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Technical Papers

Quality Systems Implementation

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TECHNICAL SESSION:
Quality Systems Implementation (I)

Stages of Quality System Implementation Driven by Management Questions

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For the last three years, we have been developing and discussing a metric to evaluate and characterize quality systems. Individuals involved in quality know that quality programs take time to develop and implement. Metrics can be used to categorize quality systems in terms of developmental stages. A metric was developed and presented at EPA's 23rd Annual Conference on Managing Environmental Quality Systems, where each stage has specific characteristics that define progress to a successful comprehensive quality system (Stage 4). The following year, as the metric was enhanced and presented to various managers, they responded positively yet asked, "What questions do we ask to move ahead?"

Thus, at the 24th Annual Conference we presented key management questions, specific for each stage, that allowed managers to assess their quality scorecard. As the questions were shared it became apparent that very few programs could begin to answer these questions.

As a continuation of these ideas, we will present an evaluation of the US EPA's Great Lakes National Program Office using the series of stage specific management questions piloted in the form of a Quality Annual Report.

Painful Stages in the Implementation of Quality Systems & Graded Approach for Assessing Quality Systems for State, Tribal and Local Agencies

Amberina Khan, Quality Staff, U.S. EPA Region 5

The presenters will address the rocky road to the implementation of Quality Management Plans and practical means to alleviate roadblocks for implementing the system. The workshop will be a presentation of different stages in the Implementation and will be applicable to organizations of various sizes. Graded approach will be discussed at different levels o f the organization. The speakers have had hands-on experience in assessing and implementing quality systems. Attendees will have a better understanding of common implementation issues but ideas which they might be able to utilize in their own quality system.

TECHNICAL SESSION:
Quality System Implementation (II)

Financing Quality Systems During Multiple Stages (1-4) of Implementation

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Over the last three years, we have discussed how organizations change as Quality Systems are implemented. We presented four stages of development from a Stage 1 organization that is just beginning with little awareness of quality value added and rampant denial, to a Stage 4 organization where quality is implemented at all levels and is recognized in a true value added way and as a common cost of conducting business.

While sharing this approach with various organizations and conducting Quality System audits, a common roadblock seems to be a lack of a critical amount of funding to develop a skeletal Quality infrastructure that provides a full time leader and a mechanism for an inventory of organizational investments relative to quality. Once this minimum baseline is reached in either a Stage 1 or 2 quality system other factors then govern success.

This presentation will discuss various options and suggestions for funding quality both at the organizational level and the project level. Funding concerns will also be presented relative to the four stages of quality system development. The outcome of this talk should allow quality professionals to be able to distinguish between "lack of funding" used as a facade versus a real impediment to quality improvement.

QA Plans for Tribal Pesticide Enforcement Programs: A Novel Approach

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Under the Federal Insecticide Fungicide & Rodenticide Act (FIFRA), enforcement activities often require that pesticide inspectors collect samples, either to ensure that pesticides in the marketplace are labeled and distributed per registration requirements or to evaluate possible situations involving use or misuse of these chemicals. Before they can take these types of measurements, the inspectors must submit an approved Quality Assurance Project Plan. Region 9 Quality Assurance and Pesticide Offices developed a template specific to tribal pesticide enforcement activities. In November 2005 tribal pesticide inspectors attended a two-day workshop where they were able to fill in the template on personal computers, using the guidance and following the trainers' instructions. We expect that the Region will use this model in developing other specialized QA trainings.

Introduction

Tribes in Region 9 with tribal grants under the Federal Insecticide Fungicide Rodenticide Act (FIFRA) who are performing enforcement activities have had difficulties preparing EPA mandated Quality Assurance (QA) Project Plans (QAPPs). This has been due to a number of factors. First, the general Agency QAPP guidance, "Guidance for the Preparation of Quality Assurance Project Plans," is not generally relevant to the types of activities conducted under a pesticide enforcement program, which often involve samples of opportunity; the guidance is more suitable for a conventional sampling and analysis project. Second, training in QA requirements and documentation at inspector training is typically limited or non-existent. Third, because regional tribal pesticide programs have had a primary focus on education and less focus on enforcement and environmental measurements in their early history, there has not been a need to prepare QAPPs.

Typical activities under FIFRA involve several components. These include investigations of pesticide use and misuse, collection of marketplace samples to check on adherence to labeling requirements, worker health and safety investigations, groundwater monitoring for pesticides, and special projects. Special projects typically involve research on alternative treatment methods such as integrated pest management (IPM), conservation tillage, side by side comparisons of different pesticides, or investigations of different pesticide application methods. Of these five areas, only the first three; use/misuse, marketplace, and worker health and safety typically result in enforcement activities under FIFRA.

