

Building a Quality System In a FIFRA Lab

“Some people change their ways when they see the light; others when they feel the heat.”¹ This statement demonstrates that you can change first, or you can change last, but for progress to occur change is inevitable. As the use of pesticide residue analysis data becomes more widely used to make global, national, and state environmental policy decisions, laboratories are being driven to change how they operate by adopting or being accredited to a national or international standard on laboratory quality. Laboratories involved in **Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)**² work, and the policy makers that use their data, need quality assurance that is both defensible and definable because this work often involves the protection of health and/or the environment. Due to these combined pressures, laboratories supporting the **United States Environmental Protection Agency (US EPA) FIFRA** compliance and enforcement work are looking at laboratory accreditation. FIFRA labs are unique because available methods rarely meet the complete needs of requests for analyses, the test requests are variable throughout the year and from year to year, and the client often needs the results as fast as possible. The unplanned nature of the work and the wide variety and variability of analyses performed to support FIFRA related activities has kept state labs from adopting a single model for laboratory accreditation. However, the **Michigan Department of Agriculture (MDA) Laboratory Division, Pesticide and Environment Section (P&E)** has begun the process of quality assurance through standardization by adopting the International Standard on laboratory competence (ISO 17025).³ P&E chose the ISO 17025 standard in part because it is becoming widely accepted by many accrediting bodies such as the American Association of Laboratory Accreditation (A2LA) and the National Environmental Laboratory Accreditation Program (NELAP).⁴ In addition compliance to this standard was preferred because incorporated in its design is the flexibility paramount for efficient, high quality results in a FIFRA lab environment. In the process of becoming compliant to this standard, P&E’s experiences discussed in this paper create a model for building and implementing an ISO 17025 quality system in a FIFRA lab.

Building a quality system is a common thread that runs through a variety of accreditation programs and is the foundation of compliance to ISO 17025. . A quality system is, in short, “saying what you do and doing what you say”, and putting it in writing. One of the first hurdles to jump in creating P&E’s Quality System was addressing the variety of documents that guide P&E’s pesticide residue analyses. In addition to specific US EPA FIFRA work, P&E serves other clients for residue analysis, some of which are Michigan police agencies, the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA), various

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1. Quote by Caroline Schoeder, Thinkexist.com
 2. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Food, Drug, and Cosmetic Act (FFDCA) As Amended by the Food Quality Protection Act (FQPA) of August 3, 1996, Unites States Environmental Protection Agency, Office of Pesticide Programs.
 3. Michigan Department of Agriculture Laboratory Division Strategic Plan, January 2003
 4. NELAC Quality Systems: The Integration OF ISO/IEC 17025 and PBMS, by Scott D. Siders, Division of Laboratories, Illinois Environmental Protection Agency; EPA 20th annual Conference on Managing Environmental Quality Systems.

university research departments, and Michigan governmental bodies responsible for urban and environmental initiatives. Several documents related to quality assurance (QA) direct P&E's activities for these projects such as Quality Management Plans (QMPs), Quality Assurance Project Plans (QAPPs), USDA Pesticide Data Program procedures, state civil service rules, state laws, and department and division policies. P&E began to define its quality system by bringing all of those documents together in a single P&E Section Quality Manual. The quality manual is the backbone of the quality system because it holds the basic policy statements and definitions related to all the laboratory practices that impact data quality. For P&E, the best way to bring the numerous client needs into a quality manual was to keep the quality manual general, listing broad policy statements, but using it to point to the specifics of laboratory operations by referencing standard operating procedures (SOPs). By keeping the specific instructions for tasks and analytical methods as separate documents from the quality manual, the quality system can be revised as needed in pieces, making the task of periodically updating the system easier.

While the general nature of the P&E Quality Manual will make the revision process easier, the original draft of the document was a daunting task because of its comprehensive nature. According to ISO 17025, all of the laboratory's quality system policies and objectives shall be defined in a quality manual which includes an overall quality policy statement and defines the roles and responsibilities of the quality manager and technical management.⁵ In order to ensure that our P&E Quality Manual met the fifteen management requirement sections and the ten technical requirement sections listed in the standard, we organized our document using the ISO 17025 outline. In addition to following the outline of the standard, we purchased software from SHOO Quality Assurance Manuals Incorporated⁶ that was designed for building a quality manual according to ISO 17025. The software provided a template quality manual with topics separated according to the ISO 17025 model. The software also provided suggested text and example SOP references for each section. Use of this program provided the essential organization needed to design a quality manual consistent with ISO 17025 and allowed contributors to focus on content rather than design. In many cases the information in other P&E quality documents could be "cut and pasted" electronically into the document, which kept the quality manual consistent with current P&E policies and procedures. Because the software quality manual model was adopted Laboratory Division wide, each section quality manual remained consistent in design with the over-all Division Quality Manual. In addition, P&E was able to borrow example language and procedures from another laboratory section that was in the process of applying for ISO 17025 accreditation. Because ISO 17025 was designed for use by a variety of laboratory types, some of the specific policy-related SOPs referenced in the quality manual were easily adapted from other sources. However, P&E designed, from the ground up, procedures to handle unique FIFRA lab concerns for core elements of the standard, Training, Method Validation and Approval, Document Control, and Corrective and Preventive Action.⁷

5. International Standard ISO/IEC 17025, First Edition 1999-12-15, General Competence of Testing and Calibration Laboratories

6. www.e-shoq.com, SHOO Quality Assurance Manuals Incorporated

7. International Standard ISO/IEC 17025, First Edition 1999-12-15, General Competence of Testing and Calibration Laboratories