



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 5

77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

MAY 01 2018

REPLY TO THE ATTENTION OF

R-19J

The Indiana Department of Environmental Management (IDEM) Quality Management Plan (QMP), dated March 2018, has been approved effective May 1, 2018. The QMP documents IDEM's current quality system which encompasses environmental data operations.

The approval of this QMP will be valid for up to five years through May 1, 2023. Revision of the QMP by IDEM may be required during the five-year period based upon: periodic assessments by Region 5, your annual internal reviews, and/or significant changes in your organization, resources or scope of mission. At a minimum, a revised and updated QMP must be submitted for Region 5 review and approval six months (i.e., November 1, 2022) prior to the end of the five-year approval period.

Under this QMP approval, with the exception of any specific programs noted below, IDEM may continue to approve its own project-level Quality Assurance Project Plans (QAPPs) for all non-competitive assistance agreements and delegated programs included under IDEM's performance partnership agreements with Region 5. Superfund pre-remedial and remedial programs under 40 CFR, Part 35, Subpart O and Superfund removal program under 40 CFR, Part 300 specify, by federal regulation, that QAPP approval for these Superfund programs cannot be delegated and require submission of such QAPPs for approval by the Region 5 Superfund Division. As determined by U.S. EPA Air Division, all Air Program QAPPs must be submitted to EPA Region 5 for review and approval. As determined by Region 5 programs, IDEM will continue to submit and update program-level QAPPs for Region 5's approval. Further, U.S. EPA competitive assistance agreements under, but not limited to, the Exchange Network programs shall require the submission of project-level quality documentation for U.S. EPA review and approval as specified in the assistance agreement terms and conditions.

U.S. EPA is required to assess the implementation of approved quality systems as well as extramural agreements for which U.S. EPA provides financial assistance. Beginning with the approval of the QMP, IDEM shall submit complete, signed electronic (i.e., pdf) copies of all self-approved QAPPs, under this QMP, to my attention on a mutually agreeable periodic basis (i.e., monthly or quarterly). In addition, IDEM shall submit an annual letter (by January 31st of each year beginning in 2019) to my attention which:

- identifies any minor revisions needed and/or incorporated into the QMP during the preceding year;
- confirms that the quality system documented in the QMP and approved by U.S. EPA is still in effect; and
- lists all QAPPs, by environmental program, which were self-approved during the preceding year.

If you have any questions, please contact me at (312) 353-7203 or adams.jacqueline@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Jackie Adams".

Jackie Adams
Regional Quality Assurance Manager
U.S. EPA Region 5



MEMORANDUM

DATE: September 7, 2021

TO: Indiana Department of Environmental Management QA Coordinator

FROM: Jackie Adams, U.S. EPA Region 5 Quality Assurance Manager *Jackie Adams*

SUBJECT: Delegation of Approval Authority for Drinking Water PFAS Quality Assurance Documents

Indiana Department of Environmental Management has been given Delegated Approval Authority for all QA documentation related to PFAS in Drinking Water. This delegation is effective September 7, 2021 and should be attached to the IDEM Quality Management Plan that was approved on May 1, 2018.

IDEML 2018 Quality Management Plan



2018

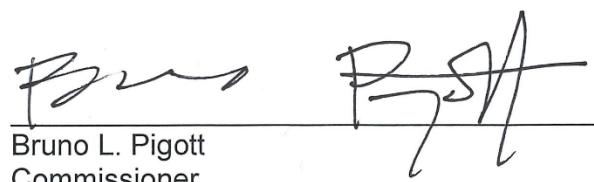
March 16, 2018

Indiana Department of Environmental Management

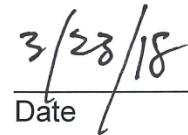
Indiana Government Center North
MC 50-01 IGCN 1301
100 N. Senate Ave.
Indianapolis, IN 46204

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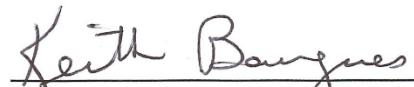
Signatures -- Indiana Department of Environmental Management



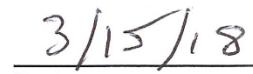
Bruno L. Pigott
Commissioner



Date



Keith Baugues, Assistant Commissioner
Office of Air Quality



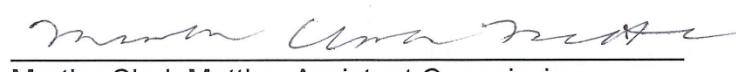
Date



Peggy Dorsey, Assistant Commissioner
Office of Land Quality



Date



Martha Clark Mettler, Assistant Commissioner
Office of Water Quality



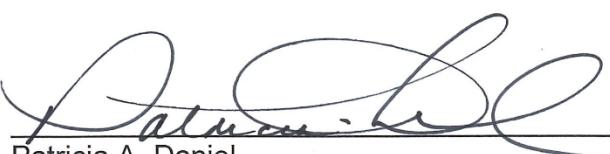
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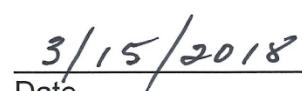
Julia A. Wickard, Assistant Commissioner
Office of Program Support



Date



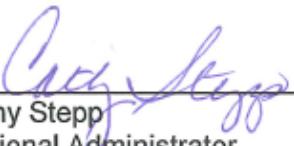
Patricia A. Daniel
Quality Assurance Manager



Date

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Signatures – U.S. Environmental Protection Agency Region 5


Cathy Stepp
Regional Administrator

5-1-18
Date


Edward H. Chu
Deputy Administrator

4/23/18
Date

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Jackie Adams
Regional Quality Assurance Manager

Date

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Water Division

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Signatures – U.S. Environmental Protection Agency Region 5, continued

TINKA HYDE

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Great Lakes National Program Office

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CHERYL NEWTON

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Cheryl Newton, Director
Resources Management Division

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Purpose

The current Indiana Department of Environmental Management (IDEF) 2012 Quality Management Plan (QMP), which is required by the U.S. Environmental Protection Agency (U.S. EPA) as a condition of federal funding.

Background

In 1986, Indiana was delegated authority by the U.S. EPA to implement federal environmental laws and rules. The Indiana legislature established IDEM as the state's entity responsible for the enforcement of those federal requirements, along with associated state statutes and administration rules.

Like environmental programs in other states, IDEM relies in part on funding from U.S. EPA to assist in accomplishing that mission. As a result the agency must meet the requirements outlined in *U. S. EPA CIO 2105.0 for U. S. EPA-funded Organizations* and *U.S. EPA QA/R-2 Requirements for Quality Management Plans*, by maintaining a quality system consistent with the standards established in *ANSI/ASQ E4-1994 Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, and any subsequent revisions. That quality system must be documented in a Quality Management Plan (QMP) that is re-approved by the U.S. EPA Region 5 (EPA R5) Quality Manager every five years, or sooner if substantially revised. The agency also must annually report to EPA R5 on its progress implementing its QMP.

However, it is not federal funding requirements alone that drive the agency to maintain a continually improving environmental quality system. IDEM recognizes that a credible quality system ensures data gathering is more efficient and accurate, resulting in agency decisions that are as reliable and defensible as possible. Because it values these quality system benefits the agency has in recent years, increased its efforts to bring its quality system into closer alignment with U.S. EPA quality requirements.

The 2012 QMP was comprised of an agency-wide QMP and office level QMPs from Air, Land, Water, Program Support (Northwest Regional Office), and Pollution Prevention and Technical Assistance. Because of the significant overlap and redundancy in those versions, the draft 2018 QMP once again combines all agency quality assurance (QA) activity into a single document. Program specific QA activities are highlighted either in the appropriate Element of the document, or in an attached appendix.

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Key Acronyms and Definitions

“Accreditation” – Acknowledgment from one of several widely recognized quality organizations that an entity is competent to perform work in a manner consistent with the quality system standards of the International Organization for Standardization (ISO). Accreditation authorities include, but are not limited to TNI (the NELAC (National Environmental Laboratory Accreditation Conference) Institute) and the American Association for Laboratory Accreditation.