Two guidance documents prepared and published by the Office of Enforcement and Compliance Assistance (OECA) and the Office of Pesticide Programs (OPP) were prepared to address the problem of the lack of pesticide program specific QA guidance. These were: "Guidance for Quality Assurance Project Plan Development for EPA Funded Cooperative Agreements with State and Tribal Agencies for the Conduct of FIFRA Pesticide Programs," (OECA Document Control Number EC-G-2000-067, December 15, 2000), and "Guidance for Quality Management Plan Development for EPA Funded Environmental Cooperative Agreements with State and Tribal Agencies," (OECA Document Control Number EC-G-1999-024, June 30, 1999). This paper will not address the Quality Management Plan (QMP) issue, but will instead focus on the QAPP aspects of the program. The

FIFRA QAPP guidance is available on the Region 9 QA website at: http://www.epa.gov/region9/qa/pdfs/finalqaappver9.pdf.

The OECA QAPP guidance is comprehensive and follows the G-5 format, discussing each of the five program areas described above with respect to each G-5 section. However, it places no special emphasis on enforcement. Although it could be used by a tribal organization, the smaller, often one to three person program of tribes, the lack of familiarity with QA systems, and the lack of direct simple guidance for enforcement programs has limited the guidance's use at the tribal level, and indeed, it is not being widely used at the state level either, at least in Region 9.

Region 9 has 10 tribes which have FIFRA enforcement grants. The programs are primarily centered on use/misuse and marketplace inspections. Although worker health and safety is also often funded, these activities generally are educational rather than enforcement related, or have been to date. Because environmental measurements are a possibility for use/misuse and marketplace activities, grant regulations require that a QAPP be prepared. Since there appeared to be a guidance void in the pesticide enforcement QAPP arena, Region 9 decided to try address this need. Region 9's approach is described below.

Approach

The approach taken involved two steps. First a template was developed which tribes could use as a starting point in developing a QAPP. Second, the template was used as the basis of an interactive training to which all Region 9 tribes with pesticide grants were invited. The template was created jointly by the QA Office and the Region 9 Pesticide Office. It simplified and streamlined available QA guidance and FIFRA reference documents. The template was created using the OECA guidance as a starting point, but the material on both groundwater monitoring and "Special Projects" was eliminated.. In the region, most Indian Country pesticide groundwater projects are funded on a one time basis, rather than as part of on-going monitoring. It was also the region's experience that the few grants in the "special projects" category funded to date had gone to universities and not to tribes. Although this could change in the future, the team felt comfortable removing references to groundwater monitoring and "Special Projects" from the template.

Further simplification was achieved based on two assumptions. Region 9 tribes are encouraged to utilize the services of their respective state's Department of Agriculture pesticide laboratory, thus the assumption was made that it was not necessary to document the laboratory's quality system; the lab's QA Plan and/or Standard Operating Procedures (SOPs) could be included by reference. The tribe was instructed to obtain the relevant documents from the laboratory, but that they did not need to submit them as Region 9 had reviewed these documents in the past. A further assumption was made that the tribe would make or had made an agreement for such support services. Since all the tribes doing enforcement work under FIFRA grants presently are located in Arizona, and the Arizona State Agriculture Laboratory has been supportive of working with tribes, this approach appears to have been justified. However, it was recognized that as other tribes from Nevada and California started receiving FIFRA funding that they would need to also establish a relationship with their respective laboratories as well. Both the California Department of Food and Agriculture Laboratory and the Nevada Department of Agriculture Laboratory have indicated a willingness to work with tribes or have worked with tribes on non-enforcement work in the past. The tribes were

told, however, that if they preferred to use a commercial laboratory, laboratory quality system documentation would be required. It was also explained that the ability to handle non-routine pesticides or unusual matrices might be beyond the capability of most commercial laboratories, or at minimum would require method development work, most probably at tribal expense.

The second major assumption made was that tribal pesticide inspectors would generally be collecting samples following the recently revised, "Federal Insecticide Fungicide Rodenticide Act (FIFRA) Inspection Manual" (Enforcement and Compliance Assistance EPA 305B-02-01, February, 2002 (available on line at: http://www.epa.gov/compliance/resources/publications/monitoring/fifra/manuals/fifra/) or possibly the National Enforcement Investigation Center (NEIC) Pesticide Sampling Guide, August 1985. The use of these references, which the team felt could be incorporated into each tribe's plan as appendices, simplified the information that needed to be provided in the QAPP itself. Both references, especially the Inspection Manual, are comprehensive in scope and cover most aspects of a sampling and analysis, including shipping and packaging of samples, documentation and most other aspects of sample collection. Neither contains actual analytical methods, but analyses are discussed.

