OFFICE OF INDIANA STATE CHEMIST

Quality Management Plan

Protecting Indiana's Agriculture and Environment-Feed, Fertilizer, Pesticide, and Seed

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<table>
<thead>
<tr>
<th>Policy Name</th>
<th>Policy Number</th>
<th>Page Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mission Statement</td>
<td>N/A</td>
<td>3</td>
</tr>
<tr>
<td>Signature Page</td>
<td>N/A</td>
<td>4</td>
</tr>
<tr>
<td>Distribution List</td>
<td>N/A</td>
<td>5</td>
</tr>
<tr>
<td>Management Responsibilities</td>
<td>1.0</td>
<td>6</td>
</tr>
<tr>
<td>Quality System</td>
<td>2.0</td>
<td>15</td>
</tr>
<tr>
<td>Personnel Qualifications and Training</td>
<td>3.0</td>
<td>17</td>
</tr>
<tr>
<td>Procurement of Items and Services</td>
<td>4.0</td>
<td>19</td>
</tr>
<tr>
<td>Documentation</td>
<td>5.0</td>
<td>20</td>
</tr>
<tr>
<td>Records</td>
<td>5.1</td>
<td>24</td>
</tr>
<tr>
<td>Documents</td>
<td>5.2</td>
<td>26</td>
</tr>
<tr>
<td>Computer Hardware and Software</td>
<td>6.0</td>
<td>34</td>
</tr>
<tr>
<td>Planning</td>
<td>7.0</td>
<td>37</td>
</tr>
<tr>
<td>Implementation of Work Processes</td>
<td>8.0</td>
<td>39</td>
</tr>
<tr>
<td>Quality Assurance Project Plan(s)</td>
<td>8.1</td>
<td>40</td>
</tr>
<tr>
<td>System Reviews</td>
<td>9.0</td>
<td>42</td>
</tr>
<tr>
<td>Auditor Responsibilities</td>
<td>9.1</td>
<td>45</td>
</tr>
<tr>
<td>Corrective and Preventive Action</td>
<td>9.2</td>
<td>46</td>
</tr>
<tr>
<td>Quality Improvement</td>
<td>10.0</td>
<td>48</td>
</tr>
<tr>
<td>Revision History</td>
<td>NA</td>
<td>49</td>
</tr>
</tbody>
</table>
Mission Statement

OFFICE OF INDIANA STATE CHEMIST
Protecting Indiana’s Agriculture and Environment- Feed, Fertilizer, Pesticide, and Seed

Mission Statement:

The mission of the Office of Indiana State Chemist is to protect the public consumer, livestock and pets, and manufacturers/producers from: Falsely represented and otherwise misrepresented feed, fertilizer, seed, and pesticide products in the market place; Misuse of feed, fertilizer, seed, or pesticides such that these may cause disease or harm to persons or animals, or unacceptably disturb the environment. This mission is accomplished by assuring truth in labeling for feed, fertilizer, seed, and pesticide products offered in Indiana commerce; by requiring training of identified users and handlers of these materials; and by regulating (e.g., certification, licensing, registration, reporting) products and persons to gain compliance with Indiana and federal laws that have been assigned to this Office. The Office of Indiana State Chemist may invoke legal remedies (fines and penalties) 1) to secure an expectation of safety in the purchase of feed, fertilizer, seed, and pesticide products marketed in Indiana for consumers, and therein, provide protection for pets or livestock; 2) to ensure responsible use of these same products through labeling and educating the user to gain compliance; and 3) to actively support an integrated food safety system and contribute to improving the Indiana environment.

The Office highly values scientific proficiency and its application in matters of policy and practice, ensuring that all data generated and evaluated by this Office will be scientifically valid, of known precision and accuracy, of acceptable completeness, of acceptable representativeness, be reproducible, be comparable to extant standards or practice, and be legally defensible.

While management within the Office of Indiana State Chemist is ultimately responsible for the quality and integrity of all data generated by this Office, every employee is accountable and is expected to perform their individual responsibilities with integrity and to the highest competencies achievable. Management, collectively, assures the attainment of quality through adherence to our policies and procedures defined in the Quality Management Plan, including the following integrated plans, i.e., Quality Assurance Project Plan (QAPP), Animal Feed Regulatory Program Standards (AFRPS), Association of Official Seed Certifying Agencies (AOSCA) standards, and through the development and adherence to Standard Operating Procedures and Methods outlined in these policies.

____________________________
Robert D. Waltz, Ph.D.
Indiana State Chemist & Seed Commissioner

____________________________
Date
<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bruce Wilkinson, EPA Region 5</td>
<td>Indiana Technical Contact</td>
<td></td>
</tr>
<tr>
<td>Mardi Klevs, EPA Region 5</td>
<td>Chemicals Management Branch Chief</td>
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</tr>
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<td>Larisa Leonova, EPA Region 5</td>
<td>Quality Assurance Officer</td>
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</tr>
</tbody>
</table>
Policy 1.0
The management within the Office of Indiana State Chemist (OISC) is responsible for the overall quality and integrity of all data generated by this agency. The management collectively assures this quality through the adherence to the policies outlined in the Quality Management Plan (QMP) and through the development of and adherence to Standard Operating Procedures (SOPs) and Methods (MTDs) defined in these policies.

The management within OISC has individual responsibilities. These responsibilities include, but are not limited to the following.

State Chemist and Seed Commissioner- Oversees all laboratory activities, field programs, as well as quality assurance and information technology activities. The State Chemist and Seed Commissioner is also responsible for the administration of the laws assigned to the Office of Indiana State Chemist.

Laboratory Director – Directs the operations of the Office of Indiana State Chemist laboratories.

Quality Assurance Director- Performs QA/QC activities for all sections of OISC. This includes, but is not limited to, the development of QA/QC programs as outlined in the QMP and the Pesticide Quality Assurance Project Plan (QAPP), and assisting with the preparation of SOPs or Methods. The Quality Assurance Director is also responsible for maintaining results and statistics for all check sample programs, performing external and internal audits, reviewing analytical data, and facilitating training for both safety and quality.

Information Technology Manager- Provides administrative and management supervision of the information technology activities of the agency, including support for both the administrative programs and laboratory functions. Provides and interface with external data processing resources, coordinates training for the Office of Indiana State Chemist personnel in all areas of data management (including office automation) and acts as lead analyst for all database administration, system administration, network administration and software application development initiatives.

Pesticide Administrator- Oversees the implementation of state and state coordination of federal pesticide laws and regulations for the State of Indiana. These laws and regulations address the registration, labeling, sale, distribution, use, storage, and disposal of pesticide products and the competency of pesticide users. The Pesticide Administrator also serves as the primary point of contact and liaison for U.S. EPA for issues related to water quality protection.

Assistant Pesticide Administrator- Advises and assists the Pesticide Administrator, and acts for the administrator in the administrator’s absence and on numerous other occasions in the administration of the pesticide laws and regulations for the State of Indiana. Develops technical policies and administrative procedures for Indiana’s pesticide product registration program and oversees implementation of these.
Policy 1.0

Manager, Pesticide Applicator Certification Program- Oversees, manages and directs the day to day operations of the statewide pesticide certification, fertilizer certification, and related certification and licensing programs for businesses, dealers, distributors, applicators, and technicians which were created to ensure that only competent and legally qualified entities are providing services regulated by OISC. Manages and implements requirements for thousands of fertilizer supply and applicator business and farms. Coordinates weekly with the Purdue Pesticide Programs office on all certification and training matters including the delivery of regulatory training presentations annually.

Pesticide Program Specialist- Oversees the targeted communications of the provisions of state and federal pesticide laws and regulations. The specialist assists and supports the goals and purposes of OISC through educational efforts to gain compliance activities related to those regulatory requirements. In addition, the Pesticide Program Specialist oversees the state’s implementation of the federal Worker Protection Standard.

Compliance Officer – Manages, coordinates, develops, tracks, prioritizes, communicates, and interprets statewide enforcement and compliance programs as well as the field activities designed to ensure pesticides and fertilizers are used and distributed safely and legally in Indiana. Also serves as the point of contact for the State Records Act for OISC.

