lab control sample) | analytical bias |
| post digestion spikes | matrix effects (inorganic) |
| Calibration Check Samples | |
| detection limit verification check | sensitivity below lowest calibration point |
| mid-range check (continuing calibration verification) | calibration drift and memory effects |
| standard verification | independent calibration verification using a NIST national standard or other external source of a certified standard |
| Replicates, splits, etc. | |
| collocated samples | matrix variability + sampling + measurement precision |
| field replicates | precision of all steps after acquisition |
| field splits | shipping + interlaboratory precision |
| laboratory splits | interlaboratory precision |
| lab/method duplicates/replicates | analytical precision |
| analysis duplicate/replicates | instrument precision |

Many QC checks result in measurement data that are used to compute statistical indicators of data quality. For example, a series of dilute solutions may be measured repeatedly to produce an estimate of the instrument detection limit. The formulas for calculating such Data Quality Indicators (DQIs) should be provided or referenced in this section or in the laboratory's quality assurance plan . This section should prescribe any limits that define acceptable data quality for these indicators (see Appendix D, "Data Quality Indicators"). The FIFRA QAPP should discuss the relation of QC to the overall program objectives for the four general areas of groundwater monitoring, formulations, use/misuse and special projects. In many cases, the FIFRA QAPP may defer to the laboratory's capabilities, but the QAPP should make clear when this is and is not the case.

This section or the laboratory's quality assurance plan or its SOPs should include information on:

- The frequency and point in the measurement process at which the check sample is introduced,
- The traceability of the standards,
- The matrix of the check sample,
- The level or concentration of the analyte of interest,
- The corrective actions to be taken if a QC check identifies a failed or changed measurement system on both an analysis and batch basis,
- The formulas for estimating DQIs, and
- The procedures for documenting QC results, including control charts. If control charts are used, the laboratory quality assurance plan or SOPs should make clear exactly what data are to be plotted at what frequency on a method and analyte specific basis, and how control chart information will be used.

Finally, this section should describe how the QC check data will be used to determine that measurement performance is acceptable. This step can be accomplished by establishing QC "warning" and "control" limits for the statistical data generated by the QC checks (see standard QC textbooks operational details).

Depending on the breadth of the potential audience for reviewing and implementing the QAPP, it may be advantageous to separate the field QC from laboratory QC requirements.

### B5.2 Corrective Action

If problems are noted as the result of the quality control checks described above, the field team/inspector, laboratory or organization responsible for collecting the sample or for performing the analyses should take corrective action. The procedures to be followed can be described in the section above, in the laboratory's QA Plan, or its SOPs, but this section should make clear who is responsible for carrying out corrective actions and who will ensure that the corrective action accomplished the desired result. Corrective action may require the collection of a new sample, flagging of data, re-analysis, or some other remedy. These remedies should be documented in either the FIFRA program QAPP or the laboratory's quality assurance plan.

## B6. INSTRUMENT/EQUIPMENT TESTING, INSPECTION, AND MAINTENANCE REQUIREMENTS

EPA QA/R-5 states: *"Describe how inspections and acceptance testing of instruments, equipment, and their components affecting quality will be performed and documented to assure their intended use as specified. Identify and discuss the procedure by which final acceptance will be performed by independent personnel (e.g., personnel other than those performing the work) and/or by the EPA project manager. Describe how deficiencies are to be resolved, when re-inspection will be performed, and how the effectiveness of the corrective action shall be determined and documented.*

*Describe or reference how periodic preventive and corrective maintenance of measurement or test equipment or other systems and their components affecting quality shall be performed to availability and satisfactory performance of the system. Identify the equipment and/or systems requiring periodic maintenance."*

The purpose of this section of the QAPP is to discuss the procedures used to verify that all instruments and equipment are maintained in sound operating condition and are capable of operating at acceptable performance levels.

### B6.1 Testing, Inspection, and Maintenance

It is expected that this information will be provided in general form in the QAPP and in detail in method specific SOPs. The procedures described should (1) reflect consideration of the possible effect of equipment failure on overall data quality, including timely delivery of program results; (2) address any relevant site-specific effects (e.g., environmental conditions); and (3) include procedures for assessing equipment status. The discussion should address the scheduling of routine calibration and maintenance activities, the steps that will be taken to

minimize instrument downtime, and prescribe corrective action procedures for addressing unacceptable inspection or assessment results. The discussion should also describe periodic maintenance procedures, the availability of spare parts, and how an inventory of these parts is monitored and maintained. The reader should be supplied with sufficient information to review the adequacy of the instrument/equipment management procedures. A specific SOP on this subject might be another way that a state sampling team/inspector or laboratory addresses this area.

## B7. INSTRUMENT CALIBRATION AND FREQUENCY

EPA QA/R-5 states:" Identify all tools, gauges, instruments, and other sampling, measuring, and test equipment used for data generation or collection activities affecting quality that must be controlled and, at specified periods, calibrated to maintain performance within specified limits. Describe or reference how calibration will be conducted using certified equipment and/or standards with known valid relationships to nationally recognized performance standards. If no such nationally recognized standards exist, document the basis for the calibration. Identify the certified equipment and/or standards used for calibration. Indicate how records of calibration shall be maintained and be traceable to the instrument."

### B7.1 Purpose/Background

The FIFRA QAPP and/or the method specific SOPs, or similar documents, should discuss calibration requirements. Calibration applies to both field instruments, such as conductivity meters, pH meters, thermometers, dissolved oxygen meters, etc and to laboratory instruments. Most of this information should be specified in either the program QAPP, field SOPs, the laboratory's quality assurance plan, or in laboratory SOPs. The information outlined in sections B7.2 through B7.3 should be included.

### B7.2 Identify the Instrumentation Requiring Calibration

The SOPs, program QAPP or similar documents should identify any equipment or instrumentation that requires calibration to maintain acceptable performance. The primary focus of this element is on instruments of the measurement system, and establishing the relationship between response and concentration.

### B7.3 Document the Calibration Method That Will Be Used for Each Instrument

The SOPs, program QAPP or similar documents must describe the calibration method for each instrument in enough detail for another qualified person to duplicate the calibration method. It is expected that this documentation will be prescriptive in its details so that

another qualified person could follow the procedure, even if he or she has had minimal exposure to the method previously.

Some instrumentation may be calibrated against other instrumentation or apparatus (e.g., NIST thermometer), while other instruments are calibrated using standard materials traceable to national reference standards.

Calibrations normally involve challenging the measurement system or a component of the measurement system at a number of different levels over its operating range. The calibration may cover a narrower range if accuracy in that range is critical, given the end use of the data. Single-point calibrations are of limited use, and two-point calibrations do not provide information on non-linearity. If single- or two-point calibrations are used for critical measurements, the potential shortcomings should be carefully considered and discussed in the SOP. Most EPA-approved analytical methods require multipoint (three or more) calibrations that include zeros, or blanks, and higher levels so that unknowns fall within the calibration range and are bracketed by calibration points. The number of calibration points, the calibration range, and any replication (repeated measures at each level) should be given in the SOP. The need for and type of calibration necessary for each piece of equipment/instrument should be considered prior to purchase and use.

The SOPs should describe how calibration data will be analyzed. The use of statistical QC techniques to process data across multiple calibrations to detect gradual degradations in the measurement system should be described. The SOPs should describe any corrective action that will be taken if calibration (or calibration check) data fail to meet the acceptance criteria, including recalibration. References to appended SOPs containing the calibration procedures are an acceptable alternative to describing the calibration procedures within the text of the QAPP.

### B7.4 Document Calibration Standards

Most measurement systems are calibrated by processing materials that are of known and stable composition. References describing these calibration standards should be included in the SOPs. Calibration standards are normally traceable to national reference standards, such as the National Institute of Standards and Technology's (NIST's) Standard Reference Materials (SRMs), as well as QC standards from vendors,, and the traceability protocol should be discussed. If the standards are not traceable, the SOPs must include a detailed description of how the standards will be prepared. The accuracy of calibration standards is important because all data will be measured in reference to the standard used. The types of standards should be noted. The acceptance limits for verifying the accuracy of all working standards against primary grade standards should also be provided. Any method used to verify the certified value of the standard independently should be described.

### B7.5 Document Calibration Frequency

The SOPs must describe how often each measurement method will be calibrated. It is desirable that the calibration frequency be related to any known temporal variability (i.e., drift) of the measurement system. The calibration procedure may involve less-frequent comprehensive calibrations and more-frequent simple drift checks. The location of the record of calibration frequency and maintenance should be referenced.

### B7.6 Calibration References

American Chemical Society. 1980. "Calibration." *Analytical Chemistry*. Vol. 52, pps. 2,242-2,249. NP:np.

Dieck, R.H. 1992. *Measurement Uncertainty Methods and Applications*. Instrument Society of America, Research Triangle Park, NC.

Dux, J.P. 1986. *Handbook of Quality Assurance for the Analytical Chemistry Laboratory*. Van Nostrand Reinhold, New York.

ILAC Task Force E. 1984. *Guidelines for the Determination of Recalibration Intervals of Testing Equipment Used in Testing Laboratories.* International Document No. 10. International Organization for Legal Metrology (OIML). 11 Rue Twigot, Paris 95009, France.

Ku, H.H., Ed. 1969. *Precision Measurement and Calibration: Selected NBS Papers on Statistical Concepts and Procedures*. Special Publication 300. Vol. 1. National Bureau of Standards, Gaithersburg, MD.

Liggett, W. 1986. "Tests of the Recalibration Period of a Drifting Instrument." In *Oceans '86 Conference Record*. Vol. 3. Monitoring Strategies Symposium. The Institute of Electrical and Electronics Engineers, Inc., Service Center, Piscataway, NJ.

Pontius, P.E. 1974. *Notes on the Fundamentals of Measurement as a Production Process.* Publication No. NBSIR 74-545. National Bureau of Standards, Gaithersburg, MD.

Taylor, J.T. 1987. *Quality Assurance of Chemical Measurements.* Lewis Publishers, Inc., Boca Raton, FL.

## B8. INSPECTION/ACCEPTANCE REQUIREMENTS FOR SUPPLIES AND CONSUMABLES

EPA QA/R-5 states: *"Describe how and by whom supplies and consumables (e.g., standard materials and solutions, sample bottles, calibration gases, reagents, hoses, deionized water, potable water, electronic data storage media) shall be inspected and accepted for use in the project. State the acceptance criteria for such supplies and consumables."*

This information is usually found in the laboratory's quality assurance plan, but may be found in sampling guides and SOPs. Its purpose is to establish and document a system for inspecting and accepting all supplies and consumables that may directly or indirectly affect the quality of the data generated for each of the four FIFRA program areas.

### B8.1 Identification of Critical Supplies and Consumables

The program QAPP should clearly identify and document all supplies and consumables that may directly or indirectly affect the quality of the activity or task. Although primarily of importance to the laboratory, this also applies to field supplies such as preservatives, decontamination materials and other such chemicals. See Figures 8 and 9 for example documentation of inspection/acceptance testing requirements. Typical examples include sample bottles, calibration gases, reagents, materials for decontamination activities, deionized water, and distilled water. Calibration standards should have been discussed previously.

For each item identified, document the inspection or acceptance testing requirements or specifications (e.g., concentration, purity, certifying agency (e.g., American Chemical Society), or source of procurement) in addition to any requirements for certificates of purity or analysis.

### B8.2 Establishing Acceptance Criteria

Acceptance criteria must be consistent with overall program technical and quality criteria (e.g., concentration must be within ± 2.5%, reagent must be analyte free, etc.). If special requirements are needed for particular supplies or consumables, a clear agreement should be established with the supplier, including the methods used for evaluation and the provisions for settling disparities. Because the FIFRA program may handle samples covering a wide range of concentrations, percent level down to ultra trace level, the laboratory may choose to have variable standards depending on the purpose to which the material will be put.

