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PESTICIDES & TOXICS BRANCH
Waste Pesticides & Toxics Division
U.S. EPA - REGION 5

Office of Indiana State Chemist Quality Management Plan

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Signature Page

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Office of Indiana State Chemist

Mission Statement

The mission of Office of Indiana State Chemist is to assure truth in labeling for feed, fertilizer, pesticide and seed products offered for sale in Indiana, plus, ensure food safety, user safety and protection of the environment.

We accomplish this by ensuring that all data generated and processed will be scientifically valid, of known precision and accuracy, of acceptable completeness, representativeness, and comparability and, where appropriate, legally defensible.

The management within our organization is responsible for the quality and integrity of all data generated by this office. The management, collectively, assures this quality through adherence to our Quality Management Plan, Quality Assurance Project/Program Plan(s) and through the development and adherence to Standard Operating Procedures.



Interim State Chemist

Signature Page


Interim State Chemist

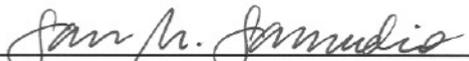
8/30/05
Date

 SS 8/30/05
State Chemist

12/2/03 SS 8/30/05
Date


Associate State Chemist/Laboratory Director

12/1/03
Date


Quality Assurance Officer

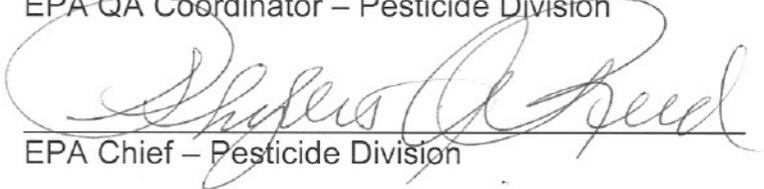
12/1/03
Date


EPA Indiana Project Officer

12/4/03
Date


EPA QA Coordinator - Pesticide Division

12/04/03
Date


EPA Chief - Pesticide Division

12/5/03
Date

Distribution List:

Name	Area	Distribution Date
Dr. Rodney Noel	Interim State Chemist	12/2003
Dr. Rodney Noel	Associate State Chemist/Laboratory Director	12/2003
David E. Scott	Pesticide Administrator	12/2003
Robert Geiger	Feed Administrator	12/2003
Mike Hancock	Fertilizer Administrator	12/2003
Larry Nees	Seed Administrator	12/2003
Ben Hands	Manager Information Systems	12/2003
Jeff Hardy	Pesticide Residue Laboratory Supervisor	12/2003
Douglas Moore	Pesticide Formulation Laboratory Supervisor	12/2003
Dr. Hussein Ragheb	Microbiology Laboratory Supervisor	12/2003
Peter Kane	Fertilizer/Automated Trace Analysis Laboratory Supervisor	12/2003
George Saxton	Pesticide Compliance Officer	12/2003
Dr. Ken Riter	Feed Laboratory Supervisor	12/2003
Sara M. Samudio	Quality Assurance Officer	12/2003
Dale Meyer	EPA Chief - Pesticide Section	12/2003
Larisa Leonova	EPA QA Coordinator - Pesticide Division	12/2003
Meonii Bristol	EPA Indiana Project Officer	12/2003

Office of Indiana State Chemist
Quality Management Plan

The Management within the Office of Indiana State Chemist is responsible for the overall quality and integrity of all data generated by this office. The Management, collectively, assures this quality through adherence to the Policies outlined in the Quality Management Plan and through the development of and adherence to Standard Operating Procedures.

The Management within the Office of Indiana State Chemist has individual responsibilities. These responsibilities include, but are not limited to:

State Chemist and Seed Commissioner - Responsible for the oversight of all laboratory activities and field programs. Responsible for the administration of the laws assigned to this office.

Associate State Chemist/Laboratory Director - Directs the operations of the Office of Indiana State Chemist laboratories. Assists the State Chemist, acting for him in his absence, in the administration of the laws assigned to the office.

Quality Assurance Officer - Performs QA/QC activities for all sections of the Indiana State Chemist Laboratories. This includes, but is not limited to, the development of QA/QC Programs for the Indiana State Chemist Office (i.e. Quality Management Plan), the preparation of SOP's, responsibility for all check sample programs, perform audits (internal and external) and facilitate training (safety and quality).

Pesticides

Pesticide Administrator - Administers state and federal pesticide laws and regulations covering pesticide products and their use as assigned to the Office of Indiana State Chemist: registration, sale, analysis, distribution and storage and use of products; certification and licensing of applicators. Directs the activities of the field staff and coordinates the administrative and clerical staff supporting the pesticide programs.

Assistant Pesticide Administrator - Advises the Pesticide Administrator, and acts for him on numerous occasions, in the administration of the state and federal pesticide laws and regulations.

Manager, Pesticide Applicator Certification Program - Provides administrative and management supervision for the commercial and private applicator certification and re-certification programs in Indiana. Coordinates these programs with Purdue Pesticide Programs, Applied Management Professionals (AMP - our remote testing provider), other

states and the EPA. Develops and validates certification exams with assistance from various state government officials and industry associations. Makes technical policy decisions regarding necessary training and certification requirements and proper handling procedures for a broad range of pesticides.

Pesticides Program Specialist - Provides oversight and planning in the area of mass communications with the general public, regulated industries, individuals and other cooperating agencies in carrying out provisions of the state and federal pesticide laws. Assists and supports the pesticide investigation/inspection staff of the Office of Indiana State Chemist with investigation procedures, case tracking and final case disposition. Oversees state implementation of the Worker Protection Standard.

Pesticide Compliance Officer - Administers an effective compliance program for the enforcement of state and federal pesticide laws. Develops and oversees the implementation of technical policies and administrative procedures to ensure compliance.

Fertilizer & Agricultural Ammonia

Administrator - Responsible for administering the Commercial Fertilizer Law, Agricultural Ammonia Law and Lawn Care Service Law, which govern sales, distribution and storage of fertilizer and the safe transportation, storage and handling of anhydrous ammonia. Consults and works with the Chief Inspector regarding field inspection activities, serving as a technical resource to this staff. Interacts with the Laboratory Director 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 the law.

Feed

Administrator - Administer State laws and 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 regarding field inspection activities and serves as a technical resource to this staff. The Administrator is a commissioned officer of the Food and Drug Administration (FDA), and as such cooperates with the 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 in the State of Indiana.

Seed Control Program

Administrator - Overall administration of the regulatory program, in cooperation with USDA, for agricultural and vegetable seeds and for legume inoculants in Indiana, and the administration of the Indiana Seed Arbitration Law, a law designed to provide a system of arbitrating disputes between sellers and buyers of seed products in the state. Develops programs and policies assisting the regulated industries to maintain compliance and minimize violations. Reviews all registration applications, label copy, advertising and product content; based on this evaluation, approves or disapproves the 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 regarding field inspection activities and serves as a technical resource to this staff.

Auditor and Chief Inspector

In coordination with the respective program administrators, manages the field staff and inspection program for inspections covering feeds, fertilizers and seeds under the laws administered by the Office of Indiana State Chemist. In conjunction with the feed administrator, coordinates joint inspections with the Food and Drug Administration for Good Manufacturing Practices (GMP's) in medicated feed production. Trains new inspectors and updates training and information base of all inspectors to assure currency in new developments and approaches to regulatory situations/problems. Designs and implements strategies for auditing firms paying quarterly inspection fees covering the distribution of feeds, fertilizers and seed. Audits quarterly and/or semi-annual tonnage reports and sales records of regulated firms.

Laboratories

Pesticide Residue Laboratory Supervisor - Supervises all activities in the Pesticide Residue Section. Issues work assignments, determines procedures for analysis, oversees instrumentation, maintains records of various analyses suitable for use as court evidence. Final responsibility for results of analysis performed by assigned personnel; interprets analytical results according to applicable Federal, State and local statutes as well as AOAC International, Good Laboratory Practices and other recognized standards.

Pesticide Formulations Laboratory Supervisor - Supervises all activities in the Pesticide Formulation Section. Oversees work assignments, procedures for analysis and instrumentation. Maintains records of various analyses suitable for use as court evidence. Final responsibility for results of analyses performed by assigned personnel; interprets analytical results according to applicable Federal, State and local statutes as well as AOAC International, Good Laboratory Practices and other recognized standards.