Fertilizer Administrator- Responsible for administering the Commercial Fertilizer Law, Agricultural Ammonia Law, and Lawn Care Service Law, governing sales, distribution, use, storage, certification and educational programs relating to the use of fertilizer and the safe transport, storage, and handling of anhydrous ammonia. Consults and works with the Chief Inspector and Auditor regarding field inspection activities, serving as a technical resource to inspection staff. Interacts with the Laboratory Director or Laboratory Supervisors and staff regarding fertilizer analysis. Maintains contact and works with related regulatory, industry and university organizations. Provides administrative overview to the Indiana Registry of Soil Scientists to include rule promulgation and guidance relevant to adherence to state law.

Agricultural Ammonia Specialist- Evaluates all (approximately 540) statewide distribution facilities and nearly all (approximately 20,000) units of portable equipment currently in active use for safety and integrity. Conducts site surveys of proposed facilities to determine compliance with legal requirements regarding the location of new facilities for storage, handling, and distribution of ammonia for agricultural use as fertilizer. Promotes public safety and the safety of those engaged with anhydrous ammonia use through education.

Fertilizer Control Specialist- Serves as lead investigator for fertilizer complaints. Investigates complaints, collects evidence, and develop a case summary. Explains and interprets rules to targets and complainants, often in difficult situations. Inspects bulk fertilizer and pesticide storage areas. Coordinates with field staff inspections and their findings. Generates inspection reports. Designs and reviews fertilizer and pesticide containment systems. Prepares documents for facilities that qualify
Policy 1.0
for the state property tax deduction of assessed value. Effectively represents OISC in a professional
manner at presentations, trade shows, public hearings and other events. Has proficient knowledge of all
OISC rules from all program areas.

Management Responsibilities

Feed Administrator- Administers state laws, state regulations and applicable federal regulations
regarding the manufacture and distribution of commercial feeds and pet foods. Has continuous contact
with companies regarding labeling and manufacturing practices. Consults with and works through the
Chief Inspector and Auditor regarding field inspection activities and serves as the technical resource to
inspection staff. The Feed Administrator is a commissioned officer for the Food and Drug
Administration (FDA) and cooperates with FDA in administering applicable federal regulations pertaining
to the manufacture of commercial feeds containing feed additives such as drugs and antibiotics through
the joint State-Federal Feed Inspection Program. Coordinates the feed control program with other
related regulatory functions performed by other agencies in the federal government, other states and
other agencies within the State of Indiana.

Seed Administrator- Responsible for administering the seed regulatory program, in cooperation
with United States Department of Agriculture (USDA), for the Indiana Seed Law, regulating agricultural
and vegetable seeds, the Legume Inoculants and Plant Growth Substance Law, the Inspections under
seed Contracts Law involving on-farm observations of investigations performed by technology providers
to determine compliance with GMO trait contracts and administration of the Indiana Industrial Hemp
Law and the Indiana Seed Arbitration Law. The Indiana Seed Arbitration Law is designed to provide a
system of arbitration for disputes between sellers and buyers of seed products in the state. The Seed
Administrator develops programs and policies and maintains contact with the regulated industries to
assist them in maintaining compliance with laws to minimize violations. Reviews all registration
applications, label copy advertising and product content; based on this evaluation, approves or
disapproves each permit. Employs, trains and maintains a competent laboratory staff; develops and
maintains a viable, modern, and dependable seed laboratory. Consults with and works through the
Chief Inspector and Auditor regarding field inspection activities and serves as technical resource to this
staff.

Chief Inspector and Auditor- In coordination with the respective program administrators, cross
trains and manages the field staff and inspection program for inspections covering feeds, fertilizers,
seeds, and select pesticide activities under the laws administered by OISC. In conjunction with the Feed
Administrator, coordinates join inspections with FDA for Good Manufacturing Practices (GMP) in
medicated feed production. Employs and trains new inspectors and updates training and information
base of all inspectors to assure that new developments and approaches to regulatory
conditions/problems are current. Designs and implements strategies for auditing firms who pay
inspection fees with respect to the distribution of feeds, fertilizers and seed. Audits quarterly and/or
semi-annual tonnage reports and sales records of regulated firms.
Policy 1.0

Pesticide Laboratories Supervisor - Supervises all laboratory activities in the Pesticide Residue and Formulations Sections. Issues work assignments, determines procedures for analysis, oversees instrumentation, leads method development efforts and maintains records of various analyses suitable for use as enforcement evidence. Final responsibility for results of analysis performed by assigned personnel; interprets analytical results according to applicable Federal and State statutes as well as AOAC International, Good Laboratory Practices, ISO 17025, and other recognized standards.

Microbiology Laboratory Supervisor - Directs the activities of the OISC microbiology laboratory and is responsible for the assay of official samples collected by the inspection staff in addition to unofficial samples submitted by other regulatory laboratories, manufacturers and researchers. Directs the work of technicians assaying feed samples for antibiotic content, vitamins, probiotic counts and bacterial contamination. Develops and evaluates new procedures and techniques of microbiological assays.

Feed/Fertilizer Automated Analysis Laboratory Supervisor - Coordinates personnel and work flow in the Feed/Fertilizer Automated Analysis Laboratory. Manages the section's developmental chemistry and troubleshooting capabilities according to laboratory priorities. Trains employees, assigns instrumentation in designated laboratory areas and maintains records of various analyses. Validates, verifies and archives data. Has final responsibility for results of analyses performed in assigned areas of the laboratory.

Feed Chromatography Laboratory Supervisor - Supervisory responsibility for all aspects of the operation of the Feed Chromatography Laboratory sections, including all testing work on mycotoxins, drugs, vitamins, and certain other general analytes in feed, pet food, or feed ingredients. Responsible for training and oversight of employees assigned to the sections, oversees instrumentations in assigned laboratory areas and maintains records of various analyses. Has final responsibility for results of analyses performed in assigned areas of the laboratory.

Attachments:

Attachment A: Office of Indiana State Chemist Organizational Chart

Attachment B: Pesticide Organizational Chart

Attachment C: Seed Organizational Chart

Attachment D: Feed Organizational Chart

Attachment E: Fertilizer Organizational Chart
Policy 1.0
Attachment C: Seed Organizational Chart

Office of Indiana State Chemist Quality Management Plan

Management Responsibilities

State Chemist and Seed Commissioner

Seed Administrator

Seed Microscopy

Seed Laboratory Staff

Chief Inspector and Auditor

Feed, Seed, Fertilizer and Urban & Agricultural Product Inspectors

Sample Prep

Quality Assurance Director

Information Technology Manager
Policy 2.0

Quality System

Overview
The Office of Indiana State Chemist has implemented a Quality System defined in this Quality Management Plan. The QMP is set up as a complete systematic quality plan based upon the ISO 17025 section 4.0-Management Requirements. The Quality System also breaks out individual areas, or modules, allowing the different administrative, programmatic, and associated laboratory sections to self-determine their own technical requirements as defined by the ISO 17025 section 5.0-Technical Requirements. The modules or functional areas develop their own Standard Operating Procedures (SOPs), Methods (MTDs) and practices within the framework of the systematic QMP (See Figure 1, below).

Systematic QMP
The system level of the QMP delineates the Policies, System Reviews (audits), Quality Assurance Project Plan(s), Training (safety and Quality Assurance) and Data Quality Objectives (DQO) and reviews for OISC. It is the responsibility of Quality Assurance (QA) to maintain the QMP, facilitate training, perform audits of the systems, assist in development of quality plans, and in the review of these quality plans, assist in the development of data quality objectives and determine if objectives are being met. It is the responsibility of all OISC management to incorporate the QMP to their respective administrative sections, to adhere to system requirements documented in the QMP and to communicate the importance of such compliance to all OISC employees.

Modular QMP
The modular (organizational systems) level of OISC delineates the SOPs, MTDs, technical assessments and training (safety and procedural) for each individual functional section. Each individual section can define their own practices within the guidelines of the systematic QMP, (i.e. training has to occur as per Policy 3.0: Training, SOPs and MTDs must follow the format as outlined in Policy 5.2: Documents, etc). Section Management/Supervisors are responsible for the development, verification, and implementation of their section SOPs, MTDs, and practices. In conjunction with Quality Assurance, management and supervisors are responsible for assuring that their employees are adequately trained in all areas that impact their employee’s ability to comply with documented procedures while performing their job assignments.