“Assistance agreement” – Per the U.S. EPA Grants and Debarment Glossary, an assistance agreement such as the IDEM-EPA R5 Performance Partnership Agreement, is a legal instrument used by U.S. EPA to transfer money, property, services, or anything of value to a recipient to accomplish a public purpose. It is either a grant or a cooperative agreement and will specify certain things including budget and project periods, the federal share of eligible project costs, a description of the work to be accomplished, and any terms and conditions/special conditions.

“Branch” – An organizational level within IDEM, a branch is a subunit of an office.

“Certification” – As defined by the ISO, certification is recognition provided by an independent body related to products, processes, systems, or persons.

“Certification” (IDEML OAQ AMB QAS) – A determination documented and signed on a designated form or label, that an instrument reading provides, within that accepted margin of error, the same measurement results as does an instrument recognized as the standard, or certifiably accurate measuring instrument.

“Confidential” – Information protected from public disclosure under Indiana Code (IC) 5-14-3 Access to Public Records, the Indiana Archives and Records Administration (IARA)’s Title 60 of the Indiana Administrative Code (IAC), and in the IDEM Records Management Policy.

“Data” – A collection of numeric and/or non-numeric information from which conclusions may be drawn.

“Data Quality Objective” – A tool for determining the type, quantity, and quality of data needed to reach defensible decisions or make credible estimates, from *Guidance on Systematic Planning Using the Data Quality Objectives Process (EPA QA/G-4)*.

“Document” – A compilation of information that describes, defines, explains, specifies, reports, certifies, requires, or provides information, data, or results. Any form or document recording actions taken or required that is subsequently initialed or signed to verify actions taken or authorize decisions made, is a record.

“Effective” – A QA document that is in use or in effect; currently operational.

“Environmental data” – Any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For U.S. EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as databases or literature.

“Environmental Data Operations” – Work performed to obtain, use, or report information pertaining to environmental processes and conditions.

“Environmental technology” – An all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil

washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

“Extranet” – IDEM’s browser driven internal staff intranet, accessible only to agency staff via login and password.

“GLNPO” – The Great Lakes National Program Office

“GLRI” – The Great Lakes Restoration Initiative

“Graded approach” – To ensure the degree of QA scrutiny applied to a data operation/data gathering project is directly and appropriately proportionate to the adverse consequences of an inaccurate or non-representative result. The greater the consequence of error, the narrower should be the allowable margin for it, and the more justified the stringent application of techniques for measuring it. Conversely, the less adverse the consequences of error, the more acceptable the tolerance for it, and/or the relaxation of means to measure it, especially when considered in relation to the costs of more stringent measurement.

“IDOA” – Indiana Department of Administration

“Office” – An office within the IDEM organizational structure, generally one with broad responsibility over activities associated with a specific environmental medium, or other significant supporting activities. IDEM offices include the:

- Office of Air Quality (OAQ)
- Office of the Chief of Staff (OCS)
- Office of Land Quality (OLQ)
- Office of Program Support (OPS), which includes the IDEM regional offices, the
 - Northwest Regional Office (NWRO)
 - Northern Regional Office (NRO)
 - Southeast Regional Office (SERO)
 - Southwest Regional Office (SWRO)
- Office of Water Quality (OWQ)

“Procedure” – A specified set of steps detailing how to perform an activity.

“Program” – Used throughout this document, always within the context of the individual part in which it appears, a program is any group of IDEM staff assigned to a specific range of tasks within the agency, within a branch of the agency, or within a section of a branch of the agency.

“Project” – A temporary endeavor undertaken to create a unique characterization or result applicable only to a specific location, and within a specific time-frame.

“Quality assurance (QA)” – An integrated system of management activities involving planning, implementation, documentation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

“QA documentation/documents” – Authorized electronic and/or paper documents, which detail plans, standards, policies, and guidance that bear directly upon the quality of agency work products or services.

“Quality assurance project plan (QAPP)” – A planning document describing the activities associated with environmental data gathering or use. A QAPP (or equivalent QA planning document) may involve the acquisition of environmental data from direct measurement

(sampling), from previously gathered environmental data of demonstrable credibility, or from a standardized modelling exercise. A QAPP also may be used to demonstrate the efficacy of environmental technology.

“Quality control (QC)” – The overall system of technical activities such as the use of sample duplicates, blanks, spikes, the use of split samples, or other techniques intended to measure the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer.

“Record” – An initialed form, signed document, or other documentation of actions completed or decisions made.

“Section” – An organizational level within IDEM, a section is a subunit of a branch.

“Standard operating procedure (SOP)” – The method for operation, analysis, or action with prescribed techniques and steps. An SOP is the approved method for performing a specific routine function or repetitive task. SOPs should be developed in consultation with the agency staff performing the work.

“Systematic planning” – The planning process used by IDEM to organize and conduct environmental data operations, it is patterned after, and very similar to the U.S. EPA recommended Data Quality Objective (DQO) process defined above. It identifies issues to consider in conjunction with planning a project or program requiring data operations at a location, or locations where an environmental evaluation and a subsequent decision are needed.

“Technical SOP (TSOP)” – A detailed procedure associated with technical operations such as the collection, evaluation, use, or reporting of environmental data, or the design, construction, and operation of environmental technology.

“Virtual File Cabinet (VFC)” – The agency’s electronic digital image document repository system that stores, files, indexes, redacts, reassembles, and securely accesses electronic documents of all types both received and created by the various program areas within the agency.

1.0. MANAGEMENT AND ORGANIZATION

Purpose - To document the overall policy, scope, applicability, and management responsibilities of IDEM's quality system.

1.1. Quality Assurance System Commitment

IDEM considers environmental data operations – the work performed to obtain, use, or report information pertaining to environmental processes and conditions – as the focus of the agency quality system. IDEM's environmentally related decisions are supported by accurately, statistically, scientifically, and defensible data.

1.1.1. *Agency Quality System Policy Statement*

IDEM continues to demonstrate a commitment to scientifically accurate and transparent agency products and services by maintaining a quality system that is consistent with federal and state requirements and agency needs.

IDEM will ensure accurate and complete documentation (See the quality documentation policy at Appendix A) of all agency activities that encompass:

- The collection, quality control, evaluation, and use of pre-existing or newly-generated environmental data.
- The design, construction, and operation of environmental technology, including permits and other pollution control devices, monitoring equipment, and sampling devices.
- A significant risk of harm to human health or the environment.

IDEM requires that any entity similarly involved in the acquisition or generation of environmental data on behalf of IDEM, such as a contractor or sub-grantee shall, if appropriate, have an approved quality system in place and shall implement any data acquisition in accordance with an approved Quality Assurance Project/Program Plan (QAPP).

1.1.2. *Importance of the Agency Quality System*

The development and ongoing use of the agency quality system has, and will continue to have a positive impact on agency efforts to meet its commitments under federal grants and assistance agreements, including the Performance Partnership Agreement (PPA). It has created a culture of quality in which QA is part of what is expected and required to adequately complete assigned work, rather than something extra to be completed in addition to that work. Effort invested in QA is rewarded with clear, consistent, speedy, and technically well supported environmental decisions protective of public health and the environment, while facilitating responsible economic activity.

1.1.3. *General Goals and Objectives of the Quality System*

IDEM commits to furthering the following goals, in developing its QA system:

- Strengthening coordination and collaboration with EPA R5, the Great Lakes National Program Office (GLNPO) and Great Lakes Restoration Initiative (GLRI) related program, as well as other R5 states' QA systems and staff;
- Expanding the availability and consistency of QA training for IDEML staff;
- Enhancing the exchange of information on QA best practices, expectations, and document review recommendations;
- Furthering the use of the data quality objective (DQO) process, the role of data quality indicators (DQIs), and the implementation of the data quality assessment (DQA) process;
- Expanding agency implementation and participation in QA system assessments.

1.1.4.

Resource Allocation of the Quality System

IDEML continues to support QA-related activities. During 2017, and as reported in its most recent QA Annual Report to EPA R5, IDEML had 63.2 fulltime equivalent (FTE) staff working on QA-related tasks. Including the agency QA manager and staff, agency staff resources committed to the quality system comprise about eight percent of total agency staff.