### B8.3 Inspection or Acceptance Testing Requirements and Procedures

Inspections or acceptance testing should be documented, including procedures to be followed, individuals responsible, and frequency of evaluation. In addition, handling and storage conditions for supplies and consumables should be documented.

## B8.4 Tracking and Quality Verification of Supplies and Consumables

Procedures should be established to ensure that inspections or acceptance testing of supplies and consumables are adequately documented by permanent, dated, and signed records or logs that uniquely identify the critical supplies or consumables, the date received, the date tested, the date to be retested (if applicable), and the expiration date. These records should be kept by the responsible individual(s) (see Figure 10 for an example log). In order to track supplies and consumables, labels with the information on receipt and testing should be used.

These or similar procedures should be established to enable personnel to (1) verify, prior to use, that critical supplies and consumables meet specified quality objectives; and (2) ensure that supplies and consumables that have not been tested, have expired, or do not meet acceptance criteria are not used for the activity.

Unique identification no. (if not clearly shown)_____
Date received_____
Date opened_____
Date tested (if performed)_____
Date to be retested (if applicable)_____
Expiration date_____

**Figure 8. Example of a Record for Consumables**

| Critical Supplies and Consumables | Inspection/ Acceptance Testing Requirements | Acceptance Criteria | Testing Method | Frequency | Responsible Individual | Handling/Storage Conditions |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |

**Figure 9. Example of Inspection/Acceptance Testing Requirements**

| Critical Supplies and Consumable (Type, ID No.) | Date Received | Meets Inspection/ Acceptance Criteria (Y/N, Include Date) | Requires Retesting (Y/N, If Yes, Include Date) | Expiration Date | Comments | Initials/Date |
|---|---|---|---|---|---|---|
| | | | | | | |

**Figure 10. Example of a Log for Tracking Supplies and Consumables**

## B9 DATA ACQUISITION REQUIREMENTS (NON-DIRECT MEASUREMENTS)

EPA QA/R-5 states: *"Identify any types of data needed for project implementation or decision making that are obtained from non-measurement sources such as computer data bases, programs, literature files, and historical data bases. Describe the intended use of the data. Define the acceptance criteria for the use of such data in the project and specify any limitations on the use of the data."*

### B9.1 Purpose/Background

This element of the QAPP should discuss under what circumstances previously collected data might be used in decision making. If possible it should identify the potential sources of these data and the information needed to consider the data complete and usable. Perhaps a tiered approach might be described that links the amount of information available on the quality of the data to the types of program decisions which would be acceptable. There should be provisions for documenting the rationale for the original collection of the data if it is known. Information that is non-representative and possibly biased and is used uncritically may lead to decision errors. The care and skepticism applied to the generation of new data are also appropriate to the use of previously compiled data.

### B9.2 Acquisition of Non-Direct Measurement Data

This element's criteria should be developed to support the objectives of element A7. Acceptance criteria for each collection of data being considered for use in this program should be explicitly stated, especially with respect to:

**Representativeness.** Were the data collected from a population that is sufficiently similar to the population of interest and the population boundaries? How will potentially confounding effects (for example, season, time of day, and cell type) be addressed so that these effects do not unduly alter the summary information?

**Bias.** Are there characteristics of the data set that would shift the conclusions? For example, has bias in analysis results been documented? Is there sufficient information to estimate and correct bias?

**Precision.** How is the spread in the results estimated? Does the estimate of variability indicate that it is sufficiently small to meet the objectives of this activity as stated in element A7?

**Qualifiers.** Are the data evaluated in a manner that permits logical decisions on whether or not the data are applicable to the current activity? Is the system of qualifying or flagging data adequately documented to allow the combination of data sets?

**Summarization.** Is the data summarization process clear and sufficiently consistent with the goals of this activity? (See element D2 for further discussion.) Ideally, observations and transformation equations are available so that their assumptions can be evaluated against the objectives of the current activity. This element should also include a discussion on limitations on the use of the data and the nature of the uncertainty of the data.

## B10 DATA MANAGEMENT

EPA QA/R-5 states: *"Describe the project data management process, tracing the path of the data from their generation to their final use or storage (e.g., the field, the office, the laboratory). Describe or reference the standard record-keeping procedures, document control system, and the approach used for data storage and retrieval on electronic media. Discuss the control mechanism for detecting and correcting errors and for preventing loss of data during data reduction, data reporting, and data entry to forms, reports, and databases.*

*Identify and describe all data handling equipment and procedures to process, compile, and analyze the data. This includes procedures for addressing data generated as part of the project as well as data from other sources. Include any required computer hardware and software and address any specific performance requirements for the hardware/software configuration used. Describe the procedures that will be followed to demonstrate acceptability of the hardware/software configuration required. Describe the process for assuring that applicable information resource management requirements are satisfied."*

This section should present an overview of all mathematical operations and analyses performed on raw ("as-collected") data to change their form of expression, location, quantity, or dimensionality. These operations include data recording, validation, transformation, transmittal, reduction, analysis, management, storage, and retrieval. A diagram that illustrates the source(s) of the data, the processing steps, the intermediate and final data files, and the reports produced may be helpful, particularly when there are multiple data sources and data files. When appropriate, the data values should be subjected to the same chain-of-custody requirements as outlined in element B3. If this information is documented in another area, such as a data management SOP, it can be referenced and included as an appendix.

### B10.1 Data Recording

Any internal checks (including verification and validation checks) that will be used to ensure data quality during data encoding in the data entry process should be identified together with the mechanism for detailing and correcting recording errors. Examples of data entry forms and checklists should be included if electronic records are maintained of FIFRA data.

### B10.2 Data Validation

The details of the process of data validation and prespecified criteria should be documented in this section of the QAPP or, if described in Part D of the QAPP, it should be referenced here. This includes addressing how the method, instrument, or system performs the function it is intended to consistently, reliably, and accurately in generating the data. Part D of this document addresses the data validation, which is performed after the data generation has been completed.

### B10.3 Data Transformation

Data transformation is the conversion of individual data point values into related values or possibly symbols using conversion formulas (e.g., units conversion or logarithmic conversion) or a system for replacement. The transformations can be reversible (e.g., as in the conversion of data points using a formulas) or irreversible (e.g., when a symbol replaces actual values and the value is lost). The procedures for all data transformations should be described and recorded in this element. The procedure for converting calibration readings into an equation that will be applied to measurement readings should be documented in the field team/inspector's SOP or the laboratory's quality assurance plan or SOPs.

### B10.4 Data Transmittal

Data transmittal occurs when data are transferred from one person or location to another or when data are copied from one form to another. Some examples of data transmittal are copying raw data from a notebook onto a data entry form for keying into a computer file and electronic transfer of data over a telephone or computer network. The FIFRA QAPP should describe each data transfer step and the procedures that will be used to characterize data transmittal error rates and to minimize information loss in the transmittal.

### B10.5 Data Reduction

Data reduction includes all processes that change the number of data items. This process is distinct from data transformation in that it entails an irreversible reduction in the size of the data set and an associated loss of detail. Most data reduction is done at the laboratory level.

For manual calculations, the laboratory quality assurance plan or SOPs should include an example in which typical raw data are reduced. For automated data processing, this information is more likely found in the laboratory quality assurance plan or SOPs which should clearly indicate how the raw data are to be reduced with a well-defined audit trail, and reference to the specific software documentation should be provided. If data reduction is not performed by the laboratory, the process that is used should be described.

### B10.6 Data Analysis

Data analysis sometimes involves comparing suitably reduced data with a conceptual model (e.g., a dispersion model, tracking a plume, etc.). The main places this might apply in FIFRA activities is in groundwater monitoring, use/misuse investigations and in special projects. It frequently includes computation of summary statistics, standard errors, confidence intervals, tests of hypotheses relative to model parameters, and goodness-of-fit tests. This element should briefly outline the proposed methodology for data analysis and a more detailed discussion should be included in the final report.

### B10.7 Data Tracking

Data management includes tracking the status of data as it is collected, transmitted, and processed. The QAPP should describe the established procedures for tracking the flow of data through the data processing system.

### B10.8 Data Storage and Retrieval

The QAPP should discuss data storage and retrieval including security and time of retention, and it should document the complete control system. The QAPP should also discuss the performance requirements of the data processing system, including provisions for the batch processing schedule and the data storage facilities.

## GROUP C: ASSESSMENT AND OVERSIGHT

The elements in this group (Table 4) address the activities for assessing the effectiveness of project implementation and associated QA and QC activities. The purpose of assessment is to ensure that the QAPP is implemented as prescribed.

| Table 4. Group C: Assessment and Oversight Elements | |
|---|---|
| C1 | Assessments and Response Actions |
| C2 | Reports to Management |

## C1 ASSESSMENTS AND RESPONSE ACTIONS

### C1.1 Purpose/Background

During the planning process, many options for sampling, sample handling, sample cleanup, sample analysis, and data reduction are evaluated and chosen depending on the nature of enforcement or monitoring activity. In order to ensure that data collection is conducted as planned, a process of evaluation and validation will be performed by the pesticide lead agency. This element describes the internal and external checks that are necessary to ensure that all elements of this QAPP are correctly implemented as prescribed; that the quality of data generated by the implementation of the QAPP is adequate; and that corrective actions, when needed, are implemented in a timely manner and their effectiveness is confirmed.

Although any external assessments that are planned should be described in the QAPP, the most important part of this element is documenting all planned internal assessments. Generally, internal assessments are initiated or performed by the FIFRA Program QA Officer or the Laboratory QA Officer so the activities described in this element should be related to the responsibilities of the QA Officers as discussed in Section A4.

### C1.2 Assessment Activities and Program Planning

Guidance under QA/R-5 indicates that the Quality Assurance Program should, *"Identify the number, frequency, and type of assessment activities needed for this project. Assessments include, but are not limited to surveillance, management systems review, readiness review, technical*

*systems audit, performance evaluations, audit of data quality, and data quality assessment."* The following sections describe various types of assessment activities available to managers in evaluating the effectiveness of environmental program implementation. Note that all of these assessments may not be applicable for all organizations. Those that are part of the QA system of the organization should be described and the rationale for not using the others provided.

### C1.2.1 Assessment of the Subsidiary Organizations

A. *Management Systems Review (MSR).* A form of management assessment, this process is a qualitative assessment of a data collection operation or organization to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained. The MSR is used to ensure that sufficient management controls are in place and carried out by the organization to adequately plan, implement, and assess the results of the program. See the *Guidance for the Management Systems Review Process* (EPA QA/G-3). A MSR is most likely to be carried out by EPA as part of its oversight responsibilities, although it can be carried out by the state or tribal organization.

   If the state's FIFRA program conducts MSRs, then the nature and purpose of these audits should be described here. The schedule and reports resulting from this type of audit should be described later in Sections C1.3 and C2.2.

B. *Readiness reviews.* A readiness review is a technical check to determine if all components of the program activity are in place so that work can commence on a specific phase.

   If the state's FIFRA program conducts Readiness Reviews, then the nature and purpose of these audits should be described here. The schedule and reports resulting from this type of audit should be described later in Sections C1.3 and C2.2.

### C1.2.2 Assessment of Program Activities

A. *Surveillance.* Surveillance is the continual or frequent monitoring of the status of a activity (for example, misuse investigations including sampling and analysis) and the review of records to ensure that specified requirements are being fulfilled.

   If the state's FIFRA program conducts surveillance, then the nature and purpose of these audits should be described here. The schedule and reports resulting from this type of audit should be described later in Sections C1.3 and C2.2.

B. *Technical Systems Audit (TSA).* A TSA is a thorough and systematic onsite qualitative audit, where facilities, equipment, personnel, training, procedures, and record keeping are examined for conformance to the QAPP. The TSA is a powerful audit tool with broad coverage that may reveal weaknesses in the management structure, policy, practices, or procedures. The TSA is ideally conducted after work has commenced, but before it has progressed very far, thus giving opportunity for corrective action. A TSA could be carried out on field activities, laboratory activities, or the entire system. They can be informal internal audits (for example, the laboratory QA Officer audits activities in one particular section of the laboratory), or they can be more formal comprehensive audits carried out by an independent third party. The level of detail can vary considerably depending on the purpose of the audit and what resources and time have been dedicated to the effort.