Organizational Systems Defined by and In Adherence to the QMP:
1. Pesticides
   a. Pesticide Investigators
   b. Pesticide Laboratories
   c. Pesticide Applicator Licensing
   d. Pesticide Product Registration

2. Feed
   a. Feed Chromatography Laboratory
   b. Feed Automated Analysis Laboratory
Policy 2.0

c. Microbiology Laboratory
d. Microscopy

3. Fertilizer
   a. Fertilizer Automated Analysis Laboratory
   b. Anhydrous Ammonia Specialist
   c. Fertilizer Containment Specialist

4. Seed
   a. Seed Laboratory
   b. Microscopy

5. Chief Inspector and Auditor
   a. Feed, Seed and Fertilizer Inspectors
   b. Urban & Agricultural Product Investigator

6. Sample Preparation
   a. Feed and Fertilizer Sample Preparation

Figure 1: OISC’s QMP is set up in the following manner:
Policy 3.0 Personnel Qualifications and Training

Qualifications
All Office of Indiana State Chemist personnel shall be appropriately qualified to perform their job function. The minimum qualifications are determined by the management of OISC. The position classification is determined by the Purdue University Human Resource (HR) Department in conjunction with OISC management and supervisory personnel.

New positions will have complete, updated job descriptions (including minimum education and/or work experience required) prior to the new position being submitted to Purdue HR for classification. Job descriptions for existing positions that need to be filled are reviewed by management prior to posting of the position. This review should evaluate the minimum requirements for the positions and determine if they are still appropriate.

Training
All training shall be accomplished through documented SOPs, MTDs, and on-the-job (OTJ) training practices, seminars, formal education, etc. per SOP 0253-GN, “Training and Education”. It is the responsibility of QA, or designee, to maintain individual training files. Additionally, new employees will receive an initial QA training and Purdue University New Employee training. QA will also conduct topical training quarterly to applicable OISC staff.

Employees will be notified of any modifications and/or new documents (documents being defined as SOPs, MTDs, Policies, QAPP or QMP) within their work areas by QA.

All affected OISC personnel shall receive, at an interval not to exceed two (2) years, training on the Office of Indiana State Chemist QMP. This training can occur via many routes, e.g. e-mail, memos, seminars, quarterly QA training, etc. QMP training shall be documented (documentation including date of training and personnel trained). This documentation shall be maintained by QA.

General
- Initial training on all general SOPs and applicable MTDs and as changes to policy, SOPs and MTDs occur thereafter.
- Annual First Aid and CPR training
- Fire Safety Training every two years
- “Ethics for State Employees” when hired then every two years
- Annual Diversity Training
Policy 3.0  Personnel Qualifications and Training

Laboratory
- Initial Training on all general SOPs, and MTDs specific to the employee’s job function, and as changes to policy, SOPs, and MTDs occur thereafter.
- Laboratory hazardous material training when hired, then every two years.
- Annual EPA Region 5 Pesticide Laboratory training as applicable for pesticide residue and formulations laboratory analysts.
- Vendor supplied training with each new piece of laboratory equipment prior to use of the instrument or equipment.
- Training prior to use of instruments and equipment for new employees
- Instrument/equipment training for all applicable laboratory employees, when changes are made to existing instruments or equipment.
- Participation in collaborative studies.
- Participation, at minimum of semi-annually, in check sample programs.

Pesticide Investigator
- Initial training to SOP 0182-IV, “Pesticide Investigator Training,” and as changes to policy, SOPs, and MTDs occur thereafter.
- U.S. EPA Pesticide Inspector in Residence Training (PIRT) and U.S. EPA Pesticide Regulator Education Program (PREP), as applicable
- Documented training on all procedures and methods needed to perform job function.

Seed Feed and Fertilizer Inspector
- Association of American Seed Control Officials Handbook on Seed Sampling
- Association of American Plant Food Control Officials Inspection Manual
- Association of American Plant Food Control Officials Label Manual
- Association of American Feed Control Officials Feed Inspector’s Manual
- Documented training on all procedures and methods needed to perform job function.

The training listed above is not the only training opportunities available to the OISC staff. The training above, however, is offered upon hiring or on a periodic basis thereafter. A training matrix will be maintained by Quality Assurance designating on which procedures each employee has been trained.
Policy 4.0  

Procurement of Items and Services

The Office of Indiana State Chemist is located at 175 S. University St., West Lafayette, IN 47907 on the campus of Purdue University and is required to follow Purdue University’s procurement policies. These policies include, but are not limited to, services costing over a present limit must go out for bid, all items purchased must be approved by the section manager, and approved purchase requests must accompany all purchased items. Purchase receipts are kept for seven (7) years by Purdue’s accounting department.

Services

The Office of Indiana State Chemist, through Purdue University Office of Contracts and Grants, contracts outside sources, independent contractors, to perform services. The Office of Contracts and Grants is responsible for ensuring that all services procured with federal funding sources (i.e. U.S. EPA) are done so in compliance with the terms required by that granting authority. OISC assures the quality of the work performed by the independent contractors through the following:

- A contract is in place between Purdue University and the independent contractor. The contract spells out what is required by OISC, what guidelines the independent contractor is to follow and any special requirements associated with the task.
- A point person within OISC is assigned to any out-sourced task. This point person continually interacts with the independent contractor. This interaction allows for constant and open dialog between OISC and the independent contractor.
- Records are generated with all out-sourced task. These records are reviewed for accuracy and completeness. These records are regarded as part of OISC quality system and are maintained as such.

Items

The Office of Indiana State Chemist purchases products(s) from reputable vendors. The product(s) purchased is/are guaranteed for specificity, purity, accuracy, durability, etc via written warranties or guarantees given by the vendor. These warranties/guarantees include, but are not limited to:

- Certificates of Analysis (CoAs)
- Certificates of Conformance (CoCs)
- Certificate Calibration
- Warranty of Operation

These warranties/certifications are maintained by each laboratory section or QA for the life of the purchased product.
Policy 5.0

Documentation

All work performed by OISC in carrying out our regulatory and contract obligations (per our mission statement) shall be documented. Each section within OISC has specific documentation requirements. The OISC Record Retention master list outlines years of records retention and is maintained by Purdue University and updated by OISC. A copy of this master list is kept by the Administrative Assistant & Accounting Supervisor. All documents shall be retained for a minimum of five (5) years unless university policy, state law or federal requirements dictates a longer period of time. Completed pesticide and fertilizer investigation case files are posted to the OISC website.

Pesticide Investigations

Note: Investigations shall be defined as anything other than a Routine Compliance Inspection. A case file with all of the required documentation and records shall be created and maintained for all investigations and for all routine compliance inspections that result in suspected violations.

All case files, at a minimum, shall contain:

- Case Summary (a publicly accessible document that summarizes the investigation findings and final disposition of the case)

Additional documentation is required for the following:

Case file for a complaint, or an investigation for cause

- Document making the investigation assignment to the investigator
- Case Summary
- Case Summary transmittal letter to complainant (if one exists)
- Case Summary transmittal letter to an alleged violator (if known)

Case file for an investigation/inspection in which a violation was determined

- Enforcement Letter (Charging Document)
- Record of Enforcement Letter delivery (e.g. return receipt for certified mail record of hand delivery, etc).

Case File in which a physical sample was taken:

- Documentation of all samples taken (e.g. Pesticide/Fertilizer Product Sample Collection Report for formulation samples; Forensic Environmental Residue Sample Chain of Custody Form for residue samples and Purdue University Plant and Pest Diagnostic Laboratory Form PPDL-1-W for plant specimen samples).
- Diagram or marked-up detailed aerial photograph of area from which the samples were taken (for residue and plant specimen samples)
- Laboratory analysis results
Policy 5.0

Case file in which photographs, videos and/or audio recordings were created:

- Printed copy of relevant photographs on the Case Summary; or
- Documentation in the case file indicated that photographs, video and/or audio recordings were created. If the aforementioned items are not physically in the case file, they should be located in the appropriate repository. This should be documented in the case file.

Case file in which the complaint was withdrawn:

- Letter or email to complainant confirming that the original complaint has been withdrawn and will not be investigated further by OISC (instead of the Case Summary).

Case file in which the complainant was unable to be contacted once the initial complaint was made:

- Letter or email (instead of a Case Summary) indicating that the case will be dismissed due to lack of information from the complainant.

Note: The case file documentation is not exclusive. A case file may require any combination of the above listed documents.