Microbiology Laboratory Supervisor - Directs the activities of the State Chemist's Microbiological Laboratory and is responsible for the assay of official samples collected by the inspectional staff. Directs the work of technicians assaying feed samples for antibiotic content and disinfectants for antibacterial activity. Develops and evaluates new procedures and techniques of microbiological assays, determines microbial counts of inoculant products.

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

Feed Chromatography Laboratory Supervisor - Coordinates all work in drugs and vitamin section and certain other general feed analyses in the Laboratory by supervising full time analysts. Trains employees, issues work assignments, determines procedures for analysis, oversees instrumentation in assigned area and maintains records of various analyses. Has final responsibility for results of analyses performed in assigned areas of the laboratory.

Attachments:

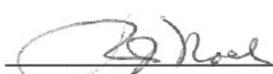
Attachment A: Pesticides Organizational Chart

Attachment B: Seed Organizational Chart

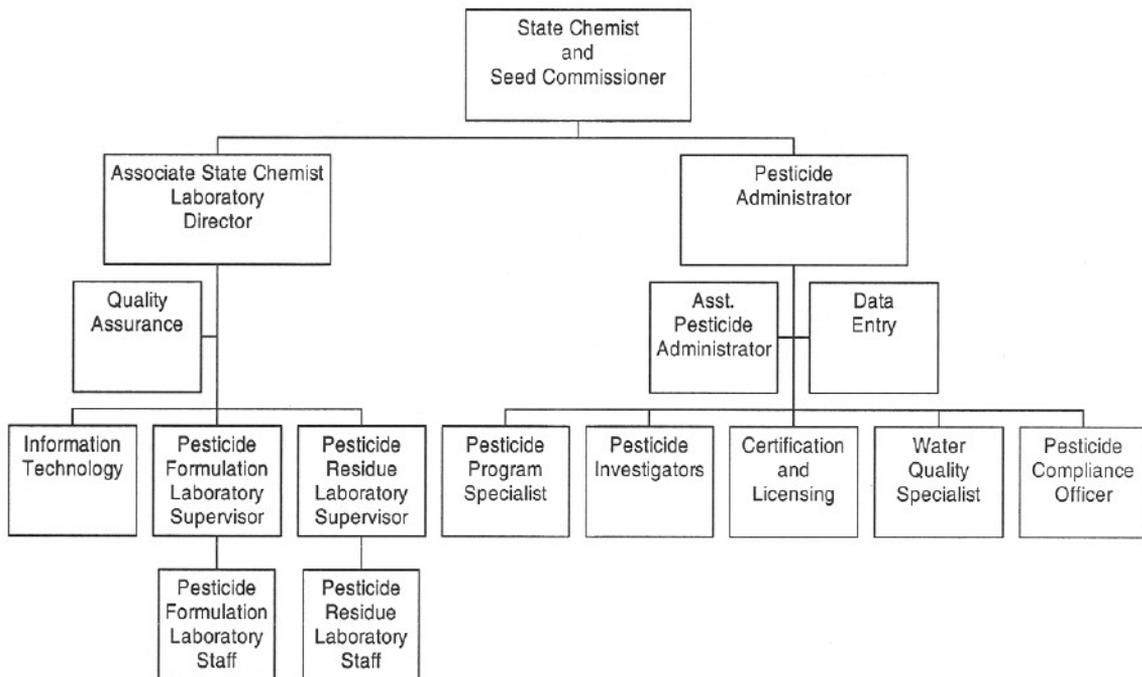
Attachment C: Feed Organizational Chart

Attachment D: Fertilizer and Agricultural Ammonia Organizational Chart

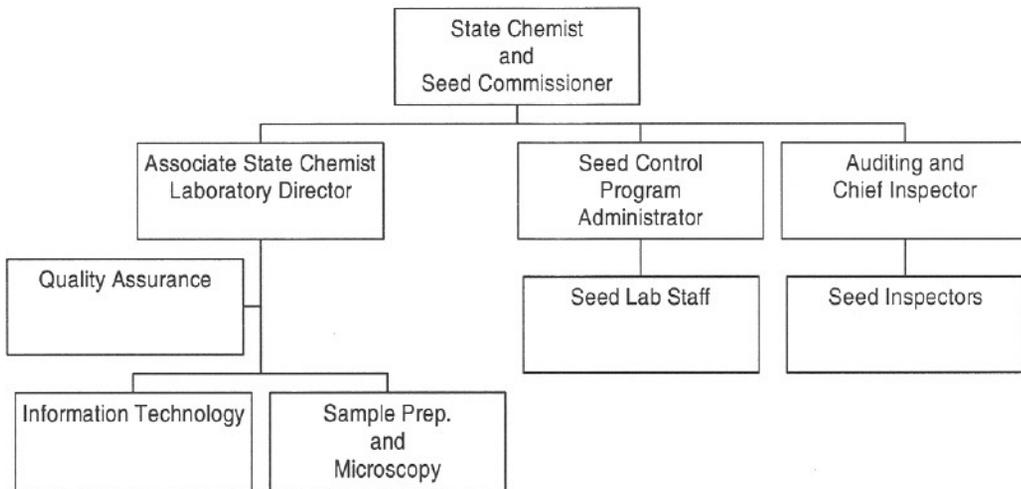
Attachment E: Office of Indiana State Chemist Organizational Chart

 Written by	<u>10/4/04</u> Date	 Approved by	<u>10/5/04</u> Date
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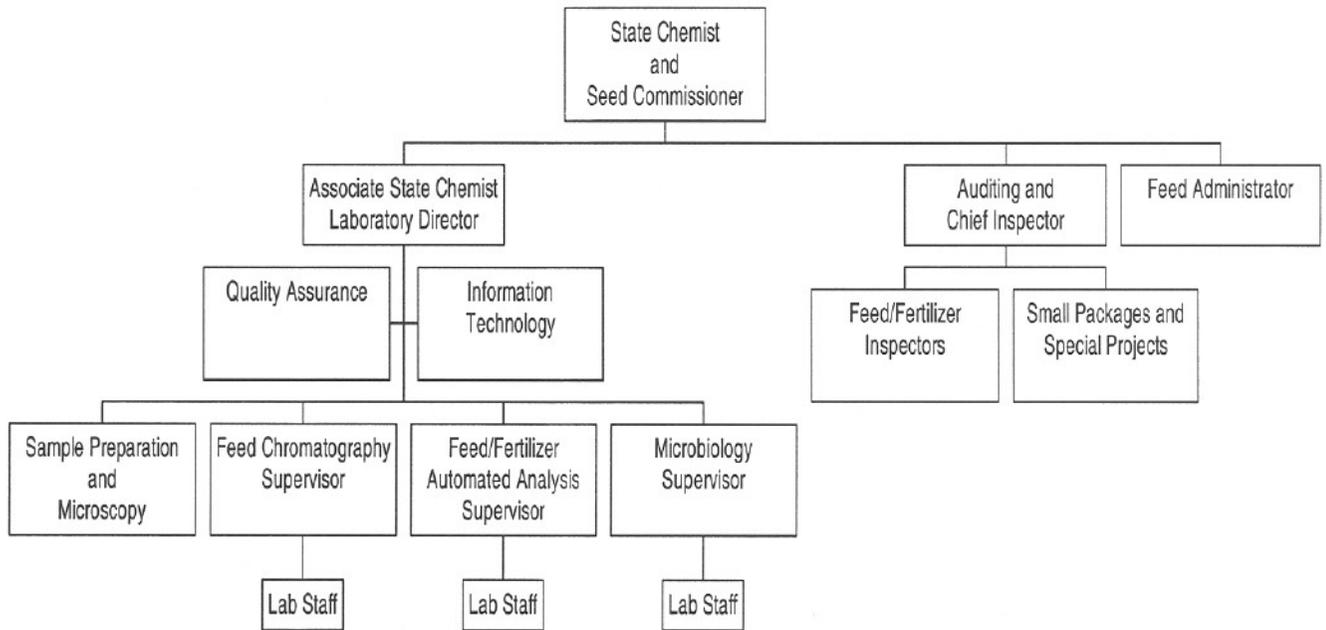
Pesticide Section