A TSA may be triggered as a result of unacceptable or questionable QC and/or sample data. As well, a TSA may result from a routine scheduled audit conducted on a quarterly or annual basis. For example, a field TSA may serve as a detailed review and/or evaluation of the various components of the measurement and sample collection procedures being used by field staff. It may be necessary to assess all or only some of those components within the scope of the field activities (such as decontamination, meter and sampler calibration, field measurements, matrix sampling, Quality Control measures, documentation, sample custody, etc.).

Similarly, a laboratory TSA may be conducted as the complement to implementation and use of internal SOPs and Quality Management Plans, in order to assure good Quality Assurance management practices. This type of audit may be a systems, project or performance audit and could be conducted to determine compliance with associated QMP, and/or QAPPs. For example, a laboratory TSA may be triggered as a result of a control spike that has exceeded 3 standard deviations from the control mean. Accordingly, the QAO may conduct an inquiry into SOP compliance for method preparation, spiking procedures and/or instrument calibration. A report of the findings should be submitted for review to management and be summarized in an annual QA report (see Section C 3.2).

It is recommended that a TSA be conducted with routine frequency such as quarterly or annually by Quality Assurance personnel or persons knowledgeable in assessing Quality Assurance management practices (see Section C 1.3.2) that are independent of and lateral to the chain of authority responsible for laboratory management. It is conceivable that field or laboratory audits of selected systems be staggered throughout the year to accomplish a comprehensive program TSA. The use of standardized audit forms or checklists can help facilitate conducting a TSA.

If the state's FIFRA program conducts TSAs, then the nature and purpose of these audits should be described here. The schedule and reports resulting from this type of audit should be described later in Sections C1.3 and C2.2.

C. *Performance Evaluation (PE).* A PE is a type of audit in which the quantitative data generated by the measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory. "Blind" PE samples are those whose identity is unknown to those operating the measurement system. A "single blind" PE samples is one where the laboratory knows it is a PE sample, but is not aware of the concentrations. Usually, the type of analysis is known and the sample comes prepared or in a ampule to be made up. A "double blind" PE often provides more representative results since they are sent as if they are a normal sample. This approach ensures that they are handled routinely and are not given the special treatment that undisguised PEs sometimes receive. The QAPP should list the PEs that are planned, identifying:

- The constituents to be measured,
- the target concentration ranges,
- the timing/schedule for PE sample analysis, and
- the aspect of measurement quality to be assessed (e.g., bias, precision, and detection limit).

A number of EPA regulations and EPA-sanctioned methods require the successful accomplishment of PEs before the results of the test can be considered valid. PE materials are now available from commercial sources and a number of EPA Program Offices coordinate various interlaboratory studies and laboratory proficiency programs. Participation in these or in the National Voluntary Laboratory Accreditation Program (NVLAP, run by NIST) should be mentioned in the QAPP. For FIFRA activities other sources of PE samples include the EPA/RTI pesticide formulation and residue check samples; AAPCO pesticide formulation check samples; EPA performance check sample for pesticide residues in water; USDA check sample for chlorinated insecticides in fat; and USDA check sample for PCB in fat. The QAPP should also discuss how acceptance criteria were established and what corrective action will be taken in the event the PE is failed. If PE samples are prepared by the field team/inspectors it is critical that spiking procedures be documented and that the person preparing the sample be trained. Improperly spiked samples can result in erroneous conclusions concerning laboratory performance. PE samples may be a process internal to the laboratory, provided by the inspector or the organization submitting the environmental samples, or provided by an independent third party.

For example, an internal PE may be performed with the agreement between laboratory management and project management/field staff who are involved with the routine sampling of established monitoring programs. In this way, a field spike may be inserted into the sample set, without the knowledge of the laboratory staff, in order to evaluate the laboratory's performance with routine work. An evaluation of issues such as sample handling, custody, and overall method performance (chromatography and result accuracy) can be assessed once the results of the PE sample are completed and submitted for management review.

D. *Audit of Data Quality (ADQ).* An ADQ reveals how the data were handled, what judgments were made, and whether uncorrected mistakes were made. Performed prior to producing a program activity's final report, ADQs can often identify the means to correct systematic data reduction errors. These audits involve an extensive review of all the data used to generate the final result, including a review of instrument print-outs and other raw data. The process is comparable to a full data validation procedure except it is carried out at the laboratory site so that information not provided in the data package can be reviewed.

An ADQ may be conducted by the laboratory QAO or section manager prior to the submitting final results. A laboratory may include an ADQ as part of a normal quality review. In this way, the ADQ will provide an additional check for data completeness by reconstructing the sample history and/or custody, as well as a review of the analytical decisions and logic that were used to arrive at the final result. In doing so, an ADQ can provide confidence in the data generated for a specific sample or set of samples and insure the defensibility of data if litigation becomes necessary.

If the state's FIFRA Program conducts ADQs, then the nature and purpose of these audits should be described here. The schedule and reports resulting from this type of audit should be described later in Sections C1.3 and C2.2.

E. *Peer review.* Peer review is not a TSA, nor strictly an internal QA function, as it may encompass non-QA aspects of a program activity and is primarily designed for scientific review. Whether a planning team chooses ADQs or peer reviews depends upon the nature of the program activity, the intended use of the data, the policies established by the sponsor of the program activity, and overall the conformance to the state's peer review policies and procedures. Reviewers are chosen who have technical expertise comparable to the program activity's performers but who are independent of the program activity. ADQs and peer reviews ensure that program activities:

- were technically adequate,
- were competently performed,

- were properly documented,
- satisfied established technical requirements, and
- satisfied established QA requirements.

In addition, peer reviews assess the assumptions, calculations, extrapolations, alternative interpretations, methods, acceptance criteria, and conclusions documented in the program activity's report. Any plans for peer review should conform with the state's peer-review policy and guidance. The names, titles, and positions of the peer reviewers should be known to the QA Officer and can be provided in the QAPP if they are known. The QAPP should outline what is expected of peer reviews, how the information will be reported, to whom it will be reported, and how the information will be used. The QAPP should also discuss when peer review will be used, since many FIFRA activities, outside special projects may not lend themselves to a peer review process. The QAPP should discuss how responses will be documented, how responses will be handled, and reference where responses to peer-review comments may be located.

Peer review can also serve as a first level quality check of analytical data review or an ADQ. Used in this way, peer review is intended to provide a check of the analytical work performed in support of sample analyses. For example, a peer reviewer may be required to perform a check to ensure that instrument calibration is linear; methodology utilized is appropriate; QC data are within proper limits; and chromatographic integration is performed properly prior to submitting data for a more in-depth ADQ. Peer review may also utilize several of the tools available to reduce and validate analytical results and is intended for the more technical aspects of reviewing data quality such as measurement of bias, standard deviation, relative percent difference, etc.

F. *Data Quality Assessment (DQA).* DQA involves the application of statistical tools to determine whether the data meet the assumptions that the DQOs and data collection design were developed under and whether the total error in the data is tolerable. *Guidance for the Data Quality Assessment Process* (EPA QA/G-9) provides nonmandatory guidance for planning, implementing, and evaluating retrospective assessments of the quality of the results from environmental data operations. Aside from special projects, and possibly monitoring activities, it is not anticipated that many enforcement activities will generate sufficient information to permit statistical assessment to take place. This section should describe when such assessments may be appropriate.

## C1.3 Documentation of Assessments

Under the documentation of assessments, the QA/R-5 requires that programs, *"List and describe the assessments to be used in the project. Discuss the information expected and the success criteria (i.e., goals, performance objectives, acceptance criteria specifications, etc.) for*

*each assessment proposed. List the approximate schedule of activities, for any planned self-assessments (utilizing personnel from within the project groups), identify potential participants and their exact relationship within the project organization. For independent assessments, identify the organization and person(s) that shall perform the assessments if this information is available. Describe how and to whom the results of the assessments shall be reported."* The following material describes what should be documented in a QAPP after consideration of the above issues and types of assessments.

### C1.3.1 Number, Frequency, and Types of Assessments

Depending upon the nature of the program activity, there may be more than one assessment. A schedule of the number, frequencies, and types of assessments required should be given.

Systems audits may be conducted by trained field or laboratory management and/or quality assurance staff to complement implementation and use of internal SOPs and Quality Management Plans, in order to assure good Quality Assurance management practices. While annual audits of all field and laboratory operations is a minimum recommendation, it is conceivable that specific portions of these respective operations (field and lab) may be scheduled to occur with routine frequency in order to satisfy the recommendation for an overall annual program assessment. In this way, audits of selected systems may be staggered throughout the year to accomplish this goal and a final report containing the results of those specific systems audits can be submitted to management at the end of an annual cycle.

To this end, field and laboratory assessments may be performed through the use of a standardized protocol and/or list of minimum requirements which will describe the style and scope of an audit and provide a list of criteria by which operational deficiencies can be detected (see Section C1.3.3). These protocols and criteria should reflect the intent of all internal SOPs and Quality Management Plans and should, at a minimum, conform to all EPA and Department regulatory requirements for procedures and documentation. The use of standardized audit forms and checklists is recommended.

### C1.3.2 Assessment Personnel

In an effort to *"Define the scope of authority of the assessors..."*, QA/R-5 requires the program management to, *"Define explicitly the unsatisfactory conditions under which the assessors are authorized to act and provide an appropriate schedule for the assessments to be performed."* To this end, the QAPP should specify the individuals, or at least the specific organizational units, who will perform the assessments. Internal audits are usually performed by personnel who work for the organization performing the program activity's work, but who are organizationally independent of the management of the program activity. External audits are

performed by personnel of organizations not connected with the program activity but who are technically qualified and who understand the QA requirements of the program activity.

It is up to the program management to designate appropriate personnel as Quality Assurance staff and charge these officials with auditing responsibility and authority, preferably independently of and lateral to the chain of authority responsible for field and laboratory operations. It is also possible that key members within a chain of command be charged with Quality Assurance responsibility such that a sample can be tracked at different end points throughout the analytical system. By way of example, the Sample Custodian may be responsible for sample tracking, history and custody; peer reviewers and/or a Quality Assurance Officer may have the responsibility of assessing data accuracy and validity; and finally, management personnel would have the responsibility of performing a final ADQ.

However, depending on the size of a programs field and laboratory operations, it may not always be possible or feasible to dedicate staff to the QA process. In this case, individuals charged with the responsibility of Quality Assurance should be in a position of supervision and/or management and responsible for the outcome of program requirements. Lastly, it is recommended that all staff members be encouraged to adopt good Quality Assurance practices, at all levels of the organization and to perceive audits as an educational opportunity.

### C1.3.3 Schedule of Assessment Activities

A schedule of audit activities, together with relevant criteria for assessment, should be given to the extent that it is known in advance of program activities. The lists provided below may serve as a guideline for field operations and laboratories developing criteria to serve in assisting audit activities. These lists are not comprehensive of all audit activities but are only an example of the type of areas that an audit would be concerned with.

Minimum Topics for Internal Laboratory Audit.

1. GENERAL PROCEDURES
   A. Documentation of Procedures,
   B. Sample Receipt and Storage,
   C. Sample Preparation,
   D. Sample Tracking.

2. ANALYTICAL METHODS
   A. General Instrumentation Performance,
   B. Calibration Procedures,
   C. Extraction Procedures,
   D. Internal Quality Control,
   E. Data Handling Procedures.

The general topics represented above can be broken down further to include specific points or areas that will be covered when performing an audit in one of the above general areas. Using General Instrumentation Performance as an example of a laboratory audit, the following points may be included during an internal audit. Please note that this list may not be inclusive of specific points or areas that are necessary for a particular laboratory's internal audit.