Routine Pesticide Compliance Inspection:

For the inspections listed below, an entry into the OISC electronic case tracking database, at a minimum, is required per event:

- Agricultural Use (AU)
- Non Agriculture Use (NAU)
- Marketplace (MRK)
- Certified Applicator Records (CAR)
- Dealer Records (DER)
- Experimental Use (EUP)
- Producer Establishment (PEI)

Additional documentation is required for the following:

Inspection in which a formulation sample is taken from the inspection location

- Pesticide Sample Collection and Dealer Affidavit Receipt
Policy 5.0
Inspection in which a violation is documented

- Case Summary
- Enforcement Letter
- Case Summary Transmittal Letter to violator

Fertilizer Investigations
Note: Investigations shall be defined as anything other than a Routine Compliance Inspection. A case file with all of the required documentation and records shall be created and maintained for all investigations and for all routine compliance inspections that result in suspected violations.

All case files, at a minimum, shall contain

- Case Summary (a publicly accessible document that summarizes the investigation findings and final disposition of the case)

Additional documentation is required for the following:

Case file for a complaint, or an investigation for cause

- Document making the investigation assignment to the investigator
- Case Summary
- Case Summary transmittal letter to complainant (if one exists)
- Case Summary transmittal letter to an alleged violator (if known)

Case file for an investigation/inspection in which a violation was determined

- Enforcement Letter (Charging Document)
- Record of Enforcement Letter delivery (e.g. return receipt for certified mail record of hand delivery, etc).

Case File in which a physical sample was taken:

- Documentation of all samples taken on Fertilizer form IS-F1 or Notice of Inspection.
- Location of sample taken documented on Fertilizer form IS-F1.
- Laboratory analysis results

Case file in which photographs, videos and/or audio recordings were created:

- Printed copy of relevant photographs on the Case Summary; or
- Documentation in the case file indicating that photographs, video and/or audio recordings were created. If the aforementioned items are not physically in the case file, they should be located in the appropriate repository. This should be documented in the case file.
Policy 5.0
Case file in which the complaint was withdrawn:

- Letter or email to complainant confirming that the original complaint has been withdrawn and will not be investigated further by OISC (instead of the Case Summary).

Case file in which the complainant was unable to be contacted once the initial complaint was made:

- Letter or email (instead of a Case Summary) indicating that the case will be dismissed due to lack of information from the complainant.

Note: The case file documentation is not exclusive. A case file may require any combination of the above listed documents.

Residue Laboratory
All laboratory cases files shall contain the following:

- DF 00023-PR: Forensic Environmental Residue Sample Chain of Custody Form
- Pesticide Residue Laboratory Case Report (Final)
- Sequence Summary Report (Chromatography packets)
- Spike/Fortification Record (if applicable)
- Case Content Sheet

Additional documentation is required, at a minimum, for the following:

Laboratory case file in which the matrix is soil:

- DF 00011: Percent (%) Moisture Worksheet

Note: The Laboratory case file documentation is not exclusive. A Laboratory case file may require any combination of the above mentioned documents.

Formulation Laboratory
All Laboratory case files, at a minimum, shall contain:

- Sample Information Sheet
- Pesticide Formulation Sample Data Packets Content Sheet
- Chain of Custody Seal Form
- Pesticide Sample Collection Report
- Results Summary Sheet

Additional documentation is required for the following:

Sub-sample taken of the product

- DF 00020-PF: In House Chain of Custody Form
Policy 5.0

Note: The Laboratory case file documentation is not exclusive. A Laboratory case file may require any combination of the above mentioned documents.

Check Samples:
All check sample files, at a minimum, shall contain:

- Sample Information Sheet
- Packet Contents Sheet
- Results Summary Sheet
Policy 5.1

Records
Records can be electronic, film, or paper. Items that fall under records for the purposes of this policy include, but are not limited to:

- Notice of Inspection
- Site inspection case files
- Laboratory case files (all data generated)
- Laboratory analytical results
- Laboratory QC data (spikes, blanks, etc.)
- Chain of custody paperwork
- Pesticide case files (inclusive)
- Sample receiving paperwork
- Check Sample results
- Audit results
- Paper Forms per SOP 0275-GN, “Paper Form Control”

Record Review
Note: non-pesticide sections include the following:

A. Sample Preparation and Microscopy
B. Microbiology
C. Feed Chromatography
D. Feed/Fertilizer Automated Analysis
E. Seed

The section manager /supervisor is responsible for the correctness and completeness of all documented records in their section. This includes, but is not limited to:

Pesticide/Fertilizer Case Files - Pesticide/Fertilizer Investigation/Routine Pesticide Compliance Inspection:

Case files are reviewed for accuracy and completeness by the Compliance Officer, or designee. Once a case file has been reviewed and found to be acceptable, it is considered complete and stored for a minimum of five (5) federal fiscal years. The Compliance Officer, or their designee, is responsible for the correctness and completeness of the records.

Laboratory Records:
Laboratory records are reviewed for accuracy and completeness. This review includes, but is not limited to, raw data, standards, laboratory notebook entries, sample preparation, equipment run parameters, internal QC samples run results, final results report, etc. Once the laboratory records have been reviewed and found to be acceptable, they are considered complete and stored for a minimum of five (5) federal fiscal years, unless stated otherwise on the OISC Record Retention Master list. The Laboratory Supervisor is responsible for the correctness and completeness of the laboratory records.
Policy 5.1

Check Sample Results
Check samples will follow the same review procedures as described above. When the check sample results are received by OISC, they will be reviewed by the Laboratory Supervisor and/or Laboratory director and Quality Assurance. QA will chart and trend all check sample results. These trends will be made available to all employees of OISC and specifically the Laboratory Supervisor or Laboratory Director. The check sample trends will be used to assist the OISC laboratories in their continuous improvement process. OISC will keep the sample results for a minimum of three (3) years and QA will keep the trend reports for a minimum of five (5) federal fiscal years.

Third Party Review of Records:
Records will be reviewed as part of a section audit. The quantity of records reviewed during a section audit will be no less than the square root of the total number of records available for a given time frame plus one (1).

\[ n = \sqrt{\text{sample set}} + 1 \]

Example: 500 completed records for "n" time frame in section being audited. Calculation: square root of 500 plus one equals 23.4 records. Twenty-three records, at a minimum, would be reviewed as part of the audit for "n" time frame. The records are picked randomly.

Audits are performed on a set schedule as outlined in Policy 9.0 System Review. The audit is performed by a qualified individual (see Policy 9.1) with no direct responsibility for what is being audited.

Record Retention
Pesticide and Fertilizer environmental data records will be kept for a minimum of five (5) federal fiscal years. Other non-pesticide data records will also be kept for a minimum of five (5) calendar years. Financial records will be kept for a minimum of seven (7) years. All records will be kept in a manner that prohibits their exposure to the environment and subsequent deterioration. Records will be kept in a secured facility and in accordance with SOP 0266-GN, “Control Maintenance and Retention of OISC Records”.
Policy 5.2
Administrative Sections within OISC prepare technical guidance documents for use within OISC. For the purposes of this QMP, the technical guidance documents prepared by OISC personnel are limited to Policies, QAPPs, SOPs, and MTDs. Policies, SOPs and QAPPs are reviewed at an interval not to exceed two (2) years to assure the practices outlined in them are still current and applicable. MTDs are to be reviewed at an interval not to exceed five (5) years. The QMP is to be reviewed yearly.

When documents are not current or applicable and require revision the “Revision” process is followed as outlined in the “Revisions” section of this document. The review of the document should be recorded as a permanent record with the signature of the reviewer and the date reviewed. The documentation of the review is captured on the document itself. Review of the technical guidance documents will be documented and verified through section audits.

Policies (internal OISC Policies)
Policies are global statements that affect OISC as a whole. The approval of a Policy is a commitment of OISC to an action or behavior. Policies should be written by a member of management and must be approved by the State Chemist and Seed Commissioner, affected Administrator, Laboratory Director or affected Laboratory Section Supervisor, and the Quality Assurance Director. The author cannot also be a reviewer.

Standard Operating Procedures (SOPs)
SOPs are documents that state an agency policy or describe a procedure for performing a particular task that is not related to testing. This document includes administrative functions within the agency and guidelines procedures and responsibilities that must be followed by personnel in the agency. SOP 001-GN, “Preparation, Issuance, and Maintenance of the Office of Indiana State Chemist Standard Operating Procedures,” is to be followed when generating new, or revising current SOPs.

Note: SOPs can either be general or section specific. SOPs ending in GN are general SOPs and may cover more than one and possibly all sections of OISC and deal in subject matter systematic to the overall quality system.