Template

The QA/Pesticide team proceeded to modify the OECA QAPP guidance and create an annotated version of the text. Most non-essential QA terminology was removed or simplified, leaving the information necessary for the collection of the samples of opportunity typical of FIFRA Enforcement. Some text was italicized, and different aspects were color coded. The colored text highlighted instructions to the QAPP writer, a tie in connecting the writer to information he or she was instructed to bring to a training class which will be described below, areas that the tribe was expected to fill out that would represent tribe specific information, and generic text that was felt would be generally applicable, with minor modification, to all tribes. The template was provided electronically in a Microsoft Word format. A number of sections were removed from the text as not relevant to pesticide enforcement work, or as being redundant.

Pre-Workshop Planning

To make sure all the tribes provided a consistent product, and to facilitate and accelerate the preparation of the QAPPs, Region 9 brought together all its tribes with FIFRA grants for a workshop to assist them in writing the first draft of their required QA Plans. The workshop was announced in the spring, but was actually scheduled for November, after the 2005 growing season had passed. Funding was put into each grant to cover the travel costs of the two day workshop. The Pyramid Lake Paiute Tribe of Nevada, which had EPA funding remaining from a prior conference, handled logistics. A training room was procured at a local hotel in Reno, Nevada, and equipped with twenty laptop computers, each connected using a wireless connection to a local printer. Each attendee was issued a flash drive and a CD. The CD contained a copy of the template and the EPA Pesticide Inspector's Manual. In all, fifteen tribal members representing all but one of the Region 9 tribes attended.

Prior to coming to the workshop, each tribe was given "homework." The homework required tribes to provide or consider two categories of information. The first was information that the inspector was requested to bring. This included a list of the tribes' FIFRA personnel and their responsibilities, a list of any documents used by the program in its enforcement activities and copies if they were available, a list of matrices which the tribe might collect, any protocols on how training records were maintained, any SOPs which described how inspections were conducted if they differed from those described in the Inspectors Manual, a list of equipment an inspector might typically take to the field, a copy of decontamination procedures, protocols for operation of any field instruments, a description of how samples were packed and shipped to the laboratory, a copy of QA plans or other information from the laboratory, a list of typical QC data reported by the laboratory, and any information on how data were entered into databases.

In addition, a second category of information was "Information that a tribal inspector should know." This information included the name(s) of people responsible for approving the QAPP; the organization of the tribe's FIFRA program; the scope and nature of the tribe's pesticide program, especially those relevant to measurement activities; training requirements; a list of data which might be obtained from other sources; and an understanding of what reports might be generated by the program, such as inspection reports or enforcement referral notices which would be sent to EPA.

Inspectors were told that topics for discussion on site included criteria to be used to make decisions on the data, how an enforcement case might proceed at their tribe (EPA credentials or tribal credential), and how or whether data would be evaluated or reviewed.

Workshop

The workshop itself was conducted through a combination of lecture and interactive formats. A QAPP section would be presented, and the purpose of the section and the information required described. Questions were addressed, then inspectors were instructed to work on the relevant section. Having the perspectives of a combination of QA and Pesticide Enforcement staff present proved advantageous, since questions often revolved around regional or OPP policy or QA requirements, and it required collaboration to determine the best approach to resolving the issue. At the end of the first day, each tribe printed out its QAPP to date which was then reviewed by the instructors. As a result of this review, common areas of misunderstanding or areas where the instructors or template had not been clear were identified. In some cases, specific topics were identified to discuss individually with a tribe, but the main objective was to examine problem areas germane to all. The beginning hour of the second day was devoted to discussing these areas in depth. A break was then provided so tribes could revise their plans and so the instructors could meet individually with tribes who seemed to have more unique problems. For example, a couple of tribes had brought in previous versions of plans they had used, mainly for groundwater projects, and this information, because it was outside the scope of the enforcement document being prepared, needed to be removed.

The most challenging area, not unexpectedly, was related to defining the areas of "decisions to be made with the data" and data quality objectives and decision criteria. Unlike some other environmental regulations, like, for example, the Safe Drinking Water Act or the Clean Water Act, FIFRA does not define acceptable or unacceptable regulatory levels. Once a pesticide has gone

through the review and approval process, and marketplace concentrations and application requirements (suitable crops, pests, application rates, etc.) are defined, the main requirement is that a pesticide be applied in a manner consistent with its registration. If it is not used according to the label or if it is used inappropriately and is found somewhere it should not have been applied, such as would be caused by drift or use on a non-target crop in an unapproved manner, this could result in an enforcement action. However, "presence/absence" is the main criterion unless a label violation is being investigated. Decisions are further complicated by the fact that an inspector may be working under a tribal credential or an EPA credential, although both cannot be used to investigate a given incident. This affects whether the tribe performs the enforcement action under tribal law or if the case is referred to EPA. Some, but, not all tribes, have developed an "Enforcement Strategy." It was concluded during the workshop that this was an essential component in the QAPP, since it dictated how data would be used.