2. ANALYTICAL METHODS
   A. General Instrumentation Performance.
      1. Instrument performance records are maintained and include the following items:
         a. Initial demonstration of capability,
         b. Determination of linear dynamic range,
         c. Method detection limits,
         d. Initial and routine instrument calibration,
         e. Performance on standard reference materials and/or QC check samples,
         f. Instrument sensitivity and stability, and
         g. Tuning checks.

Below is an example, similar to the laboratory internal audit list above, that may be utilized for a field audit. Again, this is not an inclusive list of assessment points and is provided here only to serve as an example.

Minimum Topics for Field Audit.

1. GENERAL FIELD PROCEDURES
   A. Field Standard Operating Procedures,
   B. Interviews,
   C. Investigations/Inspections, and
   D. Field Records.

Using procedures A and B as examples, the specific assessment points may include some of the following:

1. GENERAL FIELD PROCEDURES
   A. Field Standard Operating Procedures
      1. Site Assessment,
      2. Establishing Chain-of-Custody,
      3. Equipment Calibration,
      4. Decontamination Procedures,
      5. Well Development, and
      6. Sampling Records.
   B. Interviews
      1. Interview Records,

2. Questionnaires, and
3. Documentation of Site Characteristics.

### C1.3.4 Reporting and Resolution of Issues

Audits, peer reviews, and other assessments often reveal findings of practice or procedure that do not conform to the written QAPP. QA/R-5 indicates that those issues should, *"Discuss how response actions to non-conforming conditions shall be addressed and by whom."* Because these issues must be addressed in a timely manner, the protocol for resolving them should be given here together with the proposed actions to ensure that the corrective actions were performed effectively. The person to whom the concerns should be addressed, the decision making hierarchy, the schedule and format for oral and written reports, and the responsibility for corrective action should all be discussed in this element. The requirement also states the QAPP should, *"Identify who is responsible for implementing the response action and describe how response actions shall be verified and documented."* It also should explicitly define the unsatisfactory conditions upon which the assessors are authorized to act and list the program personnel who should receive assessment reports.

## C2 REPORTS TO MANAGEMENT

### C2.1 Purpose/Background

Effective communication between all personnel is an integral part of a quality system. Planned reports provide a structure for apprizing management of the program activity schedule, the deviations from approved QA and test plans, the impact of these deviations on data quality, and the potential uncertainties in decisions based on the data. Verbal communication on deviations from QA plans should be noted in summary form in element D1 of the QAPP.

Quality assurance reports are designed to keep management and/or project members informed of the performance of QA/QC activities. The reports should include all subjects which address the validity and documentation of data gathering activities. They summarize project specific audits, list significant problems, and discuss the solutions and corrective actions implemented concerning QA/QC activities.

### C2.2 Frequency, Content, and Distribution of Reports

The requirement for reporting assessment activities to management indicates that reports should, *"Identify the frequency and distribution of reports issued to inform management of the status of the project; results of performance evaluations and system audits; results of periodic data quality assessments; and significant quality assurance problems and recommended solutions."*

The QAPP should indicate the frequency, content, and distribution of the reports so that management may anticipate events and move to ameliorate potentially adverse results. An important benefit of the status report is the opportunity to alert the management of data quality problems, propose viable solutions, and procure additional resources. If program activity assessment (including the evaluation of the technical systems, the measurement of performance, and the assessment of data) is not conducted on a continual basis, the integrity of the data generated in the program activity may not meet quality requirements. These audit reports, submitted in a timely manner, will provide an opportunity to implement corrective actions when most appropriate.

A quality assurance report is generated by (field, technical and laboratory quality assurance personnel) and sent to the (Pesticide lead agency) management at least once a year. More frequent reports may also be required depending on the laboratory program. The laboratory quality assurance report is prepared by the (Laboratory Manager) with the assistance of the senior staff. The report is submitted to the (Division Administrator) in written or oral form, depending on the problems observed. Reports of this type may contain the following:

- Changes in Quality Assurance Project Plan;
- Summary of quality assurance/quality control programs, training and accomplishments;
- Results of technical systems and performance evaluation audits;
- Significant quality assurance/quality control problems, recommended solutions and results of corrective actions;
- Summary of data quality assessment for precision, accuracy, representatives, completeness, comparability and method detection limit;
- Discussion of whether the quality assurance objectives were met and the resulting impact on technical and enforcement areas;
- Limitations on use of the measurement data and discussion of the effects of such limitations on the defensibility of the data.

In addition, QA reports to management or a program leader may be required if any of the following issues occur:

- Sampling and support equipment other than that specified in the approved QAPP were used;
- Preservation or holding time requirements for any sample were not met;
- Any quality control checks (field and laboratory) were unacceptable;
- Any analytical requirements for precision, accuracy, or MDL/PQL were not met;
- Sample collection protocols or analytical methods specified in the QAPP were not met;
- Corrective action on any problems were initiated;
- An internal or external systems or performance audit was conducted; or
- Any other activity or event affected the quality of the data.

The following example contains a list of recommended topics that may be used to develop a comprehensive QA Report. The QA Reports may contain some or all of the information listed below, and may be formatted as in this example. Other information specific to program requirements or needs may also be included for the field and laboratory's reporting format.

1. Title Page - The following information must be listed:
   A. Time period of the report,
   B. QA Project Plan Title and/or Plan number,
   C. Laboratory name, address and phone number,
   D. Preparer's name and signature.
2. Table of Contents - Should be included if the report is more than ten pages long.
3. Audits - In table form, summarize all project specific audits that were performed during the specified time period:
   A. Performance audits must include the following:
      1. Date of the audit,
      2. System tested,
      3. Who administered the audit,
      4. Parameters analyzed,
      5. Reported results,
      6. True values of the samples (if applicable),
      7. If any deficiencies or failures occurred, summarize the problem area and the corrective action.
   B. Systems audits must include the following:
      1. Date of the audit,
      2. System tested,
      3. Who administered the audit (agency or department),
      4. Parameters analyzed,
      5. Results of tests,
      6. Parameters for which results were unacceptable (include the reported and true values, if applicable),
      7. Explanation of the unacceptable results. Include probable reasons and the corrective action.
   C. Copies of documentation such as memos, reports, etc. shall be enclosed.
4. Significant QA/QC Problems
   A. Identify the problem, and the date it was found,
   B. Identify the individual who reported the problem,
   C. Identify the source of the problem,
   D. Discuss the solution and corrective actions taken to eliminate the problem.
5. Corrective Actions Status
   A. Discuss the effectiveness of all corrective actions taken during the specified time frame as well any initiated during the previous report period,

B. Discuss any additional measures that may be implemented as the result of any corrective action.

## C2.3 Identify Responsible Organizations

It is important that the QAPP identify the personnel responsible for preparing the reports, evaluating their impact, and implementing follow-up actions. It is necessary to understand how any changes made in one area or procedure may affect another part of the program. Furthermore, the documentation for all changes should be maintained and included in the reports to management. At the end of a project, a report documenting the Data Quality Assessment findings to management should be prepared.

## GROUP D: DATA VALIDATION AND USABILITY

The requirement in QA/R-5 states: *"The elements in this group address the QA activities that occur after the data collection phase of the project is completed. Implementation of these elements determines whether or not the data conform to the specified criteria, thus satisfying the project objectives."*

| Table 5. Group D: Data Validation and Usability Elements | |
|---|---|
| D1 | Data Review, Verification, and Validation |
| D2 | Verification and Validation Methods |
| D3 | Reconciliation with User Requirements |

## D1 - DATA REVIEW, VALIDATION, AND VERIFICATION REQUIREMENTS

The requirement in QA/R-5 states: *"State the criteria used to review and validate–that is, accept, reject, or qualify–data, in an objective and consistent manner."*

### D1.1 - Purpose/Background

This section should discuss the criteria for deciding the degree to which data meet their quality specifications as described in Group B. Data generators, data users, and inspectors need to estimate the potential effect that each deviation from the FIFRA program QAPP, the laboratory's quality assurance plan (which would typically be included as an appendix to the program QAPP), or established SOPs or other documents may have on the usability of the associated data, its contribution to the quality of the reduced and analyzed data, and its potential effect on decisions to be made.

The process of data verification requires confirmation by examination or provision of objective evidence that the requirements of specified QC acceptance criteria were met. Verification concerns the process of examining the result of a given activity to determine conformance to the stated requirements for that activity. For example, have the data been generated according to specified methods (such as sampling SOPs or EPA Guidance manuals for collection and established methods and SOPs for analysis) and have the data been faithfully and accurately recorded and transmitted? Did the data fulfill specified data format requirements and include appropriate associated supporting information? For example, for

sampling this might include information gathered prior to the field work on pesticide use and application, inspector field reports detailing sampling conditions, descriptions of how the sample was collected, notebook information, etc. For the laboratory, this might include extraction sheets, analysis logs, calibration curve information, etc. The process of data verification effectively ensures all the information required for decision making has been generated and is readily available to the decision maker whether this is an inspector or management.

The process of data validation, as defined by EPA, requires confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use have been fulfilled. Validation concerns the process of examining a product or result to determine conformance to user needs. The validation process effectively confirms the degree to which the QC acceptance criteria or specific performance criteria have been met. The EPA data validation process typically focuses on the analytical aspects of data generation and involves a third party review of all raw data associated with the generation of the final results. It typically examines whether all aspects of the method were followed correctly, QC data were met, holding times met, calibration standards made up properly, calibration curves were acceptable, etc. The result is a qualification of the data in terms of its perceived usability, from acceptable to qualitatively acceptable but quantitatively not reliable, to rejected. Various "flags" are typically used to qualify the data. Most state or tribal FIFRA programs do not validate data per the EPA definition, nor is there a requirement to do so. However, if data are validated by a state, or if a different definition of validation is used by the state, its program QAPP should describe what is done.

Each of the following areas of discussion should be included in the FIFRA program QAPP as appropriate. The discussion applies to situations in which a sample is separated from its native environment and transported to a laboratory for analysis and data generation. In general, it is expected that for most situations involving routine enforcement activities such as use/misuse investigations, formulation checks, and groundwater monitoring data validation procedures will not need to be described in the state's QAPP, however, assessment activities, as described below should be addressed. For special projects, the QAPP should describe what the process to be followed would normally be. If not relevant to the state's QAPP, the sections can be omitted, or, preferably, a brief statement made indicating that the section does not apply to the activities covered by the QAPP. In some cases, a detailed review of the areas below may only occur on a subset of the investigations conducted or samples collected. If so, the QAPP should describe how these investigations are selected, the person conducting the review, and the review process itself.

### D1.2 - Sampling Design

How closely a measurement represents the actual environment at a given time and location is a complex issue that is discussed in Section B1. Acceptable tolerances for each critical sample coordinate and the action to be taken if the tolerances are exceeded should be specified in Section B1 and vary considerably depending on the type of sample collection activity: use/misuse, formulations, groundwater monitoring, or special project.

Each sample should be checked for conformity to any specifications which were defined, including type and location (spatial and temporal). By noting the deviations in sufficient detail, subsequent data users will be able to determine the data's usability under scenarios different from those for which the original data were generated. The strength of conclusions that can be drawn from data has a direct connection to the sampling intent and deviations from that intent. Where auxiliary variables are included in the overall data collection effort (for example, misuse information which is then to be linked to a pesticide's application), they should be included in this evaluation. This section of the QAPP should describe the process by which sample validity is checked.

### D1.3 - Sample Collection Procedures

Details of how a sample is separated from its native time/space location are important for properly interpreting measurement results. Section B2, or related appendices, provides these details, which include sampling and ancillary equipment and procedures (including equipment decontamination). Acceptable departures (for example, alternate equipment) from the QAPP/SOPs, and the action to be taken if the requirements cannot be satisfied, should be specified for each critical aspect, and the QAPP should describe how it will be confirmed that these activities occurred correctly. Review procedures should be in place to identify potentially unacceptable departures from the QAPP, departures for sampling protocols not contained as appendices in the QAPP, or SOPs not included in the QAPP. Comments from field surveillance on deviations from written sampling plans also should be noted.