The format used for writing SOPs should conform to the following:

- **Scope**- Defines the applicability of the SOP
- **Purpose**- States the objective for the SOP
- **Procedure**- Outlines the actual procedure of the SOP and includes definitions if applicable.
- **Appendices**- any document(s) associated with the SOPs, such as forms.
- **References**- Sources of information used to write the SOP.
- **Revision**- Outlines all changes made to the SOP and includes justification for changes. This functions as the document’s change control with final signatures of reviewers indicating acceptance of changes and justifications.

A signature page of all members approving the document will be included as a cover page.
Policy 5.2

For SOPs specific to a laboratory instrument or equipment the following sections will additionally be included:

- Installation Qualification (IQ)- IQ of an instrument is generally conducted by the vendor. Vendor documentation will be maintained by Quality Assurance.
- Operational Qualification (OQ)- OQ is the determination and documentation that the instrument operates across the intended ranges as specified.
- Performance Qualification (PQ)- PQ is a series of procedures and corresponding documentation that assures the instrument is operating properly.
- Cleaning and Maintenance- These procedures outline cleaning and maintenance of the instrument.

Methods (MTDs)

Methods are established and documented for a specific scientific task, methodology, sample preparation technique, instrumental analysis technique, software use, general laboratory procedures, to communicate requirements in quality and technical agreements, and investigator/inspector point of use documents. SOP 0279-GN, “Preparation, Issuance, and Maintenance of the Office of Indiana State Chemist Methods,” will be followed when new MTDs are written or current MTDs revised.

The format used for writing MTDs should conform to the following:

- Introduction-Specifies the reason for the method and provides scope and any pertinent background information to which the method is applicable.
- Materials and Instrumentation-All materials and instrumentation necessary to perform the method are to be listed.
- Procedure- Provides systematic instructions or descriptions for performing the particular test, methodology, or assay.
- Calculations- If the method requires a calculation, an example calculation must be provided.
- References- Sources of information used to write the MTD.
- Revision- Outlines all changes made to the MTD and includes justification for changes. This functions as the document’s change control with final signatures of reviewers indicating acceptance of changes and justifications.

A signature page of all members approving the document will be included as a cover page.

Revisions

Revisions for SOPs should follow SOP 0001-GN, “Preparation, Issuance, and Maintenance of the Office of Indiana State Chemist Standard Operating Procedures,” when revising current SOPs. SOP 0279-GN, “Preparation, Issuance, and Maintenance of the Office of Indiana State Chemist Methods,” will be followed when current MTDs are revised.
Office of Indiana State Chemist Quality Management Plan

QA is responsible for keeping the quality system current. This entails removal of old policies, procedures, and methods, and the posting of new/revised policies, procedures and methods. QA will keep previous revisions on file for a minimum of five (5) years.

Attachments:

Attachment A: Policy Template

Attachment B: Example of a General Standard Operating Procedure title page header and footer.

Attachment C: Example of a section specific Standard Operating Procedure title page header and footer.

Attachment D: Example of Method title page header and footer.

Attachment E: Flow Charts of Review Processes.
Office of Indiana State Chemist Quality Management Plan

Policy 5.2
Attachment A: Policy Template

(Internal OISC Policy)

Office of Indiana State Chemist
West Lafayette, IN

Contents of Policy

Reviewed by: ____________________________  Date: ______________

Approved By: ____________________________  Date: ______________
(Must be approved by Director, Administrator, Manager or Supervisor)

QA Approved by: ____________________________  Date: ______________
Attachment D: Example of Method title page header and footer

Office of the Indiana State Chemist
175 S. University St.
West Lafayette, IN 47907

Document Owner:

Reviewed and Approved By:

Reviewed and Approved By:

Example of Footer:

Title
Policy 5.2

Attachment E: Flow Charts of Review Processes

Changes in Policy required Document Review

Not approved in current state, sent back to author for revisions

Administrators/Managers, Lab Directors/Supervisor, QA Director, State Chemist (Can author Policy)

Write

Policy

Review

State Chemist, Lab Director, or Administrator, or Section Supervisor and Quality Assurance Director (Approve Policy)

Approved Policy in Place

Approved

Training & updating QMP

Biennial Review of Policies

No changes required, Document Review
Policy 5.2
Attachment E: Flow Charts of Review Processes Continued

Changes in Methods

Not approved in current state, sent back to author for revisions

Dispute Resolution
Author of SOP and reviewer:

Method

Section Manager/Supervisor, Administrator, or Laboratory Director, and QA

Not approved by QA

Approved

Dispute Resolution
QA and Section manager/supervisor: State Chemist,

OISC Employee

Write/edits

Implement

Review

Training and distribution

No changes required, Document Review

Approved

Approval signatures
Section Manager/Supervisor, Administrator, or Laboratory Director, and QA Director
Policy 6.0  Computer Hardware and Software

The following five issues are addressed in this Policy

1. Assurance that computer hardware and software used by the Office of Indiana State Chemist meets the needs of the programs using the hardware or software.
2. Control of changes to hardware or software to assess the impact of changes on performance.
3. Development of computer software, including but not limited to, validating, verifying, and documenting its use, and assuring it meets the requirements of the user.
4. Evaluation of purchased software to meet user requirements and compliance with contractual requirements and standards.
5. Assurance that data and information produced from, or collected by, computers meet applicable state and federal agency requirements and standards for information sharing.

Computer Hardware
To ensure that computer hardware used by OISC meets the requirements of the programs using the hardware, the following is adhered to:

- Computer hardware selection is performed by administrators, managers, and/or laboratory supervisors, with guidance from the OISC Information technology (IT) staff.
- Computer hardware is evaluated and chosen based on software and instrumentation requirements in consideration to program and user requirements.

To assess the impact of change on performance, computer system changes are controlled according to the following:

- Computer system changes are driven by software or hardware upgrades to existing equipment (i.e. laboratory instrumentation, computers, etc.) or the purchase of new equipment needed to fulfill the mission of OISC.
- Administrators, managers and/or laboratory supervisors have input in determining (as appropriate) necessary changes to computer systems, and appropriate time frames for making changes.
- Verification is performed when implementing new computer-integrated instrumentation, including but not limited to, parallel testing with older verified systems.
Policy 6.0

Computer Hardware and Software

Computer Software
The process for developing enterprise wide computer software encompasses the following:

- Survey Phase- Preliminary analysis of proposed project, including needs assessment, feasibility assessment, definition and scope of project, preliminary solutions with time and cost estimates and cost/benefit analyses and identification of project participants.
- Analysis Phase- Overview of current system or process, including results of observations, interviews, surveys, sampling etc, and data flow and/or entity relationship diagrams as appropriate.
- Design Phase- Requirement specifications for data inputs and outputs, processes, user interfaces, security, and archiving/retrieval. Creation of technical documentation.
- Testing Phase- Formal testing with pre-approved test plan, user testing using “live” historical data with known outcomes, covering all major and minor cyclic events and the creating of user guides.
- Implementation Phase- Delivery of new system, including user training, parallel processing in conjunction with old systems when warranted and change-over to the new system.
- Post-Implementation Phase- Minor modification, as needed, and updates to user and technical documentation.

For enterprise applications, the selected project team will be involved in validating and verifying the software during all phases of development. For these types of application development projects, selected end-users of the software will be involved in reviewing milestone documents for accuracy, completeness and ease of use. Users will be encouraged to edit user documentation for accuracy, completeness and ease of use. These controls ensure that software developed in-house meets the requirements of the users.

Purchased software for laboratory equipment is almost always the commercial product that was designed for that particular piece of equipment and is guaranteed and warranted by the vendor.

Other software is evaluated based on the following criteria:

- Features, functionality, flexibility and adaptability
- Compatibility with existing hardware and operating systems
- Performance
- User-friendliness
- Prevalence of product in the market/market share
- Endorsement by other users
- Reputation and stability of the vendor
- Availability and quality of vendor user support
Data Collection
The following describes how OISC ensures that data and information produced from or collected by computers meets applicable EPA Office of Environment Information Policies [formerly EPA Directive 2100- Information Resource Management (IRM)] requirements standards:

- Data is password protected and security is based on granting specific database access rights and privileges to appropriate users.
- Data management is performed at various security levels based on authority vested in particular positions. Major changes and/or deletions are approved by the State Chemist and/or Quality Assurance Director or their designee, and performed by the database administrator. These changes are documented.
- Only data necessary to fulfill the mission of OISC is collected.
- Data is backed up nightly; all systems on the network are backed up weekly.
- Database software is stable, flexible, up-gradable and portable.
- Automated data collection equipment is used where feasible.
Policy 7.0

The Office of Indiana State Chemist (OISC) has in place a Quality Assurance Project Plan (QAPP). The QAPP is a document that identifies how routine program operations occur. The QAPP is reviewed at a minimum biennially to assure that it is still relevant to the operations and programs of OISC.