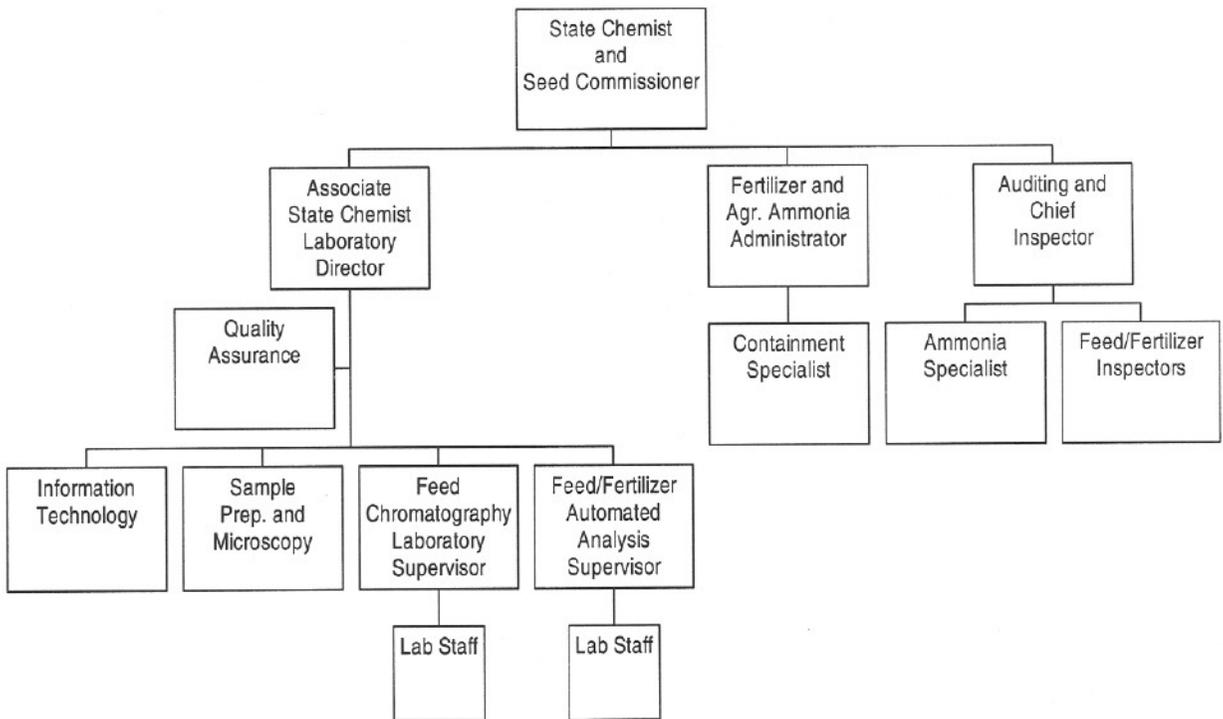
Seed



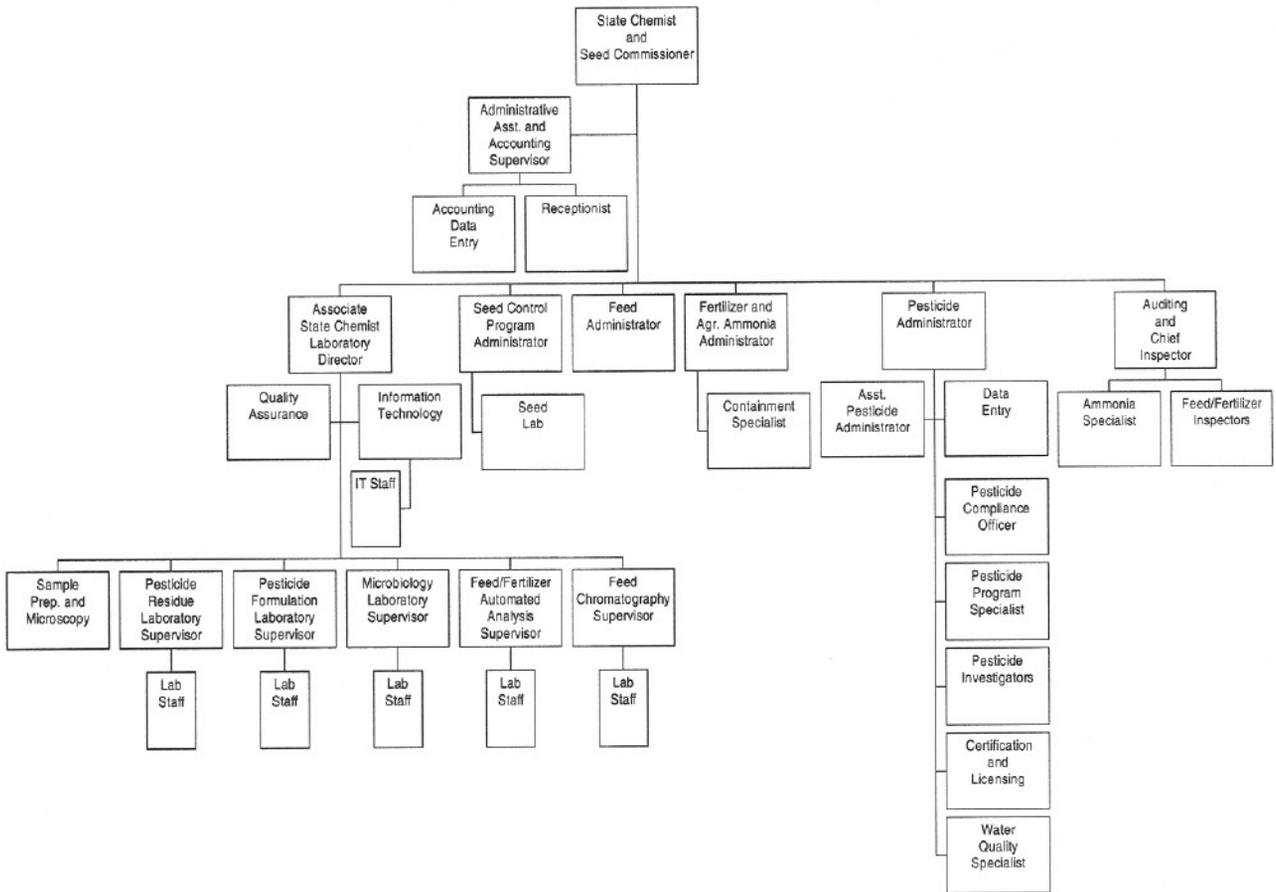
Feed



Fertilizer and Agricultural Ammonia



Office of Indiana State Chemist



OVERVIEW

The Office of Indiana State Chemist (OISC) has put into place a Quality System identified as the Quality Management Plan (QMP). The Quality Management Plan is set up as a complete systemic quality plan that breaks out into individual areas (modules). The modules develop their Standard Operating Procedures (SOP's) and practices within the systemic QMP.

SYSTEMIC QMP

The system level of the QMP delineates the Policies, System Reviews (audits), QA Project/Program Plan(s), Training (safety and QMP) and Data Quality Objectives and reviews, for OISC. It is the responsibility of the QA unit to maintain the QMP, facilitate training, perform audits of the system, assist in the development of quality plans and the review of these quality plans, assist in the development of data quality objectives and determine if they are being met. It is the responsibility of all OISC management to incorporate the QMP to their areas and to communicate the importance and benefit of the QMP to all OISC employees.

MODULAR QMP

The modular (individual systems) level of OISC delineates the SOP's, technical assessments and training (safety and procedural) for each individual system. The individual areas (systems) develop their practices within the guidelines of the systemic QMP, (i.e. training has to occur as per Policy 3.0, Training, SOP's must follow the format as outlined in Policy 5.2, Documents, etc). Area Management/Supervisors are responsible for the development, verification and implementation of their area SOP's and practices. They are, in conjunction with the Quality Assurance unit, responsible for assuring that their employees are adequately trained in all areas that impact their ability to perform their job.