### D1.4 - Sample Handling

Details of how a sample is physically treated and handled during relocation from its original site to the actual measurement site are extremely important. Correct interpretation of the subsequent measurement results requires that deviations from Section B3 of the QAPP and the actions taken to minimize or control the changes, be detailed. Data collection activities should indicate events that occur during sample handling that may affect the integrity of the samples. This section of the QAPP should describe how QA or other personnel confirm that activities took place according to required protocols.

At a minimum the QAPP should describe how inspectors, management, or QA personnel evaluate that the sample containers and preservation methods used were appropriate to the

nature of the sample and the type of data generated from the sample. The checks to be made on the identity of the sample (e.g., proper labeling and chain-of-custody records) as well as proper physical/chemical storage conditions (e.g., chain-of-custody and storage records) to ensure that the sample continues to be representative of its native environment as it moves through the sample handling process should be described.

### D1.5 - Analytical Procedures

Each sample should be verified to ensure that the procedures used to generate the data (as identified in Section B4 of the QAPP or in associated appendices) were implemented as specified. Acceptance criteria should be developed for important components of the procedures, along with suitable codes for characterizing each sample's deviation from the procedure. One way to accomplish this evaluation is through data validation, but, as previously indicated, it is not required that EPA defined data validation necessarily be a part of a state's FIFRA program.

### D1.6 - Quality Control

Section B5 of the program QAPP specifies the QC checks that are to be performed during sample collection, handling, and analysis. These might include analyses of check standards, field and method blanks, method and laboratory (blank) spikes, and field and laboratory replicates, etc. These indicators provide the means to assess the quality of data being produced by specified components of the measurement process. For each specified QC check, the procedure, acceptance criteria, and corrective action (and changes) should have been specified earlier (such as in the laboratory's quality assurance plan or SOPs or in Section B5. This section should describe how it was assessed that the appropriate corrective actions were taken, that the affected samples were appropriately identified, if necessary, and that the potential effect of the actions on the validity of the data were documented.

### D1.7 - Calibration

Section B7 addresses the calibration of instruments and equipment and the information that should be presented to ensure that the calibrations:

- were performed within an acceptable time prior to generation of measurement data;
- were performed in the proper sequence;
- included the proper number of calibration points;

- were performed using standards that "bracketed" the range of reported measurement results (otherwise, results falling outside the calibration range are flagged as such); and

- had acceptable linearity checks and other checks to ensure that the measurement system was stable when the calibration was performed.

This section should discuss the process to check that calibration problems were identified and that any data produced between the suspect calibration event and any subsequent recalibration were flagged to alert data users.

### D1.8 - Data Reduction and Processing

Checks on data integrity evaluate the accuracy of "raw" data and include the comparison of important events and the duplicate rekeying of data to identify data entry errors.

Data reduction is an irreversible process that involves a loss of detail in the data and may involve averaging across time (for example, groundwater data collected at monthly intervals which are averaged) or space (for example, compositing results from samples thought to be physically equivalent such as multiple leaves collected in a misuse investigation). Since this summarizing process by its nature relies on a few values to represent a group of many data points, how its validity will be assessed should be well-documented in the QAPP.

The information generation step may also involve the synthesis of the results of previous operations and the construction of tables and charts suitable for use in reports or databases. How this information would be checked to ensure that it is of known quality appropriate for its intended use should also be addressed in this section. The steps taken to ensure that the information is synthesized and incorporated accurately (for example, data entry issues, compatibility of electronic files or software programs, sensitivity issues (i.e., different methods were used and detection limits are not the same), comparability of methods and units, etc., are some of the issues it would be relevant to address.

## D2 - VALIDATION AND VERIFICATION METHODS

The requirement in R-5 states: *"Describe the process to be used for verifying and validating data, including the chain-of-custody for the data throughout the life of the project or task."*

### D2.1 - Purpose/Background

The purpose of this section is to describe, in detail, the process for validating (determining if data satisfy program defined user requirements as defined earlier in the QAPP) and verifying (ensuring that conclusions can be correctly drawn) program or special project data. The

amount of data validated is directly related to the program data objectives developed for the data generating activity as well as each state's perception of the need for validation. The percentage of data to be validated for the program or specific project together with its rationale should be outlined or referenced. The QAPP should have a clear definition of what is implied by "verification" and "validation" since each state's definition may vary.

### D2.2 - Describe the Process for Validating and Verifying Data

If the state or tribe does validate data, the individuals responsible for data validation together with the lines of authority should be shown on an organizational chart and may be indicated in the chart in Section A7. The chart should indicate who is responsible for each activity of the overall validation and verification processes. In some states, this responsibility may be split up depending on the nature of the measurement activity and data generation responsibilities.

It is recommended that whatever data validation procedure is followed by the state or tribe be documented in SOPs for specific data validation. EPA's guidance for verification and validation issues will be described in *Guidance on Environmental Verification and Validation*, (EPA QA/G-8) which is currently under preparation. The EPA's Contract Laboratory Program (CLP) (used by EPA for analyses under Superfund) also has a document *Functional Guidelines for the Validation of Organic Analyses,"* which can also be consulted, but its applicability may be limited since it only covers data generated using CLP protocols. The only pesticides currently included are the organochlorine pesticides. This document, however, does provide protocols which can be adapted to other analyses.

## D3 - RECONCILIATION WITH USER REQUIREMENTS

The requirement in QA/R-5 states: *"Describe how the results obtained from the project or task will be reconciled with the requirements defined by the data user or decision maker."*

### D3.1 - Purpose/Background

The purpose of Section D3 is to outline and specify, if possible, the acceptable methods for evaluating the results obtained from the sampling and analysis effort. This section includes scientific and, if appropriate, statistical evaluations of data to determine if the data are of the right type, quantity, and quality to support their intended use.

### D3.2 - Reconciling Results with DQOs

Because, as discussed earlier in Section A, DQOs will typically be defined by each individual state and often involve presence/absence tests, a formal reconciliation with DQOs process

may not be necessary for most FIFRA program QAPPs. The DQA process is potentially more useful for cases where formal DQOs have been established, such as for special projects, or possibly for groundwater monitoring. Use of EPA's *Guidance for Data Quality Assessment* (EPA QA/G-9) document should be considered, although its statistical tests may not exactly fit many projects. It focuses on evaluating data for fitness in decision making and also provides many graphical and statistical tools. For other enforcement situations, such as from use/misuse investigations and formulation investigations, a formal reconciliation with DQOs is probably not justified, since violative evidence usually leads to regulatory or legal action and the data must be defensible to support these actions.

Ideally, a DQA is a key part of the assessment phase of the data life cycle from planning through data collection to final use of the data. Normally a DQA assessment is a step that occurs after an activity was over to determine whether objectives were realistic and whether the data were appropriate and usable. The assessment phase follows data validation and verification and determines how well the validated data supported their intended use. In a way, it is a "lessons learned" phase that examines whether the whole activity was planned and carried out properly and also whether the data were appropriate. Sometimes an activity can be brilliantly carried out only to discover that the information collected was not what was needed. If an approach other than DQA has been selected, an outline of the proposed activities could be included, describing how the data will be evaluated to ensure they are satisfactory for their intended use. For the purposes of a state's FIFRA program QAPP, this section should describe when a DQA process might occur, and how it would be conducted. If most measurements are routine, this should section should indicate this and indicate that since a formal DQO process is not used, this section does not apply.

## QAPP REVISIONS

During the course of a program's evolution, it is expected that changes may occur in FIFRA requirements, how the program is organized, the way environmental data are collected, how enforcement activities are defined, etc. Thus, it is recognized that this FIFRA program QAPP is and should be a dynamic document, subject to revision as needed. EPA recommends that the document be examined and revised internally once a year by the state or tribe and that it be submitted to EPA at least once every five years for approval (this time period should be worked out by the state and its EPA Regional QA Manager and EPA Project Manager). The state should keep its document current and keep its EPA Project Officer informed of significant changes so that he/she can decide whether a more formal evaluation of the changes involving EPA review is necessary. During the five year review, the QAPP will be evaluated by the EPA QA Manager and EPA Project Officer to determine if the document still meets current EPA QA and FIFRA program requirements or needs to be updated. If so, the QAPP should be revised and reapproved, and a revised copy should be sent to everyone on the distribution list.

# Appendix A

## Acronyms Related to Quality Assurance/Pesticide Programs

| | |
|---|---|
| **ADQ** | Audit of Data Quality |
| **AOAC** | Association of Official Analytical Chemists |
| **APPCO** | American Association of Pesticide Control Officials |
| **CFR** | Code of Federal Regulations |
| **CWA** | Clean Water Act |
| **DQA** | Data Quality Assessment |
| **DQI** | Data Quality Indicators |
| **DQO** | Data Quality Objectives |
| **EPA** | Environmental Protection Agency |
| **FIFRA** | Federal Insecticide, Fungicide and Rodenticide Act |
| **FQPA** | Food Quality Protection Act |
| **GPS** | Global Positioning System |
| **ISO** | International Standards Organization |
| **MCL** | Maximum Contaminant Level |
| **MDL** | Method Detection Limit |
| **MSR** | Management Systems Review |
| **NEIC** | National Enforcement Investigations Center |
| **NIST** | National Institute of Standards and Technology |

| | |
|---|---|
| **NVLAP** | National Voluntary Laboratory Accreditation Program |
| **OECA** | Office of Enforcement and Compliance Assurance (US EPA) |
| **OSHA** | Occupational Safety and Health Administration |
| **OPP** | Office of Pesticide Programs (US EPA) |
| **PBMS** | Performance-Based Measurement System |
| **PCB** | Polychlorinated Biphenyl |
| **PE** | Performance Evaluation |
| **PQL** | Practical Quantitation Limit |
| **PREP** | Pesticide Regulatory Education Program |
| **QA** | Quality Assurance |
| **QA/G-4** | Guidance for the Data Quality Objectives Process |
| **QAO** | Quality Assurance Officer |
| **QA/QC** | Quality Assurance/Quality Control |
| **QAPP** | Quality Assurance Project Plan |
| **QA/R-5** | Requirements for QA Project Plans for Environmental Data Operations |
| **QA/G-5** | Guidance for Quality Assurance Project Plans |
| **QA/G-9** | Guidance for the Data Quality Assessment Process |
| **QC** | Quality Control |
| **QMP** | Quality Management Plan |
| **RQAM** | Regional Quality Assurance Manager (for EPA Regional Offices) |

| | |
|---|---|
| **RTI** | Research Triangle Institute |
| **SDWA** | Safe Drinking Water Act |
| **SLA** | State Lead Agency |
| **SOP** | Standard Operating Procedure |
| **TMDL** | Total Maximum Daily Load |
| **TSA** | Technical Systems Audit |
| **USDA** | United States Department of Agriculture |
| **WPS** | Worker Protection Standard (EPA regulations at 40 CFR part 170) |

# Appendix B

## Terms Associated with Pesticide Regulatory Programs

**Active ingredient** - The term "active ingredient" means-

(1) in the case of a pesticide other than a plant regulator, defoliant, desiccant or nitrogen stabilizer, an ingredient which will prevent, destroy, repel or mitigate any pest;

(2) in the case of a plant regulator an ingredient which, through the physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof;

(3) in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant;

(4) in the case of a desiccant, an ingredient which will artificially accelerate the drying of plant tissue; and

(5) in the case of a nitrogen stabilizer, an ingredient which will prevent or hinder the process of nitrification, through action affecting soil bacteria.

**Adulterated** - The term "adulterated" applies to any pesticide if -

(1) its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold;

(2) any substance has been substituted wholly or in part for the pesticide; or

(3) any valuable constituent of the pesticide has been wholly or in part abstracted.