There may be projects that are conducted and/or overseen by OISC that require more specific planning than what is outlined in OISC’s QAPP. Projects that require more specific planning shall use the Data Quality Objectives (DQO) process to outline and plan the needs of the project. The outputs of the DQO process should feed into a detailed QAPP, MTD, or pertinent section(s) of the existing QAPP. All projects have a “project leader” i.e., lead investigator, section specialist, section manager etc. The Project Leader, if required, is responsible for developing, documenting and implementing the DQO plan.

The end result of a DQO study process should be a plan that:

- Clarifies the study objectives
- Defines the most appropriate type of data to collect
- Determines the most appropriate conditions from which to collect the data
- Specifies tolerable limits on decision errors which will be used as the basis for establishing the quantity and quality of data needed to support the decision.  \(^1\)

There are six steps involved in the initial DQO process. The successful completion and output from these steps help to establish a well thought out final plan.

Outline of the DQO process:

1. State the Problem
2. Identify the Problem
3. Identify Inputs to the Decision
4. Define the Study Boundaries
5. Specify Limits on Decision Errors
6. Optimize the Design for Obtaining

\(^1\) EPA QNG-4 Guidance for the Data Quality Objectives Process, 1994
Policy 7.0

Determining if OISC’s QAPP is sufficient for a project or if a DQO plan needs to be initiated and implemented is made by the project leader, section manager, and Quality Assurance Director.

The steps for evaluating if a project is covered under the OISC QAPP or if it requires a DQO plan are as follows:

- **Did OISC Participate in this project when the QAPP was written/reviewed?**
  - Yes: **Current QAPP is acceptable**
  - No:
    - **Are the Data Objectives different/same as the Data Objectives of the project(s) covered by OISC’s current QAPP?**
      - Same: **Current QAPP is acceptable**
      - Different: Define the Study Boundaries
      - Different: Define the Study Boundaries

DQO Plans are kept as permanent records, and are maintained according to OISC Policy 5.1 Records.
Policy 8.0

Implementation of Work Processes

All work processes implemented by OISC shall adhere to the policies outlined in the OISC QMP, QAPP, and subsequent SOPs and Methods. Management and section supervisors are responsible for the work performed in their areas, as outlined in Figure 1 in Modular QMP. They are responsible for verifying that work is performed according to the following, as applicable: established Policies, SOPs, MTDs Approved QAPPs, established and approved methods from recognized sources (i.e. AOAC International or AAPCO), established training methods, Good Laboratory Practices (GLP) or ISO 17025. Deviations from established procedures should be documented. All deviations should be reviewed and evaluated by the section manager/supervisor and QA.

It is the responsibility of the section manager/supervisor to assure that their employees are qualified and properly trained in accordance with Policy 3.0 “Personal Qualification and Training.”

It is the responsibility of management/supervisors to assure that the appropriate documents (documents defined as SOPs, policies, or methods) are in place for their respective sections.
Policy 8.1 Quality Assurance Project Plans(s)
The purpose of the Quality Assurance Project Plan (QAPP) is to provide an overview of the project, describe the need for the measurements, and define QA/QC activities to be applied to the project.

The QAPP has four (4) essential elements with each element having sub-sections

1. **Project Management**
   - Title and Approval Sheet
   - Table of Contents and Document Control Form
   - Distribution List
   - Project/Task Organizational Schedule
   - Problem Definition/Background
   - Project/Task Description
   - Quality Objectives and Criteria for Measurement Data
   - Special Training Requirements/Certification
   - Documentation and Records

2. **Measurement/Data Acquisition**
   - Experimental Design
   - Sampling Method Requirements
   - Sample Handling and Custody Requirements
   - Analytical Methods Requirements
   - Quality Control Requirements
   - Instrument/Equipment Testing, Inspection, and Maintenance Requirements
   - Instrument Calibration and Frequency Inspection/Acceptance Requirements for Supplies and Consumables
   - Data Acquisition Requirements – Non-Direct Measurements
   - Data Management

3. **Assessment and Oversight**
   - Assessments and Response Actions
   - Reports to Management

4. **Data Validation**
   - Date Review, Validation, and Verification Requirements
   - Validation and Verification of Methods
   - Reconciliations with User Requirements

The adherence to the QAPP is the responsibility of the management within OISC. The QAPP shall be reviewed by the Quality Assurance Director, laboratory supervisor(s) or their designee, a program/project manager(s) or their designee, and program administrator(s), or their designee, a minimum of biennially or more frequently if required. All changes to the QAPP must be reviewed and
approved. The newest version of the QAPP will be distributed to all necessary parties, including EPA, in accordance with Policy 5.2-Documents.
Policy 9.0

System Reviews

There are many modular areas (see Figure 1) within OISC that are affected by and will adhere to the QMP. They are as follows:

1. Pesticides
   a. Pesticide Investigators
   b. Pesticide Laboratories
   c. Pesticide Applicator Licensing
   d. Pesticide Product Registration

2. Feed
   a. Feed Chromatography Laboratory
   b. Feed Automated Analysis Laboratory
   c. Microbiology Laboratory
   d. Microscopy

3. Fertilizer
   a. Fertilizer Automated Analysis Laboratory
   b. Anhydrous Ammonia Specialist
   c. Fertilizer Containment Specialist

4. Seed
   a. Seed Laboratory
   b. Microscopy

5. Chief Inspector and Auditor
   a. Feed, Seed and Fertilizer Inspectors
   b. Urban & Agricultural Product Investigator

6. Sample Preparation
   a. Feed and Fertilizer Sample Preparation

OISC acknowledges that the QMP is a dynamic document and how it is applied within each section will differ slightly. The sections within OISC, and the QMP, as it pertains to each modular area, will be reviewed at predetermined intervals to verify that the QMP is working as intended. This will be accomplished through internal audits and document reviews. The documents within the QMP will be reviewed at intervals to exceed twelve (12) months. The purpose of the document review is to verify that the Policies and SOPs used are still pertinent to the operations of OISC. The data review will be a review of all documents as outlined in Policy 5.0 Documentation. Statistical sampling will be used to
Policy 9.0  

determine how many records to review, as outlined in Policy 5.1 Records. The sections within OISC will be audited at intervals not to exceed twelve (12) months. The purpose of the internal audits is to verify the Policies, SOPs, and MTDs established are being followed and that each section is working in an effective and efficient manner.

Internal audits may be conducted by an audit team or by an individual. There may be individuals on the audit team that are critically associated with the area being audited; however, the lead auditor should be an individual who is not critically associated with the area being audited. Lead auditors and members of an audit team shall be qualified individuals. Qualifications may include internal OISC audit training, related work experience, formal training (e.g. course work, seminars, etc.) or a combination of the aforementioned.

Section internal audits will be compliance audits, compliance meaning the section’s compliance to their established SOPs, MTDs and OISC Policies. The results of the internal audit will be given to the manager/supervisor of the section being audited, State Chemist, affected Administrator, Laboratory Director and Quality Assurance Director.

Any findings, a finding being defined as an area of non-compliance, will be given to the immediate manager/supervisor for implementation of corrective action. The initial corrective action(s) will be followed-up at an interval not to exceed eight (8) weeks. Any subsequent corrective actions will be followed-up on a predetermined schedule. The internal audit of Quality Assurance must be conducted by a team or individual outside of the quality assurance unit.