IDEML has a centralized quality system implemented by the agency QA manager and three staff. The roles of this group are described in 1.3.2. Although this core group of QA staff implement the more broadly identifiable tasks of the IDEML quality system, additional staffing resources are similarly committed to the more specifically focused activities of agency environmental data operations that comprise the overall IDEML quality system.

QA staff are found within nearly every agency program and work on data gathering, as well as the development of QAPPs, SOPs, and other QA-related documents. This number includes staff that performs QA reviews of data to ensure the accuracy of data uploaded into U.S. EPA databases (consistent with its Data Quality Guidelines and comparable IDEML quality requirements). Some program QA staff assist centralized agency QA staff on several projects, such as:

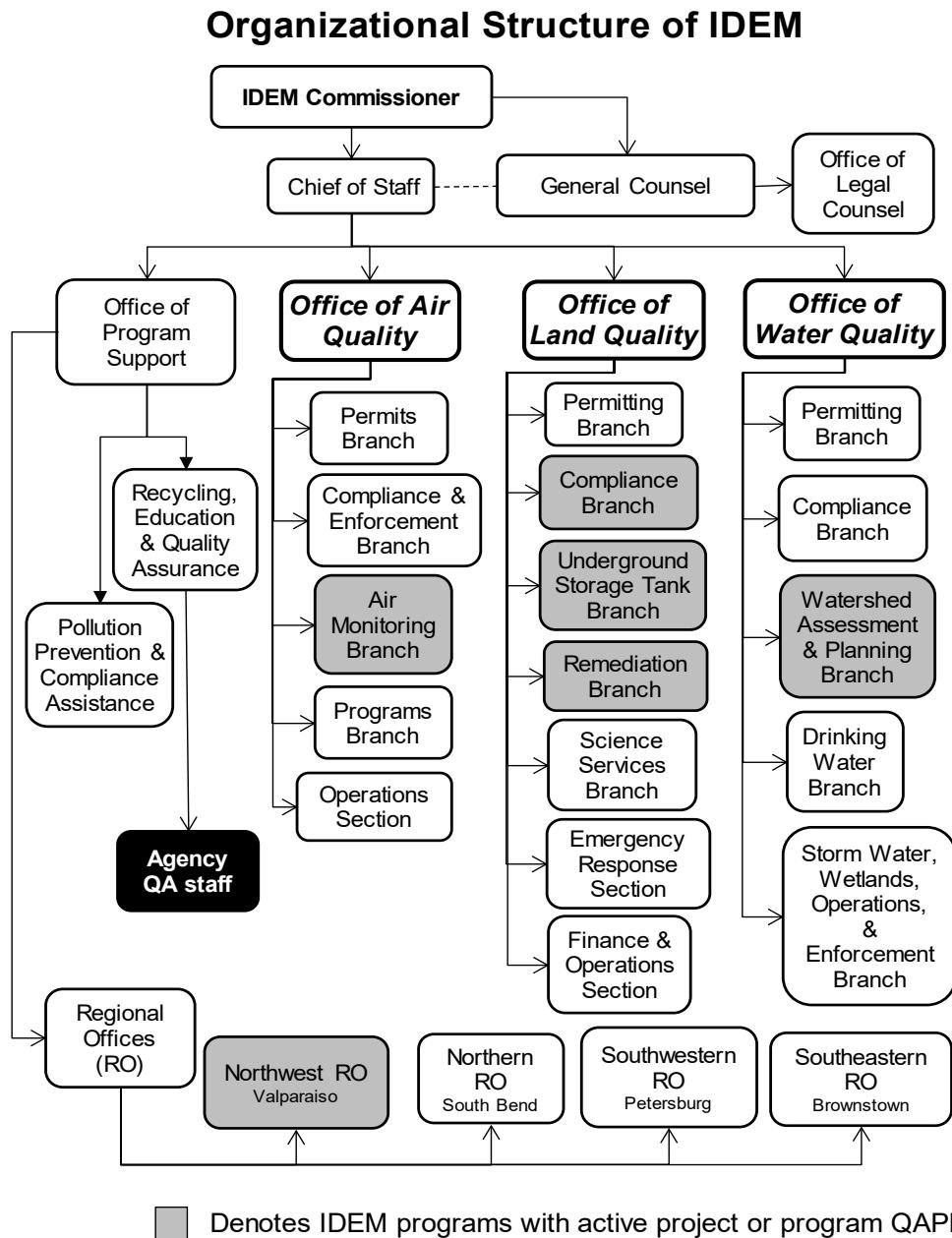
- The development, review, approval, and revision of QA documentation, and,
- Providing planning and input on overall agency QA policies and tools.

The agency calculates the total FTE staff involved in QA system tasks, by calculating the number of staff dedicating some percentage of their work time to QA related tasks multiplied by the percentage of time so engaged (see Appendix B).

1.2. Agency-wide Organizational Structure

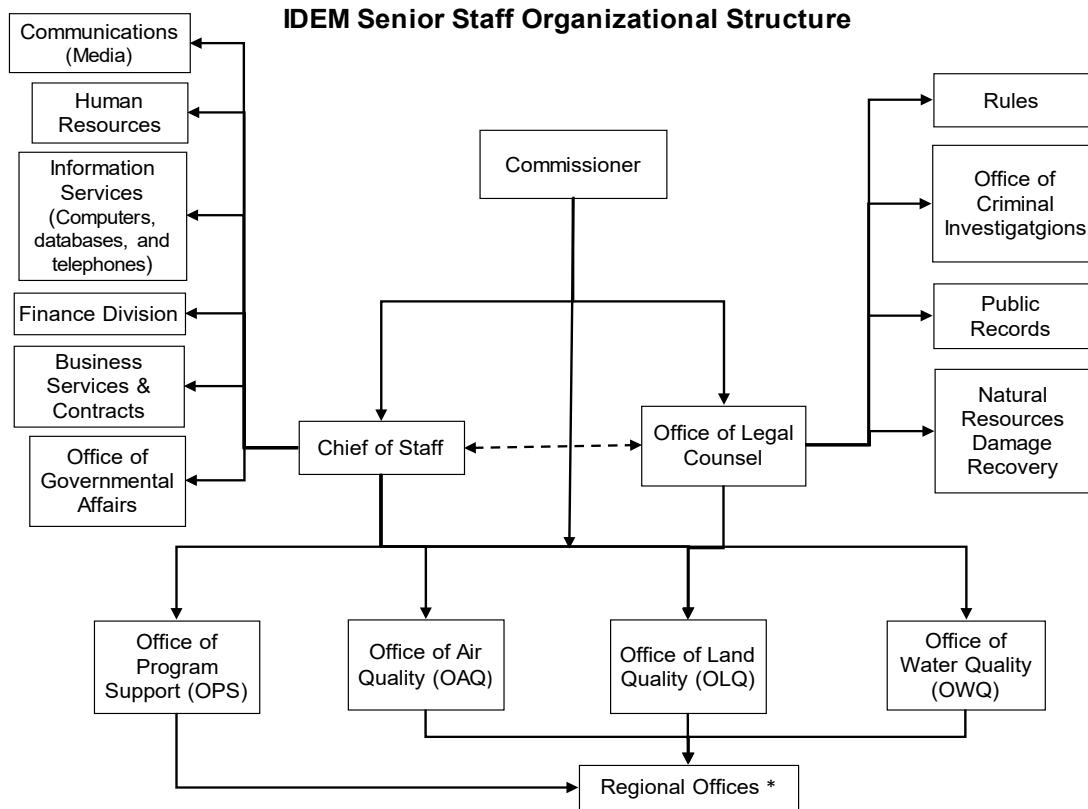
As illustrated in Figure 1, the commissioner and the Chief of Staff direct the various IDEM environmental media specific offices of air, land, and water, as well as associated supporting offices to carry out the agency mission. In addition to the information on individual program activities listed immediately below in 1.2., there are more comprehensive descriptions of each office's activities listed in 1.4.2. and Appendix C.