SYSTEMS AFFECTED BY THE QMP

Pesticides

- ▶ Pesticide Investigators
- ▶ Ground Water Program
- ▶ Pesticide Residue Laboratory
- ▶ Pesticide Formulations Laboratory

Feed

- ▶ Feed Chromatography Laboratory
- ▶ Feed Automated Analysis Laboratory
- ▶ Microbiology Laboratory

Fertilizer & Agr. Ammonia

- ▶ Fertilizer Automated Analysis Laboratory

Seed Control Program

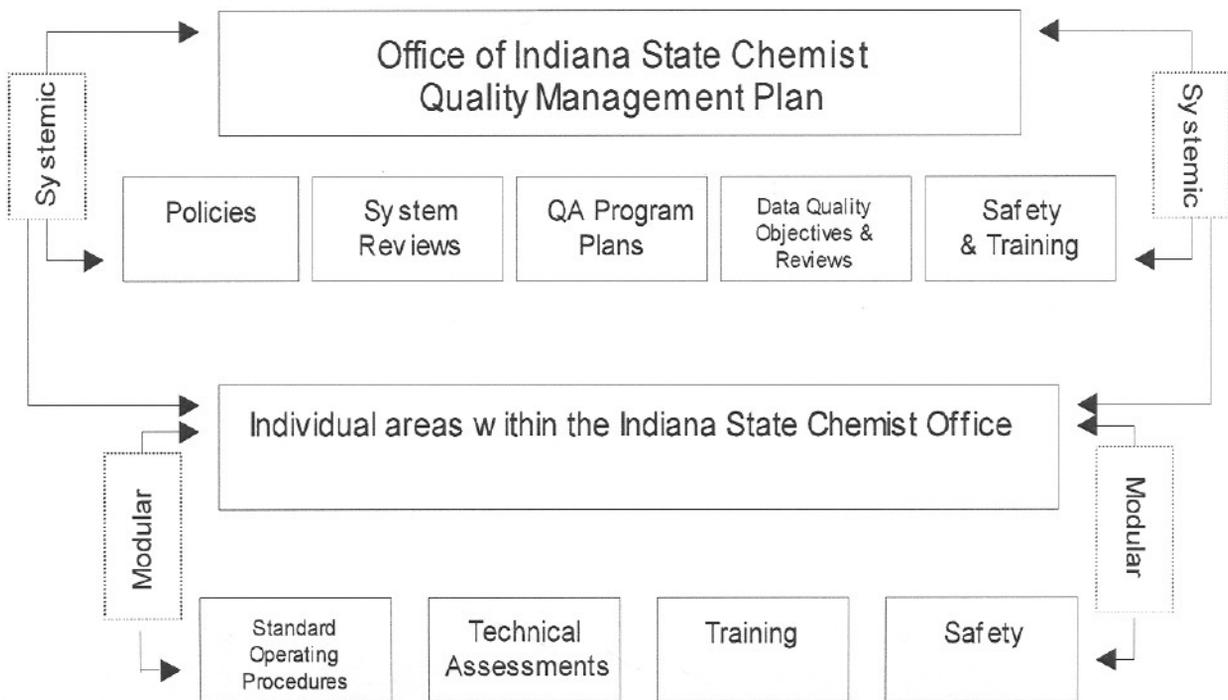
- ▶ Seed Laboratory

Auditing and Chief Inspector

- ▶ Feed, Seed and Fertilizer Sample Collection
- ▶ Inspectors

Sample Preparation

OISC's QMP is set up in the following manner:



<p><i>Jan M. Jamulio</i> Written by</p>	<p>10/4/04 Date</p>	<p><i>Rg Rose</i> Approved by</p>	<p>10/5/04 Date</p>
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Qualifications

All personnel of the Office of Indiana State Chemist 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 Purdue personnel.

New positions have a complete job description (includes minimum educational and/or work experience required) prior to the new position being submitted to Purdue personnel for classification. Job descriptions for existing positions that need to be filled are reviewed by management prior to the posting of the position (the review should evaluate the minimum requirements for the position and determine if they are still appropriate).

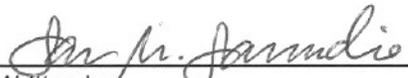
Training

Subsequent training shall be accomplished through documented On the Job Training (OJT), seminars, formal education, etc. It is the responsibility of the area manager/supervisor, or their designee, to retain the individual's training records and provide copies to the QA Officer.

Employees will be notified of any modifications and/or new documents (documents being defined as SOP's, policies, methods, QAPP's) within their work areas.

All affected OISC personnel shall receive, at an interval not to exceed one (1) year, training on the Office of Indiana State Chemist Quality Management Plan. This training can occur via many routes, e.g. e-mail, memos, seminar, etc. QMP training shall be documented (documentation including date of training and personnel trained). This documentation shall be maintained by the QA unit.

Attachments: Attachment A Training Time Table

 Written by	10/4/04 Date	 Approved by	10/5/04 Date
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General

- ◆ Annual First Aid and CPR training
- ◆ Fire Safety Training every two years
- ◆ Annual Laboratory hazardous materials training
- ◆ "Ethics for State Employees" every two years

Laboratory

- ◆ Annual EPA region 5 laboratory training (as applicable between the residue and formulation laboratories).
- ◆ Vendor supplied training with each new piece of laboratory equipment supplied within 1 year of equipment purchase.
- ◆ Participation in collaborative studies.
- ◆ Participation, at minimum of semi-annually, in check sample programs.

Field Staff

- ◆ Region 5 annual Investigator training - Pesticides staff
- ◆ Feed officials annual Inspector training - Inspection staff

The training time table listed above are not the only training opportunities available to the OISC staff. They are, however, offered on an annual or bi-annual basis.

The Office of Indiana State Chemist is located 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 'x' amount must go out for bid, all items purchased must be approved by the area manager, approved purchase requests must accompany all purchased items. Purchase receipts are kept for 'x' amount of years by Purdue's accounting department.

SERVICES

The Office of Indiana State Chemist (OISC), through Purdue University Office of Contracts and Grants, contracts outside sources, independent contractors, to perform services. OISC assures the quality of the work performed by the independent contractors through the following:

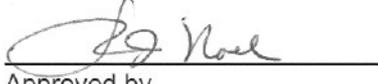
- A contract is in place between Purdue University and the independent contractor. The contract spells out what is required by OISC, what guidelines the independent contractor is to follow and any special requirements associated with the task.
- A point person within OISC is assigned to any out-sourced 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 tasks. These records are reviewed for accuracy and completeness. These records are regarded as part of OISC's quality system and are maintained as such.

ITEMS

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

- Certificate of Analysis (C of A)
- Certificate of Conformance (C of C)
- Certificate of Calibration
- Warranty of Operation

These warranties/guarantees are maintained by each laboratory for analytical standards for the life of the purchased product.

 Written by	<u>10/4/04</u> Date	 Approved by	<u>10/5/04</u> Date
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DOCUMENTATION

All work done by the Office of Indiana State Chemist (OISC) shall be documented. Each area within OISC has specific documentation requirements. All documents shall be retained for a minimum of five (5) years.

Pesticides

Complaints

All Case files, at a minimum, shall contain:

- Notice of Inspection
- Case Summary

Additional documentation is required for the following:

Case File for complaint involving an application:

- Pesticide Incident Form
- Case Summary/transmittal letter to complainant (if one exists) and alleged violator

Case File for a complaint or a tip:

- Pesticide Incident Investigation Worksheet
- Case Summary/transmittal letter to complainant (if one exists) and alleged violator

Case File for an investigation in which a violation was determined:

- Enforcement Letter
- Record of 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. Collection report for formulation samples and Pesticide Incident Form for residue samples)
- Diagram of area from which the samples were taken (for residue samples)
- Analysis results

Case File in which photographs, video and/or audio tapes were created:

- Documentation in the case file indicating that photographs, video and/or audio tapes 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:

- Copy of OISC-generated complaint withdrawal letter (Instead of a Case Summary)

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

- Copy of OISC-generated letter (Instead of a Case Summary) indicating that the case will be dismissed due to lack of cooperation from the complainant.

Note - The case file documentation is not exclusive. A case file may require all of the above mentioned documents.

Routine Inspection

For the inspections listed below, a Notice of Inspection (NOI), at a minimum, is required **per event**:

- Agricultural (AG) Use
- Non Agricultural Use
- Marketplace
- Certified Applicator (CA) Records
- Dealer Records
- Experimental Use
- Imports

For the inspection listed below, a Notice of Inspection (NOI) and a Pesticide Producer Establishment Inspection Report (Narrative), at a minimum, is required **per event**:

- Establishment

Additional documentation is required for the following:

Samples are taken from the inspection location:

- Pesticide Sample Collection Report
- Chain of Custody

Residue Laboratory

All Case files shall contain the following:

- Pesticide Incident Investigation Worksheet/(back side) Sample Submission sheet
- Pesticide Residue Lab case report (Internal)
- Pesticide Residue Lab case report (External)
- Sequence Summary Report (Chromatography packets)
- Spike/Fortification Record (if applicable)
- Chain of Custody Seal(s) form
- Case Content sheet

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

Case File in which the matrix is soil:

- Percent (%) Moisture Worksheet

Case File in which the sample was diluted:

- Sample Dilution Worksheet

Case File in which a sample required the use of the Accelerated Solvent Extractor:

- Accelerated Solvent Extractor Worksheet

Note - The case file documentation is not exclusive. A case file may require all of the above mentioned documents.