Attachments:
Attachment A: Internal Audit Schedule
Policy 9.0

Attachment A: Internal Audit Schedule

<table>
<thead>
<tr>
<th>Section</th>
<th>Quarter 1 Oct-Dec</th>
<th>Quarter 2 Jan-Mar</th>
<th>Quarter 3 Apr-Jun</th>
<th>Quarter 4 Jul-Sep</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pesticides</td>
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<tr>
<td>Pesticide Investigators</td>
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<tr>
<td>Pesticide Residue Laboratory</td>
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<td>Pesticide Formulations Laboratory</td>
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<td>Feed</td>
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<tr>
<td>Feed Chromatography</td>
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<tr>
<td>Feed Automated Analysis</td>
<td>+</td>
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<tr>
<td>Microbiology Laboratory</td>
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<td>Fertilizer &amp; Ag Ammonia</td>
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<tr>
<td>Fertilizer Automated Analysis</td>
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<tr>
<td>Sample Preparation Laboratory</td>
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<tr>
<td>Auditing and Chief Inspector</td>
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<tr>
<td>Feed and Fertilizer Sample Collection</td>
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<td>Seed</td>
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<tr>
<td>Quality Assurance</td>
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</tr>
</tbody>
</table>
**Policy 9.1**

**Overview**
The Office of Indiana State Chemist (OISC) performs compliance audits of all sections within OISC affected by the Quality Management Plan (QMP). These audits are performed by trained and qualified employees of OISC. Audits may be conducted by an audit team or by an individual. There may be individuals on the audit team that are critically associated with the section being audited; however, the lead auditor should be an individual who is not critically associated with the area being audited.

**Responsibilities**
The auditor is responsible for reviewing current area documents as defined in Policy 5.2 Documents, and comparing them to actual practices. This includes, but is not limited to, reviewing completed case files (using statistical methods outlined in Policy 5.1, Records), conducting interviews with personnel within the section including management/supervisors, reviewing data collection practices, and reviewing record retention practices. The auditor is required to write a full report of the audit, citing any quality deficiencies and/or concerns and outlining any areas of improvement. Any deficiencies noted must be ranked in terms of action items and listed as required corrective actions. A draft report is given to the section manager/supervisor for review. At this time, the section manager/supervisor can give input into any part of the audit report. This input can include explanations for perceived findings and the dispute of any findings. Once the section manager/supervisor has offered comments about the audit, the final report is written. Comments from the area manager/supervisor should be included on the final report. Copies of the audit report are given to the section manager/supervisor, State Chemist, Laboratory Director, Affected Administrator, and the Quality Assurance Director. It is the auditor’s (or lead auditor if a team) responsibility to follow up on the defined corrective actions, according to Policy 9.0, System Reviews.

**Authority**
The auditor (or audit team) is given the authority by the State Chemist and Seed Commissioner to gain access to all employees, including management/supervisors, records, completed case files, SOPs, internal QC reports, etc.

**Qualifications**
An auditor can be qualified through professional experience, education (course work, seminars, etc.) OTJ training, internal OISC audit training or a combination of the aforementioned. Auditors should have a reasonable understanding of the area that is to be audited prior to conducting an audit. If the auditor does not have a reasonable understanding of the area being audited, then an audit team, comprising of at least one individual who is familiar with the area being audited and a lead auditor should perform the audit.

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**Auditor Responsibilities**
Policy 9.2 Corrective/Preventative Action

Corrective actions are the actions taken to result in the reduction or elimination of an identified problem. Corrective actions are not the day to day improvements or fine tuning of a system.

Preventative Actions are measures taken to prevent the first time occurrence of a quality deficiency by implementing a preventive measure.

Corrective/Preventive Actions (CAPAs) can be initiated through several sources. These can be findings from an audit, findings from a self-evaluation, internal QC, employee observations and recommendations, data evaluations, etc. Once a CAPA has been identified and brought to the attention of a section manager/supervisor, it is the responsibility of the section manager/supervisor to notify Quality Assurance of the CAPA and allocate the resources necessary to validate and implement the CAPA.

Quality Assurance is responsible for documenting the identified CAPA through a CAPA Report, working with the section manager/supervisor (or their designee) to develop a plan to best implement the corrective or preventive action. QA will also verify that the CAPA has been implemented and is effective. QA maintains the CAPA reports and a CAPA log. Completed CAPA files are maintained for a minimum of five (5) federal fiscal years.

Within eight (8) weeks of the closeout of the CAPA report, QA shall follow-up to ensure the action as effective. The follow-up information will be recorded on the original CAPA report.

The CAPA system is defined in SOP 0226-GN, “Corrective and Preventive Action.”

Attachments

Attachment A: Corrective Action Flow Chart
CORRECTIVE/PREVENTIVE ACTION FLOW CHART

Audit Findings → Data Evaluation → Self-Evaluation Findings → Internal QC Findings → Employee Observation → CORRECTIVE/PREVENTIVE ACTION IDENTIFIED

Section Manager/Supervisor Notified → Quality Assurance Notified

QA in conjunction with Section Management - Develops CAPA

Corrective/Preventive Action Plan (CAPA) developed. Review root cause of problem. Incorporate short term and long term review for effectiveness of CAPA. Evaluate other areas impacted by CAPA, i.e., SOP's, training.

Address areas impacted by CAPA
Facilitate training on CAPA
Notify Areas affected by CAPA and timeframe for CAPA implementation

Implement Plan

Verify Plan Effectiveness

QA maintains Completed CAPA
Policy 10.0

Quality Improvement

The Quality Assurance Director is responsible for reviewing all quality data e.g. audits, Corrective/Preventive Action Plans, check sample results, Policies, SOPs, MTDs and Program Plans. This quality data review will occur continuously throughout the year, with a synopsis of the quality system occurring annually. Throughout the year the Quality Assurance Director will update OISC management on a monthly basis by addressing important quality issues that either have been or need to be addressed. These updates will be presented during the following monthly meetings:

- Administrative Staff Meeting
- Pesticide Investigator Meeting
- Laboratory Supervisor Meeting

The yearly overview will be part of an annual quality system report documented on the Management Review Report (DF 00008-GN). This annual report will be presented to the management of OISC, (i.e. State Chemist, Laboratory Director, Administrators, and section supervisors) at the Management Review Meeting. A copy of the report that impacts the pesticide section will also be provided to the Environmental Protection Agency (EPA) upon their request.

The annual quality report will at a minimum contain:

- Summary of the quality data reviewed
- Evaluation of the current state of the Quality Management Plan and the quality system
- Review of quality agenda for the previous year (Listing items complete and incomplete)
- Quality agenda for the upcoming year

The overview of the quality data will at a minimum cover the following items:

- Audits performed and audit findings per section
- Corrective Action Plans (how many initiated, how many completed)
- Document review and any findings
- Check sample trend report

The quality agenda will at a minimum address:

- Training schedules
- Targeted areas for continuous improvement and plan to implement improvements
Revision History