Figure 1



1.2.1. *Interaction Between the Commissioner and Agency Senior Staff*
The commissioner directs other IDEM senior staff as illustrated in Figure 2, and together they lead agency staff.

Figure 2



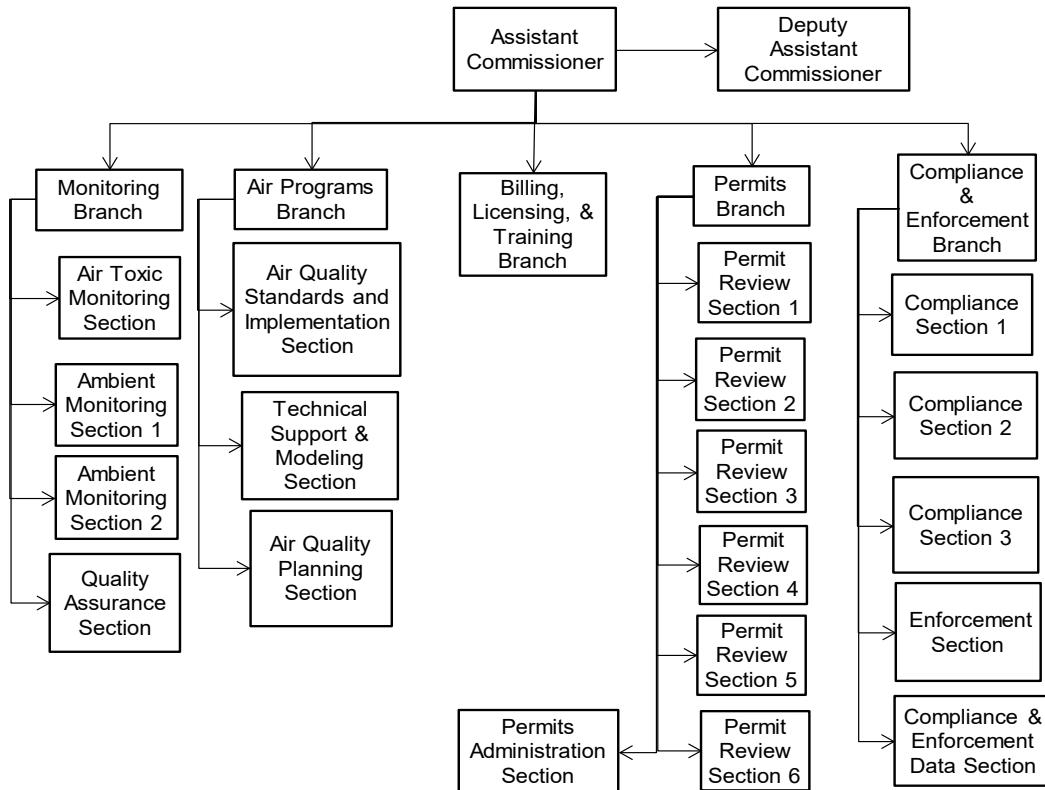
* Regional office staff engaged in compliance and/or monitoring program activities report to both their regional office management and the respective compliance and monitoring branches of the IDEM Offices of Air, Land, and Water Quality.

1.2.2. **Office of Air Quality (OAQ) Organizational Structure**

The organizational structure (Figure 3) and an overview summary of the work completed by the branches of OAQ are described below:

Figure 3

OAQ Branches and Sections



Office of Air Quality

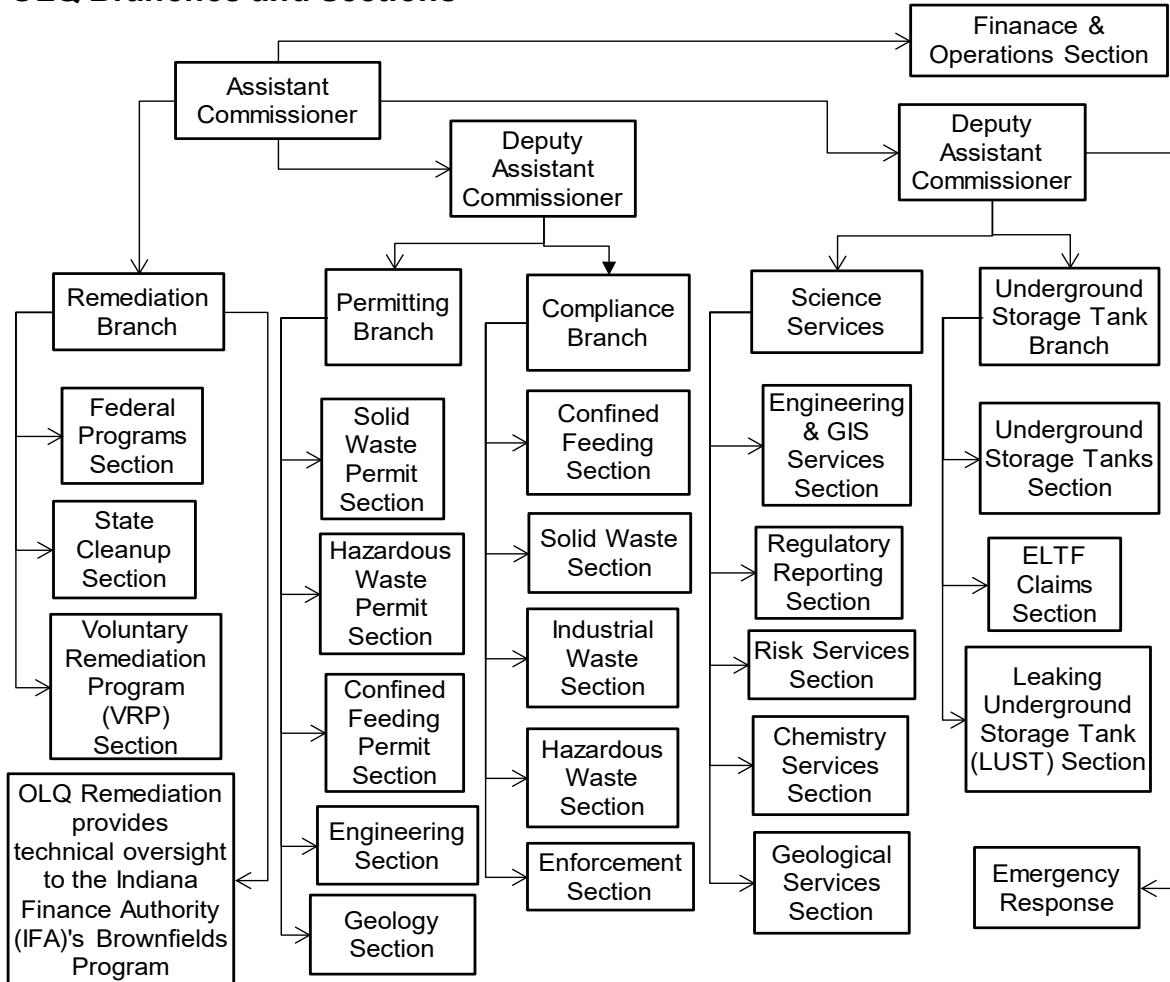
- **Air Programs Branch (APB)** performs air quality data analysis and modeling, develops the 1990 Clean Air Act Amendments State Implementation Plans (SIPs), implements the mobile source programs, and assists in rule development.
- **Air Monitoring Branch (AMB)** collects data on ambient air quality to inform decisions regarding appropriate preventive and/or corrective action options available to safeguard public health and the environment.
- **Compliance and Enforcement Branch (CEB)** verifies regulatory compliance by responding to complaints, conducting full and partial compliance evaluations, inspections, conducting compliance reviews, observing stack tests and continuous emission monitors, and providing compliance oversight of sources of air emissions. CEB pursues enforcement actions and provides compliance assistance.
- **Operations Branch (OB)** manages billing and payments, tracks asbestos licensing activities, and expedites the training requests of OAQ staff.
- **Permits Branch (PB)** acts on applications from new or existing sources with a potential to emit criteria/hazardous pollutants in excess of established limits.