Formulation Laboratory

All 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:

- Chain of custody Form

Note - The case file documentation is not exclusive. A case file may require all 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

 Written by	<u>10/4/04</u> Date	 Approved by	<u>10/5/04</u> Date
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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:

- Pesticide case files (inclusive)
- Site inspection case files
- Laboratory case files (all data generated)
- Laboratory analytical results
- Laboratory QA/QC data (spikes, blanks, etc.)
- Chain of custody paperwork
- Spent custody seals
- Sample receiving paperwork
- Check Sample Results
- Audit Results

RECORD REVIEW

Note: Non-Pesticide areas include the following:

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

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

Pesticide Case Files- Pesticide Investigation/Pesticide Site Inspection:

Case files are reviewed for accuracy and completeness by the Area Manager, e.g., Pesticide Administrator, 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 past the expiration of the current QAPP. The Area Manager, or their designee, is responsible for the correctness and completeness of the records.

Pesticide Laboratory Records:

Laboratory records are reviewed for accuracy and completeness. This review includes, but is not limited to, raw data, standards, lab notebook entries, sample preparation, equipment "run" parameters, internal QA/QC sample run results, final results report, etc. Once the laboratory 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 past the expiration of the current QAPP. The laboratory supervisor is responsible for the correctness and completeness of the laboratory records.

Non-Pesticide Laboratory Records: Lab Records are stored for a minimum of seven (7) years.

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, Laboratory Director and Quality Assurance (QA). 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 and 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 the QA unit will keep the trend reports for a minimum of five (5) years.

Non-Pesticide Check Sample Results: Check sample results are stored for a minimum of seven (7) years.

Third Party Review of Records:

Records will be reviewed as part of an area audit. The quantity of records reviewed in an area audit will be no less than the square root of the total number of records available for the time frame the audit is encompassing plus one (1).

$$\sqrt{\text{Sample set} + 1 \text{ sample}}$$

Example: 500 completed records for "N" time frame in area being audited.

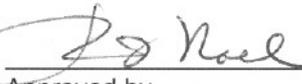
Calculation: Square root of 500 plus one equals, 23.4 records. Twenty-three records, at a minimum, would be reviewed as part of the audit for "N" time frame.

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 environmental data records will be kept for a minimum of five (5) federal fiscal years past the expiration of the current QAPP. Non-Pesticide data records will be kept for a minimum of seven (7) 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.

 Written by	10/4/02 Date	 Approved by	10/5/02 Date
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Departments within the Office of Indiana State Chemist (OISC) prepare technical guidance documents for use within OISC. For the purposes of this Policy, the technical guidance documents prepared by OISC personnel are limited to Policies, QAPP's, Standard Operating Procedures (SOP's) and Test Methods (TM's). Policies and QAPP's are reviewed, at an interval not to exceed two years, to assure that the practices outlined in them are still current and applicable. Standard Operating Procedures are reviewed, at an interval not to exceed one year, to assure that the practices outlined in them are still current and applicable. Test methods are reviewed, at an interval not to exceed two years, to assure that the practices outlined in them are still current and applicable. The Quality Management Plan is to be reviewed yearly. If the documents are not current and 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 in a permanent record with the initials of the reviewer and the date reviewed. The documentation of the review may be captured on a review form, the reviewed document itself or by another acceptable means. Review of the technical guidance documents will be documented and verified through area 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 or the Associate State Chemist.

STANDARD OPERATING PROCEDURES (SOP's)

Note: This section also applies to Test Methods (TM's).

SOP's are specific to the area for which they are written. The approval of an SOP is the commitment of a specific area to an action or behavior. SOP's may be authored by a qualified employee within OISC. The SOP is then reviewed for content by the area supervisor or manager in which the SOP will be used. Once the SOP has been reviewed and found to be acceptable by the area supervisor or manager, the SOP is given to the QA unit for approval. (QA approval is an approval of format, not necessarily of content.)

The format used for writing SOP's should conform to the following:

- Purpose: State the objective for the SOP.
- Scope: Defines the applicability of the SOP.
- Definitions: Define any terms that are specific and/or unique to the SOP. Any abbreviations that are used need to be spelled out at least once.
- Procedure: The detailed "how to" perform the task.
- Attachments: Any documents that are associated with the SOP, such as forms.

- References: Sources of information used to write the SOP.

Note - A qualified person within the area should review the document. The lab director, area administrator, manager or supervisor must approve the document and forward to the QA Officer for QA approval.

REVISIONS

Technical guidance documents are dynamic and will need revision from time to time. Changes should not occur in a vacuum. Potential changes should be discussed with the employees who perform the procedure and area supervisor or manager prior to any changes being made. The process for revising a document is as follows:

- ▶ The revised document will be forwarded to the QA Officer. The QA Officer will fill out a change control form. The document is changed to reflect the revision number; original revision is revision 0, first revision is revision 1, second is revision 2, etc. The individual who initiates the change is responsible for verifying that the changes do not affect any other documents or practices within the system. The individual initiating the document revision makes the tentative revision(s) to the document in ink. The QA Officer will assign a change control number and forward the form and the document to the reviewer.
- ▶ The document is then given to the area supervisor or manager for review. The reviewer is responsible for determining if the changes are valid and acceptable. If the changes are acceptable, the reviewer signs the document. If the changes are not acceptable, the reviewer returns the document to the individual who initiated the change with an explanation as to why the change is not acceptable. If there is a dispute between the author and the reviewer that can not be resolved, the dispute goes to the area supervisor or manager for resolution.
- ▶ The reviewed document is given to the QA officer, who reviews the document for format. If the document is acceptable, it is signed off and put into the quality system. If the document format is not acceptable, the document is returned to the area supervisor or manager for corrections. If there is a dispute between the QA officer and the area supervisor or manager that can not be resolved, the dispute goes to the Associate State Chemist or State Chemist for resolution.
- ▶ The QA unit is responsible for removing all old revisions of the document from circulation and posting the new revision. The change control form will be filed by the QA Officer.

The QA unit 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. The QA unit will keep copies of the previous revisions, up to three previous revisions, for the current document. The previous revisions will be kept on file for a minimum of five (5) years.

MANUAL CORRECTIONS:

Documents may be hand corrected without issuing a change control form if all official copies and the electronic copy on the QC Drive are updated. Any hand written changes on official paper copies of documents must be initialed and dated. The document should be officially changed through the change control process as soon as practicable.

Attachments:

Attachment A: Template of Policy

Attachment B: Template of a Standard Operating Procedure/Test Method

Attachment C: Flow Chart of review process

 Written by	<u>8/29/05</u> Date	 Approved by	<u>8/30/05</u> Date
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Quality Management Plan
Documents
Policy - 5.2

Attachment A - Template of Policy
Revision: 2

(Internal OISC policy)

Office of Indiana State Chemist
West Lafayette, IN

CONTROLLED COPY

Contents of Policy

Reviewed by: _____ Date: _____

Approved by: _____ Date: _____
(Must be approved by Director, Administrator, Manager or Supervisor.)