**Ambient monitoring** - monitoring to determine the parameters or levels of a constituent or contaminant in the environment generally or in a specific environmental medium (air, water, etc.).

**Aquifer** - A soil or rock formation which is capable of storing and transmitting a usable amount of ground water to the surface.

**Certified applicator**- Either a private or commercial applicator certified as competent in standards developed or approved by EPA, and thereby able to purchase and use restricted use pesticides (see definition of **restricted use pesticides).**

**Cooperative agreement** - a funding instrument used for the transfer of money, property, services or anything of value to the State or local government or other recipient to achieve a public purpose of support or stimulation authorized by Federal statute. With a cooperative agreement, substantial involvement is anticipated between EPA and the recipient. Much of the compliance and enforcement work carried out by State and Tribal Lead agencies is done so under a cooperative agreement with EPA.

**Deficiency** — An unauthorized deviation from acceptable procedures or practices, or a defect in an item.

**Defoliant** -Any substance or mixture of substances intended for causing the leaves or foliage to drop from a plant, with or without causing abscission.

**Desiccant** - Any substance or mixture of substances intended for artificially accelerating the drying of plant tissue.

**Device** - Any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.

**Distribute or Sell** - Under FIFRA, defined as the distribution or sale of a pesticide.

**Distribution** — 1) The apportionment of an environmental contaminant at a point over time, over an area, or within a volume; 2) a probability function (density function, mass function, or distribution function) used to describe a set of observations (statistical sample) or a population from which the observations are generated.

**Environmental samples** - Samples obtained under pesticide programs can cover a wide variety of media/objects, and can be any objects that may be exposed to a pesticide, such as: foliage, crops or food commodities, fish, bird or other wildlife carcasses, wipe samples from objects that may have been exposed to pesticide drift; air, water, soil or other environmental samples.

**Establishment** - Any place where a pesticide or device or active ingredient used in producing a pesticide is produced, or held, for distribution or sale.

**Establishment inspection** - Section 9(a) of FIFRA provides the authority for establishment inspections. Inspectors are authorized to enter an establishment where pesticides are being held for distribution or sale, for the purpose of obtaining samples of any pesticides or devices that are packaged, labeled and released for shipment.

**Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)** - An act to regulate the marketing of economic poisons and devices. Under FIFRA, pesticide products must be registered by the EPA before they are sold or distributed in commerce. EPA registers pesticides on the basis of data adequate to show that, when used according to label directions, they will not cause unreasonable adverse effects on human health or the environment.

**Financial assistance** — The process by which funds are provided by one organization (usually governmental) to another organization for the purpose of performing work or furnishing services or items. Financial assistance mechanisms include grants, cooperative agreements, and governmental interagency agreements.

**Fungicide** - an agent that destroys fungi or inhibits their growth. Except for fungicides intended for use on the human body, fungicides are regulated by FIFRA.

**General use pesticide** - a pesticide not classified by EPA as a Restricted Use product (see definition of Restricted Use) is considered to be a general use product and may be sold to and used by persons who are not certified applicators (see definition of Certified Applicator).

**Ground Water** - the water found below the surface of the earth which fills the pores, voids and fractures within soil and rock.

**Herbicide** -an agent used to destroy or inhibit plant growth. Herbicides are regulated under FIFRA.

**Impairment** - Any physical, chemical biological or radiological substance or matter which is introduced into or activated within an aquifer.

**Inert ingredient** - An ingredient which is not active, and does not perform the product's pesticidal function, for example, solvents, emulsifiers, adjuvants.

**Insecticide** - An agent that is intended to destroy insects. With the exception of insecticides intended for use on the human body, FIFRA regulates all other insecticides.

**Leach** - Move, seep, wash or drain by percolation.

**Misuse investigation** - The investigation of a pesticide use and the determination of whether the pesticide was used in a manner inconsistent with its label, and therefore in violation of FIFRA.

**Monitoring** - Data collected to study changes in environmental conditions at a site or in a specific medium over time, usually at fixed locations (monitoring stations, monitoring wells, effluent discharge points.)

Common objectives of monitoring are: to establish baseline environmental conditions, to detect variations in environmental conditions, to provide a summary of average or extreme conditions, to demonstrate compliance with environmental regulations, to assess the adequacy of controls on

contaminant releases, to detect the presence of contaminants, to determine the source(s) of specific contaminants, to assess the extent of contamination, the concentrations of contaminants and the rate and direction of contaminant movement, to detect long-term trends in contaminant distribution and to determine the effectiveness of remedial actions.

**Non-point source** - Contamination of a regional or areal extent resulting from largely undefined sources.

**Pest** - The term "pest" means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life, or virus, bacteria, or other micro-organism (except on or in living man or other living animals) which the Administrator declares to be a pest under FIFRA Section 25(c)(1).

**Pesticide** - (1)any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2)any substance or mixture or substances intended for use as a plant regulator, defoliant, or desiccant.

**Pesticide drift** - The physical movement of pesticide through the air at the time of pesticide application or soon thereafter from the target site to any non- or off-target site. Pesticide drift shall not include movement of pesticides to non-or off-target sites caused by erosion, migration, volatility, or windblown soil particles that occurs after application unless specifically addressed on the pesticide product label with respect to drift control requirements. Sampling resulting from a drift investigation can take the form of foliar samples, swab samples of objects such as cars, play structures or houses, and can also be designed so that samples are taken on a gradient. That is, from the place at which the drift is assumed to have occurred, samples are taken at various distances from that point, in order to determine the extent of the drift.

**Pesticide formulation** - The substance or mixture of substances comprising all active and inert (if any) ingredients of a pesticide product.

**Pesticide labeling** - The written, printed, or graphic matter on or attached to the pesticide or device or any of its containers or wrappers. The label is a legally enforceable document that prescribes how each pesticide must be used.

**Point source** - Point source means any discernible, confined and discrete conveyance, including but not limited to, any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, landfill leachate collection system, vessel or other floating craft from which pollutants are or may be discharged. The term does not include return flows from irrigated agriculture or agricultural storm water runoff.

**Primary enforcement responsibility** - States and Tribes that enter into pesticide enforcement cooperative agreements with EPA are considered to have "primacy", or the primary option for investigating and taking appropriate enforcement action against pesticide use violations.

**Principal Sampling Point** - Usually referred to as the first principal sampling point. Refers to the closest available point where a sample may be collected prior to any sort of treatment (water softener, purifier, etc.)if the sample cannot be collected directly from the source (usually a well). For example, a principal sampling point may be the closest spigot, faucet or pump connected to a well. The objective is to collect a sample that is representative of the source (such as an aquifer) and which minimizes changes (chemical, physical or biological)in the sample due to movement and/or storage through a delivery system from the well to the sampling point.

**Producer and Produce** - the term "producer" means the person who manufactures, prepares, compounds, propagates, or processes any pesticide or device or active ingredient used in producing a pesticide. The term "produce" means to manufacture, prepare, compound, propagate, or process any pesticide or device or active ingredient used in producing a pesticide.

**Registrant** - A person who has registered any pesticide pursuant to the provisions of FIFRA.

**Registration** - The requirement of any person to register with the EPA Administrator any pesticides that they distribute, sell, offer for sale, hold for sale, or ship or deliver for shipment in the U.S.

**Restricted use pesticide** - EPA may classify a pesticide for restricted use, if, when applied in accordance with its directions for use, it may generally cause unreasonable adverse effects to human health or the environment without additional regulatory restrictions. Restricted use pesticides can only be applied by a certified applicator or under the direct supervision of a certified applicator.

**State Lead Agency** - The State agency with lead responsibility for implementing the pesticide program in a state. It is also the agency designated as responsible for administering the State Plan for certification and training of commercial and private applicators of restricted use pesticides.

Indian Tribes may also enter into cooperative agreements with EPA and be granted authority for certification and training of applicators and/or for enforcement of FIFRA regulations on lands under their jurisdiction. Thus, statements about the responsibilities and roles of State Lead Agencies in pesticide-related guidance and policy documents, including this one, may generally be considered as applicable to Tribal entitities that have such cooperative agreements with the Agency.

# Appendix C

## Checklists Useful in Quality Assurance Review

This appendix contains three checklists:

C.1 Sample Handling, Preparation, and Analysis Checklist
C.2 QAPP Review Checklist
C.3 Chain-of-Custody Checklist

These three checklists were developed as tools for quality assurance (QA) managers to screen for completeness of documentation. This appendix was not intended to be used or adapted for auditing purposes. The items listed on the checklists are not ranked or identified to indicate which items are trivial and which are of major importance. When using these checklists, it is extremely important to ensure that a mechanism be established for assessing and addressing important comments or violations during the data assessment (e.g., Data Quality Assessment [DQA]) stage.

### C1. SAMPLE HANDLING, PREPARATION, AND ANALYSIS CHECKLIST

This checklist covers most of the appropriate elements performed during the analysis of environmental samples. Functions not appropriate for a specific analysis should be annotated.

Information on the collection and handling of samples should be completely documented to allow the details of sample collection and handling to be re-created. All information should be entered in ink at the time the information was generated in a permanently bound logbook. Errors should not be erased or crossed-out but corrected by putting a line through the erroneous information and by entering, initialing, and dating the correct information. Blank spaces should have an obliterating line drawn through to prevent addition of information. Each set of information should have an identifying printed name, signature, and initials.

Sample Handling

| | |
|---|---|
| C Field Logs | Documentation of events occurring during field sampling to identify individual field samples. |
| C Sample Labels | Links individual samples with the field log and the chain-of-custody record. |
| C Chain-of-Custody Records | Documentation of exchange and transportation of samples from the field to final analysis. |
| C Sample Receipt Log | Documentation of receipt of the laboratory or organization of the entire set of individual samples for analysis. |

Sample Preparation and Analysis

| | |
|---|---|
| C Sample Preparation Log | Documents the preparation of samples for a specific method. |
| C Sample Analysis Log | Records information on the analysis of analytical results. |

- Instrument Run Log — Records analyses of calibration standards, field samples, and quality control (QC) samples.

Chemical Standards

- Chemical Standard Receipt Log — Records receipt of analytical standards and chemicals.
- Standards/Reagent Preparation Log — Records of the preparation of internal standards, reagents, spiking solutions, surrogate solutions, and reference materials.