1.2.3. *Office of Land Quality (QLQ) Organizational Structure*

The organizational structure (Figure 4) and an overview summary of the work completed by the branches of OLQ are described below:

Figure 4

OLQ Branches and Sections



Office of Land Quality

- **Compliance Branch (CB)** conducts regulatory compliance inspections, and may pursue enforcement actions or provide compliance assistance. CB reviews "Contained-In Approval" requests for managing wastes with small concentrations of hazardous material(s).
- **Permits Branch (PB)** engineers and geologists provide technical expertise to review requests for registrations, permits, and permit modifications to transport, handle, store, treat, or dispose (including 're-use' via land application) solid and hazardous waste, or septage and animal feeding operation wastes. Permits may review facility or activity closure requests. Although most OLQ inspections are conducted by CRB, PB is responsible for ground water and explosive gas monitoring, and CFO and landfill construction inspections.

- **Remediation Services Branch (RSB)** conducts site assessments and oversees long-term cleanups of contaminated properties to levels safe for their intended use(s) for the following programs:
 - Comprehensive Environmental Response Compensation and Liability Act (CERCLA or "Superfund") activities.
 - State cleanups of sites not on the National Priorities List (NPL).
 - Voluntary cleanups of contaminated sites in return for the resolution of liability associated with the future use or transfer of involved properties.
 - The leaking underground storage tank remediation program.
 - Defense Environmental Restoration Program (DERP) sites are investigated and assessed for potentially hazardous waste and possible ranking on the Superfund National Priorities List.
 - Indiana Brownfields Program receives technical oversight and review from RSB for all projects receiving assistance from the Indiana Finance Authority (IFA) or U.S. EPA brownfield grants. The Brownfields Program was created in 2005 by state legislation that merged brownfield financial and technical review into a single program which offers educational, financial, technical, and legal assistance to eligible entities.
- **Science Services Branch (SSB)** maintains much of the agency's hazardous and solid waste program data, and provides technical and scientific assistance to the other branches of OLQ in five disciplines:
 - Chemistry
 - Geology
 - Engineering
 - Geographical Information Systems
 - Risk evaluation
- **Underground Storage Tank (UST) Branch** oversees the registration and operation of, and the response to environmental releases from underground chemical and petroleum storage tank systems. It manages the Excess Liability Trust Fund (ELTF), which allows owners and operators of underground petroleum storage tanks to establish financial responsibility for, and if necessary, remediate petroleum releases.
- **Emergency Response Section (ER)** provides immediate, uninterrupted, around-the-clock environmental evaluations of emergency releases.
- **Finance and Operations Section (FO)** manages budgeting; permit billing and payments; and operations, facility, and contract support services.

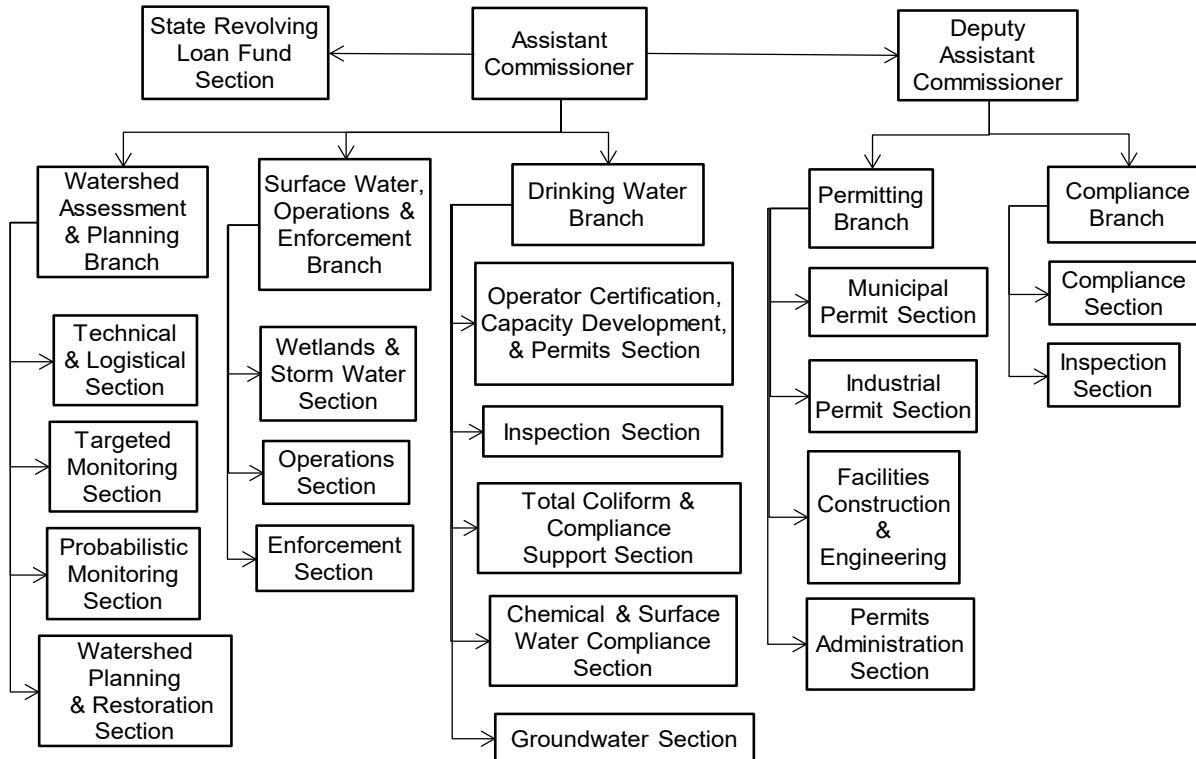
1.2.4.

Office of Water Quality (OWQ) Organizational Structure

The organizational structure (Figure 5) and an overview summary of the work completed by the branches of OWQ are described below:

Figure 5

OWQ Branches and Sections



Office of Water Quality

- **Compliance Branch (CB)** oversees 47 delegated municipal pretreatment programs, inspects National Pollutant Discharge Elimination System (NPDES) permitted facilities, and ensures the proficiency of their laboratories. The CB provides operator assistance and training, administers the wastewater operator certification/continuing education program, uploads compliance data to the federal Integrated Compliance Information System (ICIS) database, evaluates compliance data, issues noncompliance letters, and makes enforcement referrals.
- **Drinking Water Branch (DWB)** oversees public drinking water system permitting and construction, operator certifications, and the process to ensure new public water systems (PWSs) have the necessary technical, financial, and managerial qualifications to deliver safe water. The Drinking Water Branch carries out the requirements of the federal Safe Drinking Water Act (SDWA) which is designed to ensure that PWSs deliver water to Hoosier homes and businesses that is adequate in quantity and is safe to drink. It does this by evaluating information about the water from the source to the tap. The branch's main activities include performing inspections at PWSs, verifying water quality compliance, issuing construction permits, following up on PWS noncompliance, responding to citizen complaints,

providing technical assistance, making sure that PWS are under appropriate supervision, and generally ensuring they provide safe water to Indiana citizens.