QA Approved by: _____ Date: _____

Policy #, Rev. #, Rev. date

Page (current page #) of Total Pages

Office of Indiana State Chemist
West Lafayette, IN

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Document Title

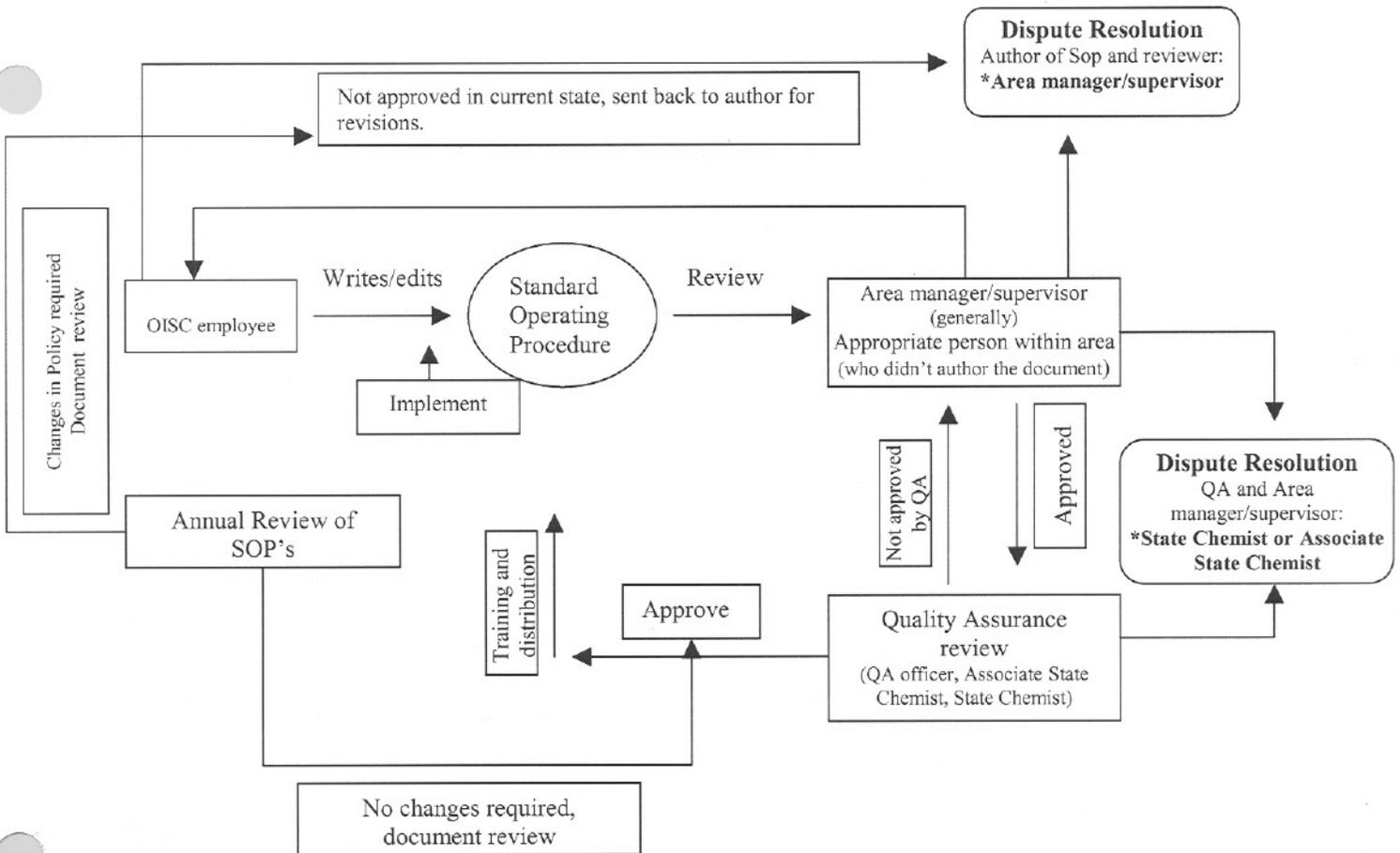
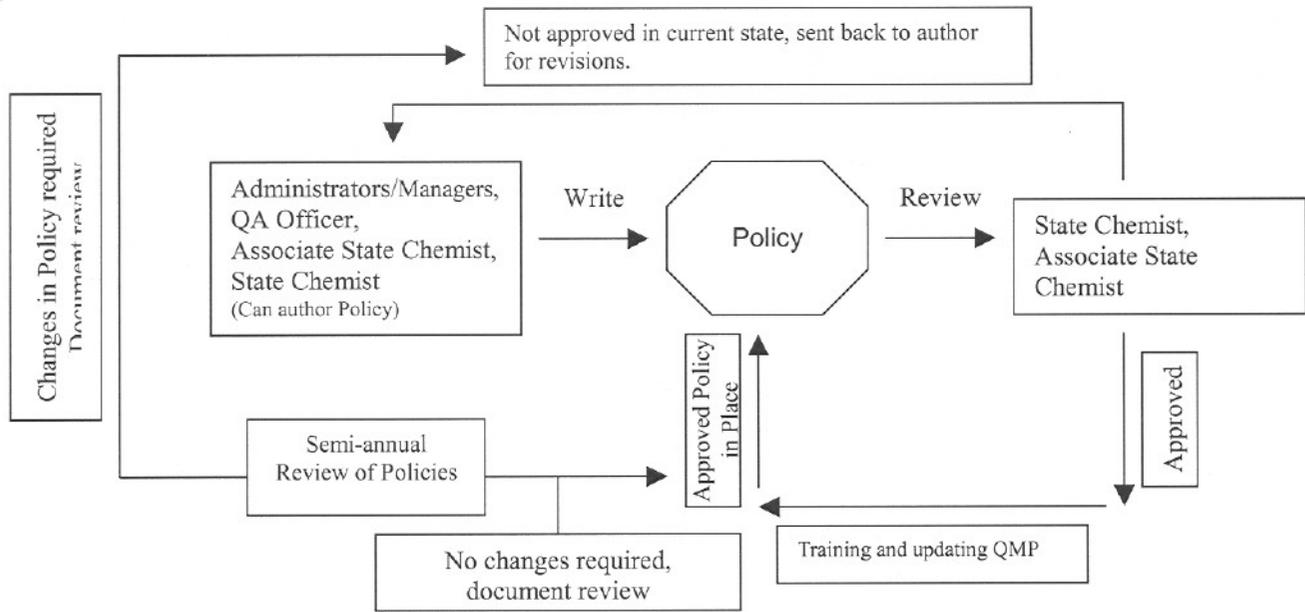
- 1.0 PURPOSE
- 2.0 SCOPE
- 3.0 DEFINITIONS
- 4.0 PROCEDURE
- 5.0 ATTACHMENTS
- 6.0 REFERENCES

Reviewed by: _____ Date: _____

Approved by: _____ Date: _____
(Must be approved by Director, Administrator, Manager or Supervisor.)

QA Approved by: _____ Date: _____

SOP/TM #, Rev. #, Rev. date



* Indicates the responsible party for resolving disputes regarding SOP's

The following five issues are addressed in this Policy:

1. Assurance that computer hardware used by Office of Indiana State Chemist (OISC) meets the needs of the programs using the hardware.
2. Control of changes to hardware 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 that 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 Information Resource Management (IRM) requirements and standards.

Computer Hardware

To ensure that computer hardware used by OISC meets the requirements of the programs using the hardware, the following is followed:

- Computer hardware selection is performed by area administrators, area managers and/or laboratory supervisors, with guidance from the OISC information system (IS) staff.
- Computer hardware is evaluated and chosen based on software and instrumentation requirements which are based on program and user requirements.

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

- Computer hardware changes are driven by software or hardware upgrades to existing equipment (i.e., lab instrumentation, computers, etc.) or the purchase of new equipment needed to fulfill the mission of OISC.
- Area administrators, area managers and/or laboratory supervisors determine necessary changes to computer hardware, 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.

Computer Software

The process for developing 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 a pre-approved test plan, user testing using "live" historical data with known outcomes, covering all major and minor cyclic events and the creation of user guides.

Implementation Phase

Delivery of new system, including user training. Parallel processing in conjunction with old system when warranted and change-over to the new system.

Post-implementation Phase

Minor modifications, as needed, and updates to user and technical documentation.

For major applications, the users on the project team will be involved in validating and verifying the software during all phases of development. For all application development, all 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.

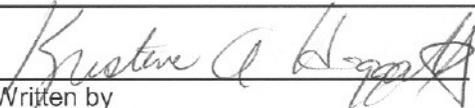
Other software is evaluated based on the following criteria:

- 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 IRM requirements and 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 Associate State Chemist/Laboratory 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.

 Written by	<u>12/1/03</u> Date	 Approved by	<u>12/1/03</u> Date
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The Office of Indiana State Chemist (OISC) has in place a Quality Assurance Program Plan (QAPP). The QAPP is a document that identifies how routine program operations occur. The QAPP is reviewed, at a minimum, of bi-annually to assure that it is still relevant to the operations and programs of OISC.