A second, and as yet unresolved issue, is the reporting of data by state laboratories. The industry standard is to only report the sample results without any of the associated quality control (QC) data. The QC data are generated, but not reported. This hinders any data review on the part of the tribes, but is consistent with the practice used by EPA in its FIFRA enforcement actions. To date, the absence of supporting QC data has not hindered any cases within the experience of pesticide office personnel. Although this raised some concerns on the part of the QA Office, it was felt that this was an issue beyond the ability of the tribes to resolve in the short term, so the data review discussion of the QAPP was left very generic.

At the conclusion of the workshop, participants evaluated the course and feedback was positive about its interactive nature and user friendly format. However, none of the QAPPs could be completed on site. It quickly became obvious that few of the tribes had assembled all of the suggested material or had the all the answers to the question posed to them. This was attributed to the lack of lead time (approximately three weeks), to other time commitments or to a failure to receive the questions altogether. It was also recognized that the EPA Project Officers (most of whom were not present) had not followed up with their tribes to emphasize the importance of gathering the necessary information, whether in written or other form. In hindsight, this is an area that could have been improved, although the amount of information required and limited time available would have made it difficult to complete the QAPP in two days, regardless. However, most tribes said that they had made a good start on their QAPPs, were not as intimidated by it as formerly, and felt that they had sufficient information to proceed on their own.

Conclusions

The final proof of whether this different type of approach was successful will be if the tribes attending the workshop can use the template to prepare a Pesticide Enforcement QAPP. Only one has been submitted to date, and it has not yet been reviewed. However, it is hopeful that this approach will considerably expedite the process between initial submittal and final approval. The goal is to have all tribes complete their plans prior to the end of the current fiscal year. Region 9 adopted a modified version of this approach at a recent workshop on developing a QA Plan for water quality monitoring. However, that workshop had the benefit of the recently released QAPP Development Tool CD-ROM. The CD contains considerable references and resources, and that workshop benefited from a much more established history within the Agency of the development of

water monitoring QA plans. In conclusion, it is felt that the template/workshop approach is a viable and effective one, and could be applied to a wide variety of programs. It might be especially useful in circumstances where QA plan writers are relatively inexperienced and/or the organization has had limited exposure to EPA's Quality System requirements.

America's Next QAPP Model

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A model may well be the least expensive and sometimes even the only way to produce a description of an important environmental situation. It is so much easier and cheaper to model the conditions in a lake or an air shed than it is to measure those conditions over the entire lake or air shed covering years, or decades. A model is, of course, the only way to predict that environmental condition, subject to one or more sets of what-if conditions. In other words, it is clear that models can be extremely valuable. But there's an old saying in the Quality Assurance Community that applies to modeling work as well as to monitoring: Bad data are worse than no data, and data of unknown quality are worse than bad data. For monitoring data, we have a lot of experience in understanding the quality of the data. We know that everything is relative, and that what matters about the quality of the data is how it compares to the quality that we need for a given situation. For models, though, even the target may be fuzzy. For some very common and important types of modeling projects, it is not possible to specify ahead of time the necessary quality of the results. In this sense, modeling resembles some research projects in which what you get is good enough, by definition.

The biggest problem with modeling projects, though, from a QA point of view, is that we in the QA community don't have nearly enough experience with them. Most QA people have very little understanding of how models work, how to predict or assess the quality of the results, or even what factors contribute to the quality of the results, or to the variability and uncertainty.

There is help on the way – but caution will still be needed. A number of guidance documents have been developed in the last decade that can greatly assist Project Officers who are responsible for directing and overseeing model development and use. They can also assist the QA Officers who are responsible for providing confidence that the development, calibration, and other model processes are appropriate and working. There is also a small but growing number of QA practitioners with model oversight experience. In this presentation I will summarize the QA issues associated with model development and use, and the guidance that is currently available. As you would expect (from the title of the talk and from your knowledge of QA), the Quality Assurance Project Plan (QAPP) will be at the center of the investigation. We will see how a QAPP might best be developed, what is really needed in order for the QAPP to be "approvable", and how the QAPP can be of benefit to the project outcome. We will also look at the skill mix that is necessary in the "Officer Corps" that will be overseeing the model process, and how to use Peer Review and Expert Panels to supplement your Project and QA Officers. Along the way, we will look at those projects mentioned earlier that do not fit into the traditional "specify the objectives up front" framework, including TMDLs.