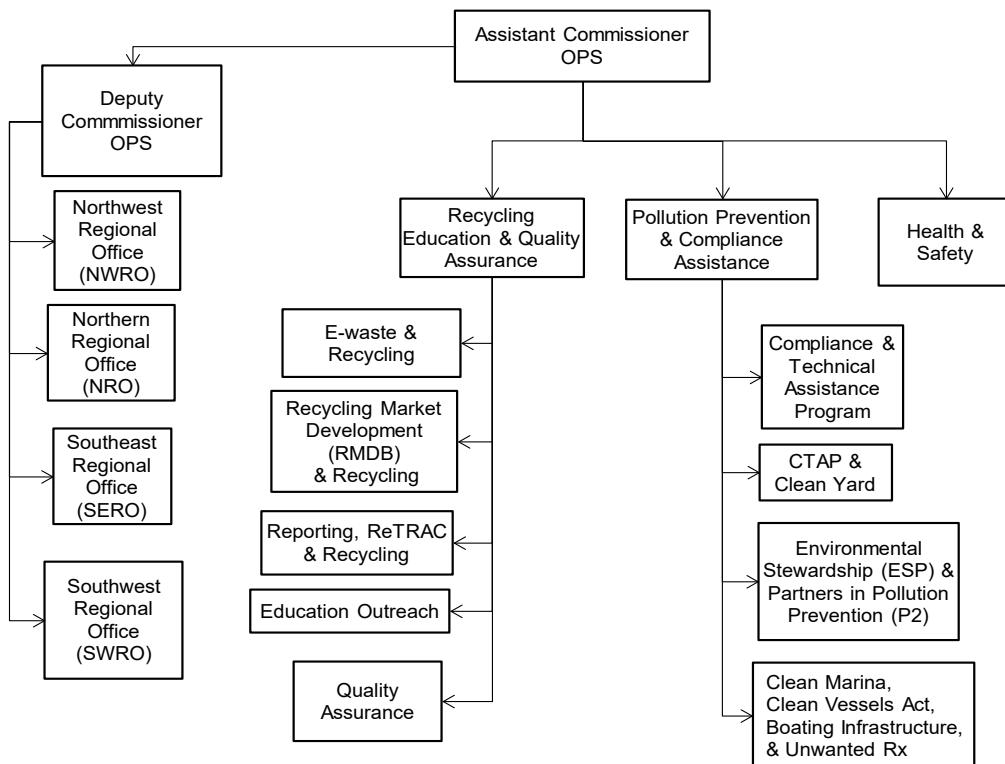
- **Permits Branch (PB)** regulates the construction of, and point source discharge from sanitary and industrial wastewater treatment or pretreatment facilities under the NPDES delegated permitting program.
- **Surface Water, Operations, and Enforcement Branch (SWOE)** oversees the OWQ budget and operations, manages permit fee billing, provides 401 water quality certifications for dredge and fill projects, issues state isolated wetland permits, regulates storm water discharges, and manages OWQ enforcement cases.
- **Watershed Assessment and Planning Branch (WAPB)** samples and assesses the quality of Indiana surface waters and their biotic communities on either a routinely revolving or case specific basis. WAPB uses surface water quality and various physical data inputs to develop watershed restoration plans and TMDLs and implements the nonpoint source program for the purpose of improving water quality.

1.2.5. *Office of Program Support (OPS) Organizational Structure*

The organizational structure (Figure 6) and a summary of the work completed by OPS is described below:

Figure 6

OPS Organizational Units



In addition to the regional office staff illustrated above, OPS Compliance and Technical Assistance staff are subject to dual reporting, with work products overseen by the Assistance and Outreach Branch, as well as by regional office management.

Office of Program Support

Supporting the technical missions of the other IDEM offices, OPS:

- Ensures the four IDEM regional offices have the infrastructure and supporting technical expertise necessary to provide the public with in-person environmental management services in the northern and southern portions of the state. These regional offices, headquartered in: South Bend (Northern Regional Office), Valparaiso (Northwest Regional Office), Brownstown (Southeast Regional Office), and Petersburg (Southwest Regional Office), provide local access to IDEM permitting, compliance inspection, technical assistance, and outreach services.
- Encourages the regulated community to understand, achieve, and exceed their environmental responsibilities through voluntary participation in outreach programs in technical compliance assistance, environmental stewardship, pollution prevention, recycling, and recycling market development.
- Leads the agency quality system, interfacing with the EPA R5 quality manager, and providing QA management and assistance throughout IDEM.

Northwest Regional Office (NWRO)

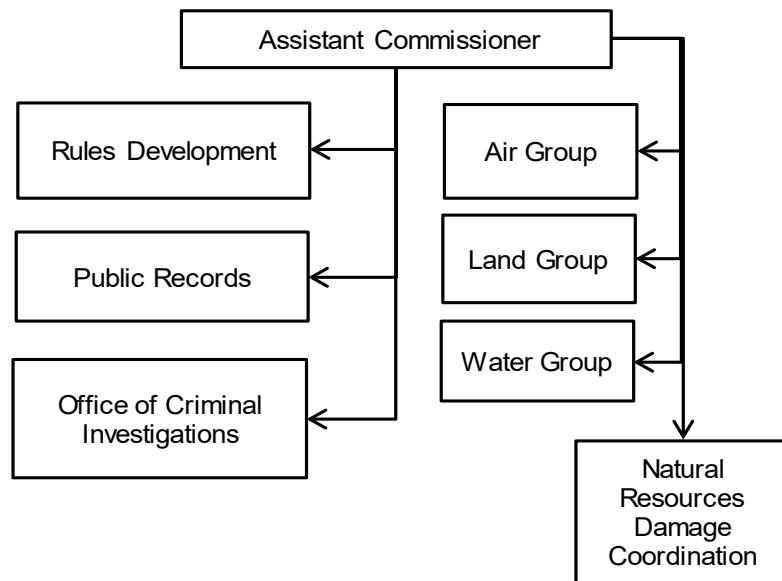
The IDEM NWRO coordinates a number of agency programs focused on environmental conditions in northwestern Indiana, where it oversees the Partners for Clean Air, Indiana Clean Marinas, the Lake Michigan Beaches Monitoring and Notification Program, the Lake Michigan Lakewide Action and Management Plan (LAMP), and the Grand Calumet River/Indiana Harbor Ship Canal Area of Concern (AOC) Remedial Action Plan (RAP) programs.

1.2.6. *Office of Legal Counsel (OLC) Organizational Structure*

The organizational structure (Figure 7) and an overview summary of the work completed by OLC are described below:

Figure 7

OLC Organizational Chart



Office of Legal Counsel (OLC):

OLC addresses issues across all environmental media. They provide legal guidance to, drafting communications for, and acting on behalf of agency programs, the office is responsible for:

- **Office of Records Management**

The office oversees the management and accessibility of IDEM records. Responses to records requests must ensure the protection of confidential and privileged information.

- **Rules Development**

OLC works with the Commissioner, the Indiana Environmental Rules Board, Indiana Legislative Services Administration (LSA), and the programs to develop, modify, or repeal – with Board and gubernatorial approval – administrative rules under IDEM jurisdiction and reports actions in the *Indiana Register*.

- **Natural Resource Damage Program**

NRD staff and the other NRD Trustees, IDNR and USFWS, work with a variety of partners to address negative impacts to Indiana's natural resources (e.g., fish kills or habitat destruction caused by uncontrolled discharges of hazardous substances.) One particular focus area of the NRD program has been Northwest Indiana, where they have worked closely with GLNPO, EPA R5, the Citizens Advisory for the Restoration of the Environment (CARE), and IDEM NWRO staff to conduct projects which address Beneficial Use Impairments (BUIs) in the Grand Calumet River AOC.

1.3. Quality Assurance Lines of Responsibility and Authority

The authority (Figure 8) for agency decision making rests with IDEM senior management, as shown by the solid arrowed lines. As a result of the investment in quality system resources described in 1.1.4., IDEM management are more confident that any QA concerns associated with data they are relying on for decision making, have already been addressed during the data operations processes conducted by their staffs.

In addition, agency management and key technical staff within each respective program have ongoing, and often long-standing, histories of interaction and institutional memory. This generally includes management knowledge and understanding of QA concerns based on their:

- Past work histories and experience addressing QA issues,
- Awareness of the QA considerations already built into some agency decision processes over time, and
- Knowledge that each program strives to keep staff up-to-date on the most recent required program specific technical training. Especially trainings that include new measures to address QA concerns, and that are provided or referred by EPA R5 divisional staff who are the technical counterparts of IDEM staff.