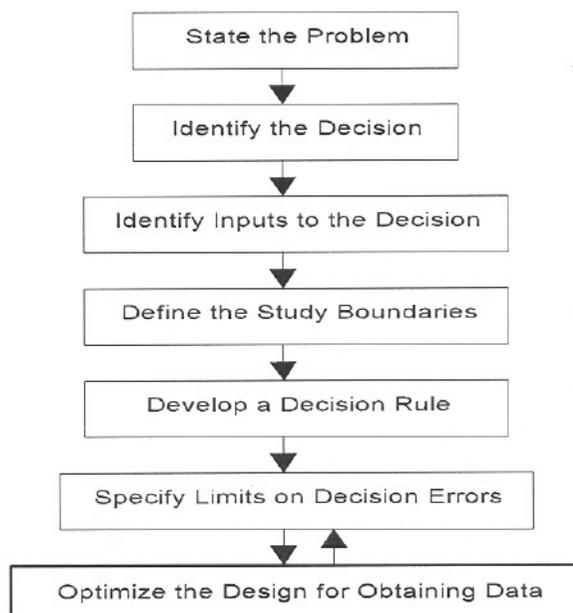
There may be projects that are conducted and/or overseen by OISC that require more specific planning than what is outlined in OISC's QAPP. Projects that require more specific planning shall use the Data Quality Objectives (DQO) process to outline and plan the needs of the project. The outputs of the DQO process should feed into a detailed QAPP or pertinent section(s) of the existing QAPP. All projects have a "project leader" i.e., lead investigator, area specialist, area 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.

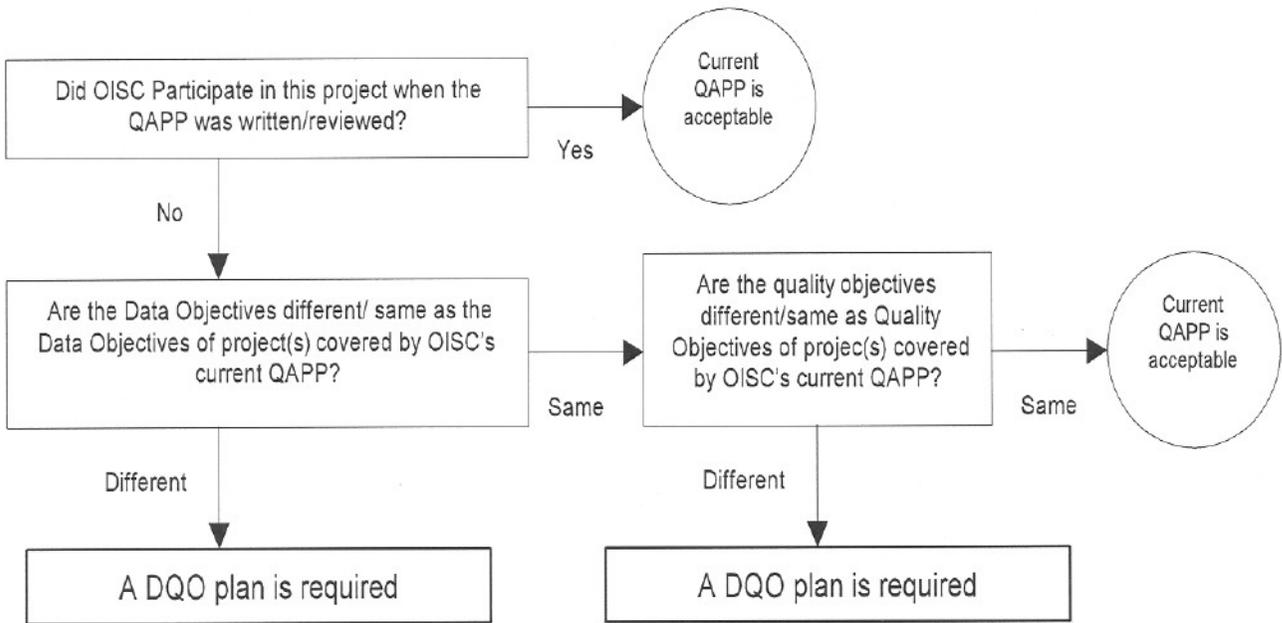
Outline of the DQO Process:



¹ EPA QA/G-4 Guidance for the Data Quality Objectives Process, 1994

The determination as to if the OISC QAPP is sufficient for a project, or if a DQO plan needs to be initiated and implemented is made by the project leader, area manager and Quality Assurance.

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



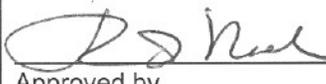
DQO plans are kept as permanent records, and are maintained according to OISC Policy 5.1 Records.

<u><i>J. M. J. J. J.</i></u> Written by	<u>12/1/03</u> Date	<u><i>[Signature]</i></u> Approved by	<u>12/1/03</u> Date
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All work processes implemented by OISC shall adhere to the policies outlined in the OISC Quality Management Plan, QAPP and subsequent SOP's. Management and area supervisor(s) are responsible for the work performed in their areas. They are responsible for verifying that work is performed according to the following, as applicable: established Policies, Standard Operating Procedures (SOP's), Test Methods (TM's), Approved QAPP's, established and approved methods from recognized sources (i.e., AOAC International, AAPCO), established training methods and Good Laboratory Practices. Deviations from established protocols should be documented. All deviations should be reviewed and evaluated by the area manager/supervisor.

It is the responsibility of the area manager/supervisor to assure that their employees are qualified and properly trained, in accordance with Policy 3.0- Personnel Qualification and Training.

It is the responsibility of area management/supervisor to assure that the appropriate documents (documents being SOP's, policies, methods) are in place for their areas.

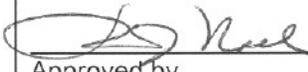
 Written by	<u>10/4/04</u> Date	 Approved by	<u>10/5/04</u> Date
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The purpose of the Quality Assurance Program Plan (QAPP) is to provide an overview of the project, describe the need for the measurements, and define QA/QC activities to be applied to the project.

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

- ▶ 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
- ▶ 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
 - Data Management
- ▶ Assessment Oversight
 - Assessments and Response Actions
 - Reports to Management
- ▶ Data Validation
 - Data Review, Validation and Verification Requirements
 - Validation and Verification Methods
 - Reconciliation with Data Quality Objectives

The adherence to the QAPP is the responsibility of the management within the Office of Indiana State Chemist. The QAPP(s) shall be reviewed by the Quality Assurance Officer, laboratory supervisor(s) or their designee, program/project manager(s) or their designee and program administrator(s) (or their designee), a minimum of bi-annually and 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.

 Written by	12/1/03 Date	 Approved by	12/1/03 Date
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There are many areas within the Office of Indiana State Chemist (OISC) that are affected by and will adhere to the Quality Management Plan (QMP). They are as follows:

- Pesticides
 - ▶ Pesticide Investigators
 - ▶ Ground Water Specialist/Groundwater program
 - ▶ Pesticide Residue Laboratory
 - ▶ Pesticide Formulation Laboratory
- Feed
 - ▶ Feed Chromatography Laboratory
 - ▶ Feed Automated Analysis Laboratory
 - ▶ Microbiology Laboratory
- Fertilizer & Agr. Ammonia
 - ▶ Fertilizer Automated Analysis Laboratory
- Seed
 - ▶ Seed Laboratory
- Auditing and Chief Inspector
 - ▶ Feed, Seed and Fertilizer Sample Collection
 - ▶ Inspectors
- Sample Preparation

OISC acknowledges that the QMP is a dynamic document and how it is applied within each area will differ slightly. The areas within OISC, and the QMP as it pertains to each area, will be reviewed at predetermined intervals to verify that it is working as intended. This will be accomplished through internal audits and document reviews. The documents within the QMP will be reviewed at intervals not to exceed twelve (12) months. The purpose of the document review is to verify that the Policies and SOP's 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 determine how many records to review, as outlined in Policy 5.1, Records. The areas within OISC will be audited at intervals not to exceed twelve (12) months. The purpose of the internal area audits is to verify that the Policies, Standard Operating Procedures and analytical methods established are being followed and that each area is working in an effective and efficient manner.

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

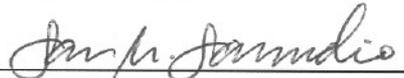
training (e.g. course work, seminars, etc.) or a combination of the aforementioned.

Area audits will be compliance audits, compliance meaning the area's compliance to their established SOP's, analytical methods and OISC Policies. The results of the audit will be given to the manager/supervisor of the area being audited, State Chemist, Associate State Chemist and Quality Assurance.

Any finding(s), finding(s) being defined as areas of non-compliance, will be given to the area manager/supervisor for 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.