## C.1 SAMPLE HANDLING, REPORTING, AND ANALYSIS CHECKLIST

*Field Logs*

| ELEMENT | COMMENT |
|---|---|
| Project name/ID and location | |
| Sampling personnel | |
| Geological observations including map | |
| Atmospheric conditions | |
| Field measurements | |
| Sample dates, times, and locations | |
| Sample identifications present | |
| Sample matrix identified | |
| Sample descriptions (e.g., odors and colors) | |
| Number of samples taken per location | |
| Sampling method/equipment | |
| Description of any QC samples | |
| Any deviations from the sampling plan | |
| Difficulties in sampling or unusual circumstances | |

*Sample Labels*

| ELEMENT | COMMENT |
|---|---|
| Sample ID | |
| Date and time of collection | |
| Sampler's signature | |
| Characteristic or parameter investigated | |
| Preservative used | |

*Chain of Custody Records*

| ELEMENT | COMMENT |
|---|---|
| Project name/ID and location | |
| Sample custodian signatures verified and on file | |
| Date and time of each transfer | |
| Carrier ID number | |
| Integrity of shipping container and seals verified | |
| Standard Operating Procedures (SOPs) for receipt on file | |

| | |
|---|---|
| Samples stored in same area | |
| Holding time protocol verified | |
| SOPs for sample preservation on file | |
| Identification of proposed analytical method verified | |
| Proposed analytical method documentation verified | |
| QA Plan for proposed analytical method on file | |

## C.1 SAMPLE HANDLING, REPORTING, AND ANALYSIS CHECKLIST (CONTINUED)

*Sample Receipt Log*

| ELEMENT | COMMENT |
|---|---|
| Date and time of receipt | |
| Sample collection date | |
| Client sample ID | |
| Number of samples | |
| Sample matrices | |
| Requested analysis, including method number(s) | |
| Signature of the sample custodian or designee | |
| Sampling kit code (if applicable) | |
| Sampling condition | |
| Chain-of-custody violations and identities | |

SAMPLE PREPARATION AND ANALYSIS

*Sample Preparation Logs*

| ELEMENT | COMMENT |
|---|---|
| Parameter/analyte of investigation | |
| Method number | |
| Date and time of preparation | |
| Analyst's initials or signature | |
| Initial sample volume or weight | |
| Final sample volume | |
| Concentration and amount of spiking solutions used | |
| QC samples included with the sample batch | |
| ID for reagents, standards, and spiking solutions used | |

*Sample Analysis Logs*

| ELEMENT | COMMENT |
|---|---|
| Parameter analyte of investigation | |
| Method number/reference | |
| Date and time of analysis | |

| | |
|---|---|
| Analyst's initials or signature | |
| Laboratory sample ID | |
| Sample aliquot | |
| Dilution factors and final sample volumes (if applicable) | |
| Absorbance values, peak heights, or initial concentrations reading | |
| Final analyte concentration | |
| Calibration data (if applicable) | |
| Correlation coefficient (including parameters) | |
| Calculations of key quantities available | |
| Comments on interferences or unusual observations | |
| QC information, including percent recovery | |

## C.1 SAMPLE HANDLING, REPORTING, AND ANALYSIS CHECKLIST (CONTINUED)

*Instrument Run Logs*

| ELEMENT | COMMENT |
|---|---|
| Name/type of instrument | |
| Instrument manufacturer and model number | |
| Serial number | |
| Date received and date placed in service | |
| Instrument ID assigned by the laboratory (if used) | |
| Service contract information, including service representative details | |
| Description of each maintenance or repair activity performed | |
| Date and time when of each maintenance or repair activity | |
| Initials of maintenance or repair technicians | |

CHEMICAL STANDARDS

*Chemical/Standard Receipt Logs*

| ELEMENT | COMMENT |
|---|---|
| Laboratory control number | |
| Date of receipt | |
| Initials or signature of person receiving chemical | |
| Chemical name and catalog number | |
| Vendor name and log number | |
| Concentration or purity of standard | |
| Expiration date | |

*Standards/Reagent Preparation Log*

| ELEMENT | COMMENT |
|---|---|
| Date of preparation | |
| Initials of analyst preparing the standard solution or reagent | |
| Concentration or purity of standard or reagent | |

| | |
|---|---|
| Volume or weight of the stock solution or neat materials | |
| Final volume of the solution being prepared | |
| Laboratory ID/control number assigned to the new solution | |
| Name of standard reagent | |
| Standardization of reagents, titrants, etc. (if applicable) | |
| Expiration date | |

## C.2 QAPP REVIEW CHECKLIST

| ELEMENT | COMMENTS |
|---|---|
| A1. Title and Approval Sheet | |
| Title | |
| Organization's name | |
| Dated signature of project manager | |
| Dated signature of quality assurance officer | |
| Other signatures, as needed | |
| A2. Table of Contents | |
| A3. Distribution List | |
| A4. Project/Task Organization | |
| Identifies key individuals, with their responsibilities (data users, decision-makers, project QA manager, subcontractors, etc.) | |
| Organization chart shows lines of authority and reporting responsibilities | |
| A5. Problem Definition/Background | |
| Clearly states problem or decision to be resolved | |
| Provides historical and background information | |
| A6. Project/Task Description | |
| Lists measurements to be made | |
| Cites applicable technical, regulatory, or program-specific quality standards, criteria, or objectives | |
| Notes special personnel or equipment requirements | |
| Provides work schedule | |
| Notes required project and QA records/reports | |
| A7. Quality Objectives and Criteria for Measurement Data | |
| States project objectives and limits, both qualitatively and quantitatively | |
| States and characterizes measurement quality objectives as to applicable action levels or criteria | |
| A8. Special Training Requirements/Certification Listed | |
| States how provided, documented, and assured | |
| A9. Documentation and Records | |
| Lists information and records to be included in data report (e.g., raw data, field logs, results of QC checks, problems encountered) | |
| States requested lab turnaround time | |
| Gives retention time and location for records and reports | |
| B1. Sampling Process Design (Experimental Design)<br>States the following: | |
| Type and number of samples required | |
| Sampling design and rationale | |
| Sampling locations and frequency | |

## C.2 QAPP REVIEW CHECKLIST (CONTINUED)

| ELEMENT | COMMENTS |
|---|---|
| Sample matrices | |
| Classification of each measurement parameter as either critical or needed for information only | |
| Appropriate validation study information, for nonstandard situations | |
| B2. Sampling Methods Requirements | |
| Identifies sample collection procedures and methods | |
| Lists equipment needs | |
| Identifies support facilities | |
| Identifies individuals responsible for corrective action | |
| Describes process for preparation and decontamination of sampling equipment | |
| Describes selection and preparation of sample containers and sample volumes | |
| Describes preservation methods and maximum holding times | |
| B3. Sample Handling and Custody Requirements | |
| Notes sample handling requirements | |
| Notes chain-of-custody procedures, if required | |
| B4. Analytical Methods Requirements | |
| Identifies analytical methods to be followed (with all options) and required equipment | |
| Provides validation information for nonstandard methods | |
| Identifies individuals responsible for corrective action | |
| Specifies needed laboratory turnaround time | |
| B5. Quality Control Requirements | |
| Identifies QC procedures and frequency for each sampling, analysis, or measurement technique, as well as associated acceptance criteria and corrective action | |
| References procedures used to calculate QC statistics including precision and bias/accuracy | |
| B6. Instrument/Equipment Testing, Inspection, and Maintenance Requirements | |
| Identifies acceptance testing of sampling and measurement systems | |
| Describes equipment preventive and corrective maintenance | |
| Notes availability and location of spare parts | |
| B7. Instrument Calibration and Frequency | |
| Identifies equipment needing calibration and frequency for such calibration | |
| Notes required calibration standards and/or equipment | |
| Cites calibration records and manner traceable to equipment | |
| B8. Inspection/Acceptance Requirements for Supplies and Consumables | |
| States acceptance criteria for supplies and consumables | |
| Notes responsible individuals | |
| B9. Data Acquisition Requirements for Nondirect Measurements | |
| Identifies type of data needed from nonmeasurement sources (e.g., computer databases and literature files), along with acceptance criteria for their use | |

## C.2 QAPP REVIEW CHECKLIST (CONTINUED)

| ELEMENT | COMMENTS |
|---|---|
| Describes any limitations of such data | |
| Documents rationale for original collection of data and its relevance to this project | |
| B10. Data Management | |
| Describes standard record-keeping and data storage and retrieval requirements | |
| Checklists or standard forms attached to QAPP | |
| Describes data handling equipment and procedures used to process, compile, and analyze data (e.g., required computer hardware and software) | |
| Describes process for assuring that applicable Office of Information Resource Management requirements are satisfied | |
| C1. Assessments and Response Actions | |
| Lists required number, frequency and type of assessments, with approximate dates and names of responsible personnel (assessments include but are not limited to peer reviews, management systems reviews, technical systems audits, performance evaluations, and audits of data quality) | |
| Identifies individuals responsible for corrective actions | |
| C2. Reports to Management<br>Identifies frequency and distribution of reports for: | |
| Project status | |
| Results of performance evaluations and audits | |
| Results of periodic data quality assessments | |
| Any significant QA problems | |
| Preparers and recipients of reports | |
| D1. Data Review, Validation, and Verification | |
| States criteria for accepting, rejecting, or qualifying data | |
| Includes project-specific calculations or algorithms | |
| D2. Validation and Verification Methods | |
| Describes process for data validation and verification | |
| Identifies issue resolution procedure and responsible individuals | |
| Identifies method for conveying these results to data users | |
| D3. Reconciliation with User Requirements | |
| Describes process for reconciling project results with DQOs and reporting limitations on use of data | |

## C.3 CHAIN-OF-CUSTODY CHECKLIST

| Item | Y | N | Comment |
|---|---|---|---|
| 1. Is a sample custodian designated?<br>If yes, name of sample custodian. | | | |
| 2. Are the sample custodian's procedures and responsibilities documented?<br>If yes, where are these documented? | | | |
| 3. Are written Standard Operating Procedures (SOPs) developed for receipt of samples?<br>If yes, where are the SOPs documented (laboratory manual, written instructions, etc.)? | | | |
| 4. Is the receipt of chain-of-custody record(s) with samples being documented?<br>If yes, where is this documented? | | | |
| 5. Is the nonreceipt of chain-of-custody record(s) with samples being documented?<br>If yes, where is this documented? | | | |
| 6. Is the integrity of the shipping container(s) being documented (custody seal(s) intact, container locked, or sealed properly, etc.)?<br>If yes, where is security documented? | | | |
| 7. Is the lack of integrity of the shipping container(s) being documented (i.e., evidence of tampering, custody seals broken or damaged, locks unlocked or missing, etc.)?<br>If yes, where is nonsecurity documented? | | | |
| 8. Is agreement between chain-of-custody records and sample tags being verified and documented?<br>If yes, state source of verification and location of documentation. | | | |
| 9. Are sample tag numbers recorded by the sample custodian?<br>If yes, where are they recorded? | | | |
| 10. Are written SOPs developed for sample storage?<br>If yes, where are the SOPs documented (laboratory manual, written instructions, etc.)? | | | |
| 11. Are samples stored in a secure area?<br>If yes, where and how are they stored? | | | |
| 12. Is sample identification maintained?<br>If yes, how? | | | |
| 13. Is sample extract (or inorganics concentrate) identification maintained?<br>If yes, how? | | | |
| 14. Are samples that require preservation stored in such a way as to maintain their preservation?<br>If yes, how are the samples stored? | | | |

| Item | Y | N | Comment |
|---|---|---|---|
| 15. Based upon sample records examined to determine holding times, are sample holding time limitations being satisfied? Sample records used to determine holding times: | | | |
| 16. Are written SOPs developed for sampling handling and tracking? If yes, where are the SOPs documented (laboratory manual, written instructions, etc.)? | | | |
| 17. Do laboratory records indicate personnel receiving and transferring samples in the laboratory? If yes, what laboratory records document this? | | | |
| 18. Does each instrument used for sample analysis (GC, GC/MS, AA, etc.) have an instrument log? If no, which instruments do not? | | | |
| 19. Are analytical methods documented and available to the analysts? If yes, where are these documented? | | | |
| 20. Are QA procedures documented and available to the analysts? If yes, where are these documented? | | | |
| 21. Are written SOPs developed for compiling and maintaining sample document files? If yes, where are the SOPs documented (laboratory manual, written instructions, etc.)? | | | |
| 22. Are sample documents filed by case number? If no, how are documents filed? | | | |
| 23. Are sample document files inventoried? | | | |
| 24. Are documents in the case files consecutively numbered according to the file inventories? | | | |
| 25. Are documents in the case files stored in a secure area? If yes, where and how are they stored? | | | |
| 26. Has the laboratory received any confidential documents? | | | |
| 27. Are confidential documents segregated from other laboratory documents? If no, how are they filed? | | | |
| 28. Are confidential documents stored in a secure manner? If yes, where and how are they stored? | | | |
| 29. Was a debriefing held with laboratory personnel after the audit was completed? | | | |
| 30. Were any recommendations made to laboratory personnel during the debriefing? | | | |

## Appendix D

### Frequently Asked Questions and Answers Pertaining to QAPPs

**Q1:** What is a Quality Assurance Project Plan (QAPP)?

**A1:** A document which describes in detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. The QAPP components are divided into four classes: 1) Project Management, 2) Measurement/Data Acquisition, 3) Assessment/Oversight, and 4) Data Validation and Usability. Requirements and additional guidance for on QAPPs can be found in EPA QA/R-5 and EPA QA/G-5.