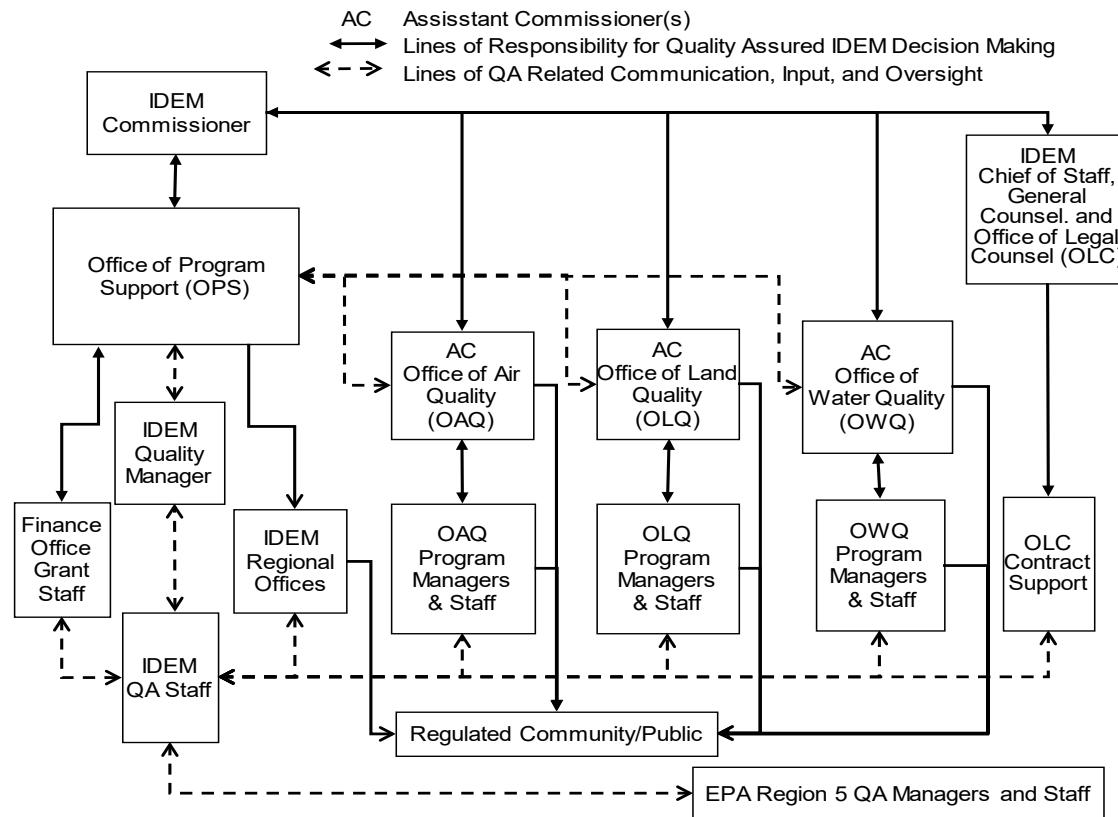
1.3.1. Lines of Quality Assurance Authority

As illustrated by the dashed arrowed lines, or lines of "QA Related Communication, Input, and Oversight" also depicted in Figure 8, agency QA staff interact regularly with those program area staff with the training and experience to address QA issues. As part of these interactions, those

same program staff are regularly advised and updated regarding existing and/or new U.S. EPA and/or IDEM QA requirements. The culture of quality promoted by the ongoing input from agency QA staff serves as the line of QA authority that impacts agency decision making as they discuss, remind, refresh, update and always stand ready to assist with additional QA resources.

Figure 8

IDEMLines of Quality Assurance Authority



1.3.2. Role of IDEM QA Manager and Staff

The Office of Program Support, IDEM QA Managers, and staff are independent of the authority of the Offices of Air, Land, and Water Quality. This independence helps to shield QA from the external interests such as deadlines, public pressures, and resource limits faced by the Offices of Air, Land, and Water.

The agency quality managers and, IDEM QA staff perform the following related tasks:

- Ensure the quality system is appropriately documented in a QMP and subsequently approved by EPA R5.
- Annually report progress on the implementation of the agency quality system to EPA R5.
- Continually promote adherence to QA principles.

- Review and approve agency program QA documentation to ensure all QA standards are met.
- Store and manage all IDEM QA documents.
- Maintain all IDEM QA training materials, templates, forms, and other supporting resources.
- Distribute QA policies, resources, training materials, and updates to agency staff via the IDEM Extranet.
- Coordinate with program staff regarding any QA services that may be needed.
- Serve as liaisons between IDEM and EPA R5 QA management and staff.
- Schedule regular IDEM QA Committee meetings. Since August 2005, the committee has served as a forum where IDEM QA staff can share information with, and solicit input from, program appointed representatives as part of an ongoing effort to advance the IDEM quality system and associated policies, documents, and process tools.
- Advocate for quality-related programs, evaluations, and decisions independent of the interests and objectives of agency program management.

1.4. Technical Activities and Programs Supported by the Quality System

As stated in the agency quality policy at 1.1.1., all work performed to obtain, use, or report information pertaining to environmental processes and conditions – in other words, all environmental data operations – are to be encompassed by the agency quality system. The three primary IDEM program area offices; air, land, and water, as well as the NWRO (which manages the Beach, LAMP, and RAP programs), are engaged in activities meeting that criteria. Each is involved with:

- Gathering data to characterize environmental conditions, and/or re-gathering data for a second time in the exact same manner for comparison, in order to characterize the impact of actions resulting from an agency decision.
- Assuring the quality of existing or newly generated data to demonstrate that it accurately characterizes the conditions measured, and that it fits within the scope of the decision making that may be required.
- Using environmental data in a comparative or relative manner to make decisions such as whether to revise a rule, adjust a standard, issue or deny a permit, determine compliance or noncompliance with a permit or order, or to recommend enforcement, remedial action, or inaction.
- Reporting environmental data submitted to, or collected by the agency to the EPA R5, the legislature, interested parties, stakeholders, the scientific community, or any other subgroup; all of which fall under the broader mantle of “the public.”

Any internal disagreement among program staff regarding QA related issues is resolved with input from other staff from the same program that has no direct stake in the outcome of the disagreement.

1.4.1. *Specific agency program activities with a QA component*

The following is a representative listing of the QA and quality control activities implemented by agency programs that include a QA component. A more comprehensive listing is available for review in Appendix C.

Office of Air Quality

Permitting:

- Calculating the potential to emit (PTE) calculations to determine appropriate permitting levels
- Evaluating applicant submitted data

Compliance:

- Stack testing
- Evaluation of continuous operations and emissions monitoring
- Onsite collection of sampling or observational data
- Accurate examination of throughput data

Air Programs and Planning:

- Emissions reporting
- Modelling of:
 - Source modifications
 - Transportation conformance

Air Monitoring:

- Operation and maintenance of monitoring network stations throughout the state
- Operation of laboratories for quantifying toxic and particulate pollutant measurements
- Certification of monitoring network equipment and of some instrumentation owned by stakeholders that are required to gather and report data to U.S. EPA, IDEM, or into the Air Quality System database.

Office of Land Quality:

Permitting:

- Recording reviews of submitted data
- Tracking and evaluation of leachate and leachate recirculation reports
- Groundwater borehole sampling

Compliance:

- Inspections at facilities that treat, store, or dispose (TSD) hazardous wastes
- Use of the LaMotte kit for water sampling at confined feeding operations (CFOs) and confined animal feeding operations (CAFOs)

Remediation/Emergency Response:

- Site investigations
- Development of sampling plans
- Site scoring
- Investigation and investigation oversight
- Remediation oversight
- Monitoring and monitoring oversight

Science Services:

- Laboratory contract processing

- Monitoring (Under the IDEM OLQ Professional Laboratory Services Contract 2018-2021) the competency of individual laboratories to perform requested analyses
- Sampling set-up and laboratory assignment
- Maintaining the sampling database
- Technical memos that review and evaluate data

Office of Water Quality:

Permitting:

- Calculate/model stream waste load allocation limits.
- Review anti-degradation demonstrations.

Compliance:

- Evaluate performance tests of laboratories operating under a NPDES permit.
- Review outfall sampling and analysis.

Watershed Assessment and Planning:

- Develop QAPPs and related sampling and analysis work plans.
- Conduct field sampling of a variety of media that includes surface water, sediments, fish community and tissue, macroinvertebrates, and habitat assessments.
- Operate field and in-house laboratories.
 - Field audit program
 - Taxonomy of cyanobacteria, diatoms, macroinvertebrates, and fish
 - Analysis of samples for cyanotoxins and coliforms
- Review of lab packets, using the data acquired to:
 - Characterize waters as meeting, or not meeting, or making progress toward meeting statewide standards.
 - Establish stream total maximum daily loads (TMDLs) for use in establishing waste load allocations for NPDES discharge permits.
 - Investigate the effectiveness of a permit's conditions.
 - Identify previously unknown sources of water pollution.
 - Quantify suspected threats to public health.
 - Monitor the fitness of fish populations for human consumption.
- Actively work with communities in watershed planning efforts.