Attachments:

Attachment A: Audit Schedule

 Written by	<u>10/4/04</u> Date	 Approved by	<u>10/5/04</u> Date
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Area	Quarter 1 Oct - Dec	Quarter 2 Jan - Mar	Quarter 3 Apr - Jun	Quarter 4 Jul - Sep
Pesticides	✓			
Pesticide Investigators	✓			
Pesticide Residue Laboratory	✓			
Ground Water Program	✓			
Pesticides Formulations	✓			
Feed			✓	
Feed Chromatography			✓	
Feed Automated Analysis			✓	
Microbiology Laboratory				✓
Fertilizer & Agr. Ammonia				✓
Fertilizer Automated Analysis				✓
Auditing and Chief inspector		✓		
Feed and Fertilizer Sample Collection		✓		
Seed, Inoc. & Plant Growth Substitutes				✓
Sample Preparation		✓		

OVERVIEW

The Office of Indiana State Chemist (OISC) performs compliance audits of all areas 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 area 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 practices. This includes, but is not limited to, reviewing completed case files (using the statistical method outlined in Policy 5.1, Records), conducting interviews with personnel within the area including management/supervisors, reviewing the raw data generated vs. the reports generated, review internal QC practices, review previously identified corrective action areas, review sample storage practices, review data collection practices and review record retention practices. The auditor is required to write up 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 area manager/supervisor for review. At this time, the area manager/supervisor can give input into any part of the audit report. This input can include explanations for perceived finding and the dispute of any findings. Once the area 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 area manager/supervisor, State Chemist, Associate State Chemist/Laboratory Director and the Quality Assurance Officer. It is the auditor's (or lead auditor if team audit) 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 to gain access to all employees, including management/supervisors, records, completed case files, SOP's, internal QC reports, etc.

QUALIFICATIONS

An auditor can be qualified through professional experience, education (course work, seminars, etc.), On the Job Training (OJT), 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

Quality Management Plan
Policy - 9.1

Auditor Responsibilities
Revision: original

lead auditor, should perform the audit.

<p><u>Mr. A. J. J. J. J.</u> Written by</p>	<p><u>12/1/03</u> Date</p>	<p><u>D. J. Reed</u> Approved by</p>	<p><u>12/1/03</u> Date</p>
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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.

Preventive actions are measures taken to prevent the first time occurrence of a quality deficiency by causing prevention.

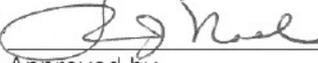
Corrective/Preventive Actions (CAPA's) can be initiated through several sources; findings from an audit, findings from a self evaluation, internal QC, employee observations and recommendations, data evaluation, etc. Once a CAPA has been identified, and brought to the attention of the area manager/supervisor,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

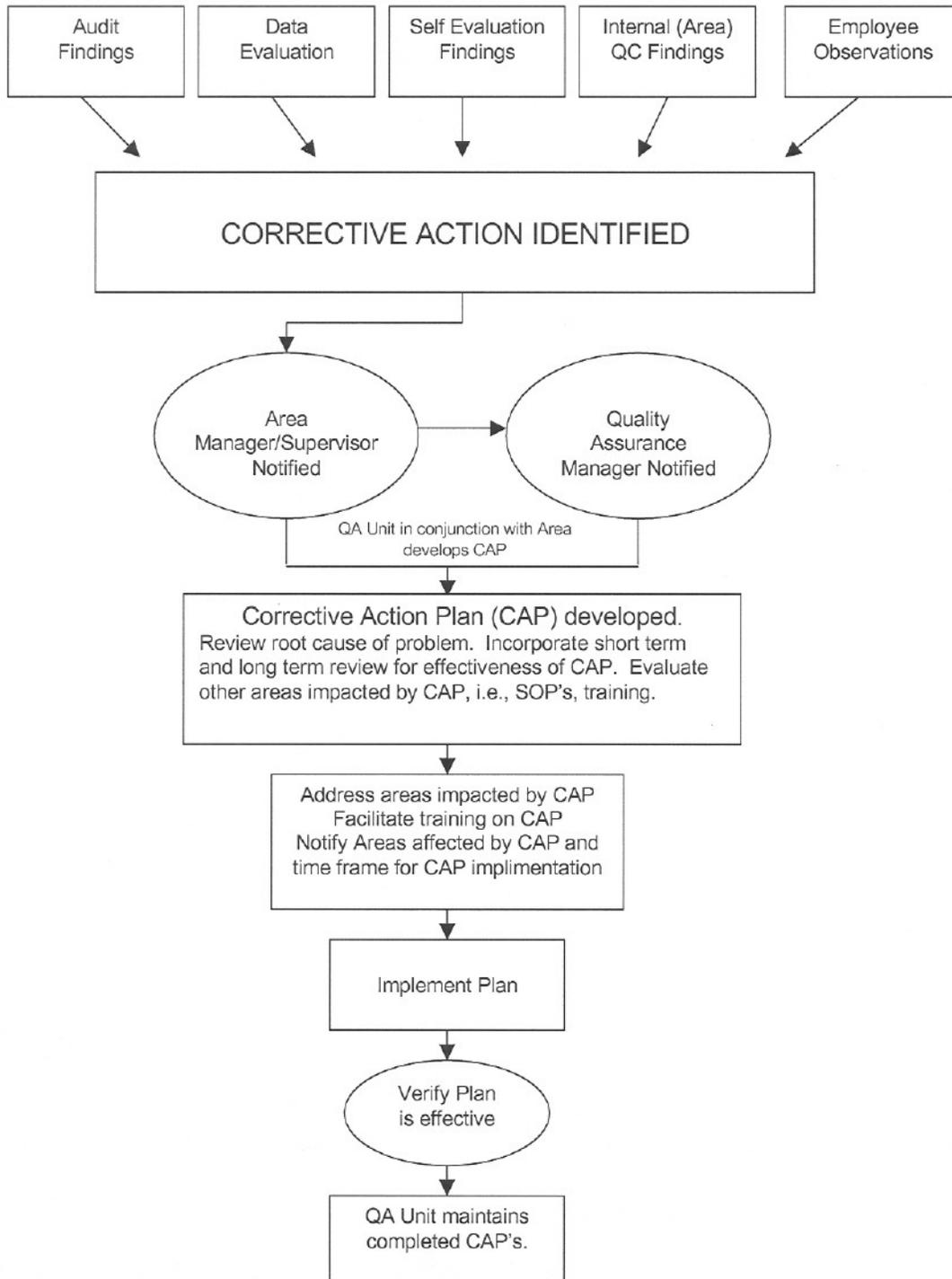
The Quality Assurance (QA) unit is responsible for documenting the identified CAPA through a CAPA Report, working with the area manager/supervisor (or their designee) to develop a plan to best implement the corrective or preventive action. The QA Unit will also verify that the CAPA has been implemented and is effective. The QA unit maintains the CAPA Reports and a CAPA Log. Completed CAPA files are maintained for a minimum of (7) seven years.

Within (8) weeks of the closeout of the CAPA Report, the QA Unit will follow-up to ensure the action was effective. The follow-up information will be recorded on the original CAPA Report.

Attachment:

Attachment A: Corrective Action Flow Chart

 Written by	<u>12/1/03</u> Date	 Approved by	<u>12/1/03</u> Date
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The Quality Assurance Officer is responsible for reviewing all quality data, e.g., audits, Corrective Action Plans, check sample results, Policies, Standard Operating Procedures and Program Plans. This Quality data review will occur continuously throughout the year, with a synopsis of the quality system occurring annually. The synopsis will be part of an annual quality report. The annual quality report will be given to the Management of the Office of Indiana State Chemist, i.e., State Chemist, Associate State Chemist/Laboratory Director, area administrators and area supervisors. A copy will also be provided to the Environmental Protection Agency.

The annual quality report will at a minimum contain:

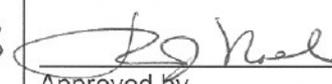
- Synopsis of the quality data reviewed.
- Evaluation of the current state of the Quality Management Plan and the quality system.
- Review of quality agenda for previous year (listing items complete and incomplete).
- Quality agenda for the upcoming year.

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

- Audits performed and audit findings per area.
- Corrective Action Plans (how many initiated, how many completed/area).
- 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.

 Written by	<u>12/1/03</u> Date	 Approved by	<u>12/1/03</u> Date
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