**Q2:** What is EPA's policy for QAPPs?

**A2:** EPA policy requires that all projects or program activities involving the generation, acquisition, and use of environmental data be planned and documented and have an Agency-approved QAPP prior to the start of data collection. Activities that solely involve training and education rather than data collection do not require QAPPs.

**Q3:** Our laboratory already has a Quality Assurance plan (or QAPP). Do we have to do a new one? .

**A3:** No. The Agency recognizes that laboratories generally have quality assurance documentation already, and there is no need to discard adequate documents. In addition to Standard Operating Procedures, sampling plans, compendia of methods, and the like, these documents may include overall QA plans that have been called QAPPs for some years. The Agency strongly believes, however, that it is of substantial benefit to a pesticide regulatory program that quality assurance procedures for field investigation and sampling should be integrated with laboratory QA procedures in a single Agency-approved QAPP. To the extent that laboratory procedures are already adequately documented in a QA plan (regardless of what it has been called in the past) this plan can be referenced or incorporated as an Appendix to the QAPP. It is not the intent of this guidance to ask that existing QA plans be discarded (assuming they adequately address specific QAPP requirements). Rather, this guidance recommends the use of the term "laboratory QA plan" to describe such existing documentation in order to avoid the impression that a laboratory needs to have a separate EPA-approved QAPP.

**Q4:** Must a QAPP be approved before work begins?

**A4:** Yes, the QAPP facilitates communication among clients, data users, project staff, management, and external reviewers. An approval process allows for effective implementation of the QAPP. It should be noted that on-going enforcement and compliance programs are usually covered by a previously approved QAPP, which do not expire on specific dates. Thus, a new or revised QAPP reflecting new EPA requirements or changes within a state's program can generally be prepared without interrupting program operations.

**Q5:** Where are the content requirements for QAPPs defined?

**A5:** In the document entitled "EPA Requirements for Quality Assurance Project Plans: EPA QA/R-5". See also "EPA Guidance for Quality Assurance Project Plans: EPA QA/G-5". These and other quality assurance policy and guidance documents are available from the EPA website: http://www.epa.gov/quality1/qa_docs.html

**Q6:** When must a QAPP be revised and should it be submitted for re-approval?

**A6:** During the course of any environmental data collection activity, changes may occur and revisions to the QAPP will have to be made. Any changes to the technical procedures should be evaluated by the EPA QA Officer and Project Officer to determine if they significantly affect the technical and quality objectives of the project. Similarly, substative changes in program management roles, organizational structure or responsibilities need to reflected in a revised QAPP. The QAPP should be revised and reapproved, and a revised copy should be sent to all the persons on the distribution list.

**Q7:** How does the QAPP fit into the EPA Quality System?

**A7:** The management tools used in the organizational level of the EPA Quality System include Quality Management Plans (QMPs) and Management Systems Reviews (MSRs). The technical tools used in the project or program level of the EPA Quality System include the Quality Assurance Project Plans (QAPPs), Data Quality Objectives Process (DQOs), Standard Operating Procedures (SOPs), Technical Assessments TSAs), and Data Quality Assessments (DQAs).

**Q8:** How does the QAPP relate to Data Quality Objectives (DQOs)?

**A8:** The QAPP discusses the systematic procedure for planning data collection activities, to ensure the right type, quality, and quantity of data are collected to satisfy the data user's needs. DQOs are the qualitative and quantitative statements that clarify the intended use of the data; define the type of data needed to support the decision; identify the conditions under which the data should be collected; and specify tolerable limits on the probability of making a decision error due to uncertainty in the data.

**Q9:** Who should be involved in the planning process that is documented in the QAPP?

**A9:** To the extent possible, include the principal data users. In FIFRA programs, this always includes the pesticide regulatory program staff and management who are the immediate customers for data collected. Others should include project managers, laboratory managers, QA officers, and all persons responsible for the implementation of the QAPP. Also included should be the person responsible for maintaining the QAPP itself and any individual approving deliverables other than the project manager.

## Appendix E

### Response to Comments Received on Draft of this Guidance

On September 15, 2000, a draft of the present guidance document was made available for comment. Copies were sent to all 10 EPA Regional Offices, along with a request to forward copies to State and Tribal pesticide program managers and laboratory directors. Copies were also sent to the board of directors of the Association of American Pesticide Control Officials (AAPCO), and the coordinator of the Tribal Pesticide Program Council. Comments were collected up to November 3. Four sets of comments were received from EPA Regional Offices, some of them reflecting comments from EPA Regional Quality Assurance staffs, and some of them compiling comments from State program and laboratory officials. Editorial comments that corrected errors, asked for minor clarifications or up-dated references have been incorporated. The workgroup appreciates the efforts of those who read this document closely and made these useful editorial comments.

This appendix provides the workgroup's response to some comments which raised general issues or made suggestions on what to include or how to present material in a QAPP. These responses supplement the Frequently Asked Questions (FAQs) in Appendix D. The description of each issue represents the workgroup's summary of that issue, not necessarily a direct quote of comments received, because similar or overlapping issues were presented in different sets of comments.

In general, commenters indicated that the draft guidance was useful and appropriate in its present format and the workgroup believes that rather than attempt detailed revisions to the document in order to capture all the concerns raised in comments, these responses will be sufficient to clarify the issues brought to our attention.

**1. Issue/concern:** Several commenters asked that the guidance specify criteria or minimum requirements for a QAPP that state and EPA quality assurances manager could approve. One commenter suggested that a generic model QAPP should be provided.

**Response:** The workgroup understands the appeal for having clear criteria for an approvable QAPP, but believes that the request can not be met without creating more problems than the attempt would solve. The workgroup gave substantial consideration to the value of attempting a model, or generic QAPP, and concluded that it would not be the most beneficial form of guidance for our customers. State and tribal pesticide programs differ from each other in scope of responsibilities and available resources to such a degree that any attempt to establish a "model plan", or a specific, even though minimal, list of requirements, would inevitably be perceived as overly prescriptive and inappropriate for some of the delegated programs. However, a state or tribal agency may very well benefit from looking at already-developed QAPPs produced by others, and should feel free to ask for such potential models or examples from their colleagues.

The essence of the Agency's requirements for quality system documentation is to achieve the goal that grant recipients carrying out pesticide program responsibilities on EPA's behalf take reasonable steps to ensure that data collected are of known and adequate quality for the purposes

of the program. An acceptable QAPP should be an accurate fit between the real activities and capabilities of a particular program, and the Agency's need for effective quality assurance from its grant recipients. This requires judgement and flexibility on the part of both the state and tribal agencies which develop QAPPs to acknowledge what their individual programs actually do and how they do it, and equal flexibility from the EPA quality assurance managers who review them to recognize what individual pesticide programs can and need to do to carry out their commitments on EPA's behalf. As a practical matter, the components of a QAPP, as set forth in the Agency-wide document QA/R-5, and reflected in the present document, is a listing of the topics the Agency believes should be covered in some way in an acceptable QAPP, with the understanding that for some programs, accounting for a program component in the QAPP may mean explaining why it does not apply.

**2. Issue/concern:** Several comments raised the general issue of how prescriptive the Agency intends to be about the format and content of QAPPs. The introduction states that this guidance "is emphatically not intended to be a literal model..." and that QAPPs "will have to be adapted to describe the actual organizational structure, responsibilities and resources of the agency developing a QAPP...". However, other language appeared to some commenters to be more prescriptive about developing one integrated QAPP to cover all field and laboratory activities, and to require following the exact format used in this draft.

**Response:** As some comments correctly noted, EPA's own Quality Order refers to the requirement for "Approved Quality Assurance Project Plans (QAPPs), or equivalent documents defined by the QMP, for all applicable projects and tasks involving environmental data with review and concurrence having been made by the EPA QAM (or authorized representative defined in the QMP)" [emphasis added]. All of the discussion in the Quality Order is about ensuring that data collection is adequate to its intended purposes, and not about required formats for documenting procedures.

The text of the guidance has been modified in several places to clarify that the agency preparing a QAPP has considerable latitude in the documentation procedure. Having said that flexibility is allowable, it should also be noted that consistency has its benefits. For example, the Agency's Quality Assurance Managers who will review QAPPs will be most familiar with the format used in Agency-wide documents such as QA/R-5 or QA/G-5, which are also the basis for the present document, so using this format will generally facilitate review. Nevertheless, the overriding consideration has to be that the QAPP offers a suitable and accurate description of the programs/activities it documents.

The workgroup continues to believe that integrating the quality assurance aspects of field and laboratory activities in a single document is a benefit to the pesticide regulatory program as a whole, and this approach is generally recommended. However, commenters are correct that a state or tribal program should have the option of developing a separate QAPP for a specific pesticide program activity if that seems appropriate and useful. Groundwater monitoring for pesticides was cited as one likely example of a program area that might warrant a separate QAPP. A state/tribal program should consult with the Regional Quality Assurance Manager about the utility of such an approach, particularly if it proposes to separate field and laboratory activities.

**3. Issue/concern**: The guidance seems to direct that the QAPP be "comprehensive" in the sense of literally attaching relevant supporting documents, such as SOPs, sampling plans, etc., which can be voluminous. Commenters felt this is not practical.

**Response:** The workgroup agrees that complete documentation cannot accompany every copy of a QAPP, and may be referenced rather than attached. The important thing is that such supporting documents are available in known locations to those who need them to conduct their work, and to QAPP reviewers. It is recommended that at least one complete set of all the documentation supporting the FIFRA program be available in a central location.

**4. Issue/concern:** Several commenters noted that the discussion of quality objectives (section A-7) seemed to overlook the fact that regulatory levels which could be used in defining data quality objectives rarely exist for pesticides, and that most of their work is not conducted to enforce regulatory standards, but are essentially forensic investigations. The workgroup agrees that this is the case, and that the agency developing the QAPP needs to be very specific about the kind of forensic sampling and investigations it conducts, and candid about the limitations that poses for determining data quality objectives. The text of the draft guidance has been modified in several places to reflect this concern.

**5. Issue/concern:** The draft guidance refers to classifying measurements as critical or non-critical (section B1.6, several sub-paragraphs). This is not part of the latest Agency version of QA/R-5.

**Response:** The commenter is correct, but the distinction may be important to some programs. The agency developing the QAPP should determine if making such a determination is important to their procedures, and discuss it as appropriate. The text has been modified to reflect this concern.

**6. Issue/concern:** Several commenters raised questions about how the QAPP should reflect QA documentation for contractors. One commenter noted that all of their laboratory work was done on a contract.

**Response:** Contractors for EPA grant recipients are clearly required to meet QA documentation requirements; the question is how to do that efficiently. This guidance assumes that a contractor's quality assurance plan can be referenced and/or attached just like any other supporting document. As noted in the text of the guidance, the work done by contractors is described in the QAPP. The contractor's QA documentation must be available for review as part of the QAPP approval process.

**7. Miscellaneous suggestions:** Commenters made various suggestions about the appropriate contents and level of detail to include in QAPPs. For example:

– one commenter suggested that in providing examples of forms, filled-in examples or directions for completing the form are more useful to reviewers than blank forms.

– several commenters wanted more detailed discussion of how and why pesticide programs collect and analyze pesticide product formulations.

– some comments requested additional guidance on subjects such as preservation of samples collected for enforcement cases and performance criteria for monitoring and enforcement activities.

The workgroup believes that these and other requests for both simplification and amplification of the QAPP are reasonable, but are really situations in which the agency developing the QAPP needs to choose an approach that seems appropriate to its own needs, and reach agreement on it with their Regional Quality Assurance Manager. Requests for additional guidance are also reasonable, but beyond the scope of what this workgroup can provide in a general guidance document. The requests will be passed on to the Office of Enforcement and Compliance Assurance for its consideration. Some changes have been made to the text to discuss preservation of samples.

## Appendix F

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## Appendix G

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