Revision 4 on 12/29/2014: (a) Revised the mission statement (Justification: to better capture the mission of the Office of Indiana State Chemist. Statement changed by State Chemist and Seed Commissioner). (b) Added EPA signature page (Justification: For EPA signature for the Pesticide portion of the QMP per EPA SOP “Review and Approval of Quality Assurance Documents”). (c) Added all Administrators and IT to the signature page (Justification: since this document covers all OISC quality policies, signatures are required from each section’s management.) Updated the job descriptions in Policy 1.0-Management Responsibilities for the following positions; Quality Assurance Director, Pesticide Administrator, Manager, Pesticide Applicator Certification Program, Pesticide Program Specialist, Compliance Officer, Fertilizer Administrator, Seed Administrator and Microbiology Laboratory Supervisor (Justification: to better reflect current duties of those individuals). (d) Removed Water Quality & Endangered Species Specialist job description (Justification: this position no longer exists. Job duties were added to Pesticide Administrator’s job description). (e) Added job descriptions for Agricultural Ammonia Specialist and Fertilizer Containment Specialist (To capture these new positions in OISC) (f) Updated organizational charts for all sections (Justification: to reflect current job alignments). (g) Included new training requirements for initial training on all general SOPs, job specific MTDs and Policies and any updates on those procedures thereafter (Justification: so all employees are trained on pertinent procedures). (h) Added that QA will maintain a training matrix that designates on which procedures employees are trained (Justification: to have documentation of this) (i) Updated training requirements for both Pesticide Investigators and Seed, Feed, and Fertilizer inspectors to include U.S. EPA training and specific manuals Inspectors must train on (Justification: to capture the required training). (j) Removed signature block at the bottom of each page (Justification: document will be signed by all management on the signature page indicating approval). (k) Removed the revision of each policy (Justification: the entire QMP was updated and will be under one revision number). (l) Update Policy 4.0-Services to include the Office of Contracts and Grants is responsible for ensuring all services procured with federal funding sources are done so in compliance with the terms required by the federal granting authority (Justification: to capture this requirement). (m) Removed Fertilizer Investigations from the Pesticide Investigations in Policy 5.0-Documentation and gave Fertilizer Investigations its own section within the Policy (Justification: Fertilizer Investigations have some of its own required documentation for investigations that differs from the documentation for pesticide investigations). (n) Removed reference to form DF 00013 PR: Accelerated Solvent Extractor Worksheet in Policy 5.0-Residue Laboratory (Justification: This form is no longer in use). (o) Removed “Pesticide” in Policy 5.1-Records for Laboratory Records (Justification: the requirements outlined in this section will encompass all laboratory records, not just Pesticides). (p) Added sections in Policy 5.2-Documents for Section Specific SOPs and Methods (Justification: These are types of documents available to employees to outline OISC procedures) (q) Updated Policy 5.2-Documents, Revisions section (Justification: To reflect current practice per updated and new procedures SOP 0001-GN, “Preparation, Issuance, and Maintenance of the Office of Indiana State Chemist Standard Operating Procedures” and SOP 0279-GN, “Preparation, Issuance, and Maintenance of the Office of Indiana State Methods”). (r) Added examples of General and Section Specific Standard Operating Procedures title page header and footer and example of Method title page header and footer as attachments to Policy 5.2 (Justification: to show as, as an example, the different
types of documents). (s) Updated the Flow Charts of document review processes to Policy 5.2 (Justification: to reflect practice outlined in SOP 0001-GN, “Preparation, Issuance, and Maintenance of the Office of Indiana State Chemist Standard Operating Procedures” and SOP 0279-GN, “Preparation, Issuance, and Maintenance of the Office of Indiana State Methods”). (t) Added Quality Assurance to the Internal Audit Schedule (Justification: to add the requirement of an annual audit of Quality Assurance to ensure QA’s adherence to policies and procedures). (u) Added the requirement to Policy 9.0-System reviews that the internal audit of Quality Assurance must be lead and conducted by those outside of the quality assurance unit (Justification: to prevent a bias during the internal audit on Quality Assurance). (v) Added to Policy 10.0—Quality Improvement that a copy of the Management Review Report that impacts the pesticide section will be made available to EPA upon request by the agency (Justification: to describe how the report is made available to EPA) (w) Added reference to the OISC Record Retention Master list (Justification: to capture the length of time documents are kept according to Purdue University policy). (x) Added to section 7.0: Planning that the DQO process will feed into a method additionally to the QAPP (Justification: the method followed by an investigator will be developed due to the DQO process). (y) Removed the Distribution List. (Justification: The QMP will be trained on by all employees of OISC and will be distributed to the entire agency). (z) Made editorial changes.
Delegation of Authority

I have ensured that the following delegates have the necessary education, training, and experience to approve general Standard Operating Procedures (SOPs) for Laboratory Director.

<table>
<thead>
<tr>
<th>Document Number and Title</th>
<th>General SOPs designated with a –GN per SOP 001-GN Rev. 05</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delegate</td>
<td>D. Brett Groves or David E. Scott</td>
</tr>
</tbody>
</table>

Reviewer Signature: [Signature]

Date: 9-3-2014
Robert D. Waltz, Ph.D.
Indiana State Chemist & Seed Commissioner
Purdue University
175 South University Street
West Lafayette, Indiana 47907-2063

Re: Office of Indiana State Chemist (OISC)
Quality Management Plan (QMP)

Dear Dr. Waltz:

The U. S. Environmental Protection Agency, Region 5, Land and Chemicals Division (LCD), has carefully reviewed the OISC’s QMP for the pesticide program, as conducted under the EPA Performance Partnership Agreement for pesticide regulation and enforcement.

A review team recommended that your QMP be accepted and approved. Accordingly, I am pleased to approve your QMP for a period of three years beginning January 20, 2015.

Revision of this QMP may be required prior to its final expiration, based on such events as periodic assessments by EPA Region 5, changes in EPA regulations or policy, your review of your Quality System, or significant changes in your organization, resources or scope of mission.

If you have any questions regarding FIFRA Quality Assurance programs, please contact me or your staff may contact Bruce Wilkinson, the Technical Contact, at (312) 886-6002 and/or Dr. Larisa Leonova, FIFRA/TSCA Quality Assurance Coordinator, at (312) 353-5838.

Sincerely,

Margaret M. Guerrieri,
Director
Land and Chemicals Division

RECEIVED
FEB 28 2015
INDIANA STATE CHEMIST
Change Control Form

<table>
<thead>
<tr>
<th>Requestor Name Print</th>
<th>Signature</th>
<th>Request Date</th>
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<tbody>
<tr>
<td>Carrie A. Leach</td>
<td>Carrie A. Leach</td>
<td>7/8/2015</td>
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<table>
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<tr>
<th>Type of Change Requested</th>
<th>Reason for Change (Include procedure name(s) and number(s), instrument/computerized system name(s), specification types, form number, etc)</th>
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<tbody>
<tr>
<td>Raw Material</td>
<td>In the Policy 5.0 Documentation section of the Quality Management Plan (page 23) a reference is made to DF 00011: Percent (%) Moisture Worksheet. Changes made to MTD 0008-PR Rev. 02 removes the requirement of this form.</td>
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<td>Specification</td>
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<td>Instrument/Equipment</td>
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<td>Computerized System</td>
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<td>Cleaning Procedures</td>
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<tr>
<td>SOP/MTD/QMP/QAPP</td>
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<td></td>
<td>(specify which in reason for change)</td>
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<tr>
<td>Form</td>
<td></td>
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<tr>
<td>Policy</td>
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Justification for Change

Removing moisture from sample degrades or removes the semi-volatile pesticides and herbicides and should not be performed on modern samples. Moisture determination on soil is an old practice. The procedure itself is time consuming and brings little value to the data quality objectives of the pesticide misuse investigations. Many State Regulatory Pesticide Labs that perform testing to support the pesticide investigation for soil samples no longer report soil moistures. DF 00011 “Percent (%) Moisture Worksheet” and GLAB-009 “Determination of Percent Moisture in Soil or Plant Materials” will be made obsolete with issuance of Rev. 02 of MTD 0008-PR. Refer to form 29 “Form to Obsolete a MTD” # 697 for obsolescence of GLAB 009 Rev. 2 and DF 00011. See also the revision history of MTD 0008-PR Rev. 02 for the changes and justifications.

Acceptance of this change by approval signatures on this form indicates DF 00011 is no longer necessary documentation for the laboratory case file as indicated in Policy 5.0 Documentation of the QMP. This change will be included in the next update of the QMP.
List all Procedures that will need to be updated due to this change including revision numbers

☐ NA

This change is due to an update to MTD 0008-PR (supersedes GLAB-008 Rev. 1)  

<table>
<thead>
<tr>
<th>Approvals</th>
<th>Signature</th>
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</thead>
<tbody>
<tr>
<td>Robert D. Waltz</td>
<td>[Signature]</td>
<td>State Chemist and Seed Commissioner</td>
<td>7-8-15</td>
</tr>
<tr>
<td>D. Brett Groves</td>
<td>[Signature]</td>
<td>Chief Inspector/Auditor</td>
<td>7-8-15</td>
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<td>Ping Wan</td>
<td>[Signature]</td>
<td>Pesticide Laboratory Supervisor</td>
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<tr>
<td>H. Dorota Inerowicz</td>
<td>[Signature]</td>
<td>Feed Chromatography Laboratory Supervisor</td>
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<tr>
<td>James Bartos</td>
<td>[Signature]</td>
<td>Feed/Fertilizer Automated Analysis Supervisor</td>
<td>2-8-15</td>
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<td>Mark Moelhman</td>
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<td>Microbiology Laboratory Supervisor</td>
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<td>Larry Nees</td>
<td>[Signature]</td>
<td>Seed Administrator</td>
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<td>Robert Geiger</td>
<td>[Signature]</td>
<td>Feed Administrator</td>
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<td>Matthew E. Pearson</td>
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<td>Fertilizer</td>
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<td>Justification if deadline was or cannot be met</td>
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<td><strong>Mark Sobers</strong></td>
<td>IT Manager</td>
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<tr>
<td><strong>Carrie A. Leach</strong></td>
<td>Quality Assurance Director</td>
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<td><strong>QA Use:</strong></td>
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<td>QA Initial and Date</td>
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