Drinking Water:

- Review lab data and report to U.S. EPA under the SDWA (Indiana drinking water labs are certified by the Indiana Department of Health).
- Enforcement of the 10-states standards for:
 - Water treatment equipment and
 - Materials that contact the water

Office of Program Support – NWRO:

LAMP Program:

- Review of Lake Michigan basin water quality and ecosystem data against the General, Substance, and Lake Ecosystem Objectives specified in Annex 2 of the 2012 Great Lakes Water Quality Agreement or developed pursuant to that Annex.
- Development of Lake Michigan Lake Ecosystem Objectives.

RAP Program:

- AOC Aesthetics monitoring data collection and evaluation.
- Field audits of habitat restoration and monitoring activities.
- Field audits of beach water sample collection and notification.
- Review of *E. coli* enumeration data against notification decisions and quarterly progress reports.
- Review of invoices submitted by contractors working on AOC or Beach Program projects.
- Evaluation of monitoring data for use in Beneficial Use Impairment removal and Area of Concern delisting decisions.

Beach Program:

- Field audits of beach water sample collection and notification.
- Review of *E. coli* enumeration data against notification decisions and quarterly progress reports.
- Review of invoices submitted by contractors working on Beach Program projects.

1.4.2. *Oversight of Contracted, Delegated, or Extramural Programs*

As stated in the agency quality policy, at 1.1.1., each IDEM program area office that engages contractors or grantees (see Appendix D) to assist with environmental data gathering, analysis, or use is responsible for ensuring the quality assurance component of those activities is adequately addressed by that contractor or grantee acting on behalf of IDEM. All IDEM contract laboratories must have current quality management systems in place and must provide demonstrations of competence to perform the work for which they are hired, as described in Element 4, Procurement of Items and Services.

1.4.3. *Management Assurance That Applicable Quality System Elements Are Understood and Implemented*

Agency assistant commissioners and management clearly signal to staff the importance they place on QA through their:

- Support for agency funding and staff allocated to the QA program,
- Reliance on QA staff to track the development and storage of QA related documentation, including on the EPA R5 QA Track database,
- Approval of QA staff acting as liaisons with EPA R5 QA management on behalf of program staff,
- Insistence that QA staff remain involved with QA document development agency-wide,

- Confidence that materials maintained by QA staff on the IDEM Extranet QA site are accurate, current and applicable,
- Expectation that direct reports participate in value added QA trainings provided or arranged by QA staff,
- Assignment of program staff resources for;
 - QA document development
 - Submittals for the QA annual report
- Incorporation of QA associated tasks in annual performance expectations, and
- Acknowledgment of QA related accomplishments by program staff during the annual IDEM Awards Presentations.

2.0. QUALITY SYSTEM DESCRIPTION AND COMPONENTS

Purpose - To document how IDEM manages its quality system and defines the primary responsibilities for managing and implementing each component of the system.

The IDEM quality system encompasses four principle components that define most of the agency's work. The agency considers quality to be an integral part of each of the components' design, and the responsibility of everyone at IDEM. IDEM staff is expected to plan, execute, document, and review all work performed to ensure that it conforms to the data objectives established for the program, project, and/or service provided. The principal components of the IDEM quality system are 1) systematic planning, 2) quality system documentation, 3) program and project-level assessments, and 4) quality assurance training for managers and staff. The following tools are used to implement the principal components of the agency's quality system:

- An EPA-approved Quality Management Plan (QMP)
- Systematic Planning Processes
- Quality Assurance Annual Report and Work Plan(QAARWP)
- Quality Assurance Program Plans (QAPPs)
- Quality Assurance Project Plans (QAPPs)
- Standard Operating Procedures (SOPs)
- Technical SOPs
- Data Quality Assessments
- Performance Evaluations and Proficiency Testing
- Quality Assurance Training

2.1. Systematic Planning Processes

Several agency programs engage in routine, if not annual, systematic planning to identify elements of concern, means of measurement, and proposed strategies for evaluating the data generated from data gathering projects.

The principles associated with systematic planning are central to the IDEM quality system. The essentials of systematic planning are identified in Table 1, Elements of Systematic Planning (See Appendix E), from page 3 of the *U.S. EPA QA/G-4 Guidance on Systematic Planning Using the Data Quality Objectives Process*.

The systematic planning process involves:

- Framing the question(s) that need to be answered.
- Identifying the roles and responsibilities of involved staff.
- Scheduling the actions and resources required to complete the investigation.
- Specifying what will be measured (sampled for).
- Determining how many measurements are needed, and within what range.
- Selecting where, when, and how measurements should be taken, and identifying any potential obstacles to the measurement process.
- Establishing the type and number of quality control samples that should accompany the collected measurements and any additional assessment of field or lab activities that also should be conducted to minimize the possibility of measurement error.

- Describing how the data will be analyzed and assessed against pre-selected performance criteria to demonstrate that the level of confidence in the accuracy of the final measurement data adequately supports its use.

This sequence of actions makes up the development of program and project QAPPs. Its use is required by agency program staff in the early stages of planning environmental data operations. This requirement similarly applies to contractors and other entities acting on behalf of IDEM. Such quality planning is often specifically required in the terms and conditions associated with data operations involving:

- Grants and sub-grants,
- State-U.S. EPA cooperative agreements, and/or
- Responses to statutory or regulatory requirements and consent agreements.

The program areas currently using the principles of systematic planning on a routine or an annual basis are:

- OAQ Air Monitoring for ambient monitoring of criteria pollutants and air toxics
- OLQ Remediation for site investigation projects
- OLQ Industrial Waste Compliance for PCB sampling
- OLQ Underground Storage Tanks regarding leak detection
- OWQ Watershed Assessment for:
 - Probabilistic monitoring
 - Targeted monitoring
- NWRO for habitat restoration and beach monitoring activities

Data operations conducted on a smaller scale, such as the work plans described in 2.2.6., rely in part on the principles of systematic planning.

2.2. Quality System Documentation

Quality system planning of an activity or set of activities, however comprehensive, must be adequately documented to ensure:

- All participants have an opportunity to provide input to correct and improve the activity being documented.
- That for data operations, all participants have access to the final QA document so that:
 - Each staff can know what tasks to perform and in what manner, and,
 - Each identical task is performed identically, even if conducted by different staff, so that results are not skewed by varied implementations.
- Field and lab (bench) notes of activity implementation can be reviewed to verify that the agreed upon plan was carried out as written.
- Staff evaluating data generated as a result of the documented activity can review what processes were to be used against the record of actual field activity. If process variations occur, information is available to determine whether data can be adjusted or must be discarded.
- Peers in the scientific and environmental protection community wishing to use the data at some future date have the opportunity to reference the methods and techniques originally used to generate it, to determine applicability.

Types of QA tools used by the agency include:

2.2.1. *Quality Management Plan*

As a state agency delegated to perform work for, and receive financial assistance from, U.S. EPA, the agency will develop, implement, and maintain an EPA R5 approved QMP. The agency's QMP is the overarching, agency level quality system policy for ensuring environmental data are of the type and quality needed for its intended use. The QMP provides information on how the agency will plan, document, implement, evaluate, and improve upon environmental data operations. The QMP documents agency practices that support data operations including:

- Identification of QA system staff roles and responsibilities
- QA training requirements
- Related procurement and services oversight practices
- QAPP and administrative and technical SOP development, review, and approval procedures
- Standards and practices associated with the electronic management of work practices and resulting data
- Quality system assessments and follow up corrective actions

2.2.2. *Quality Assurance Annual Report and Work Plan*

IDE� QA staff, with input provided by program area QA staff, prepares and submits an annual quality assurance report and work plan to EPA R5, which measures the agency's implementation of its QMP. The report summarizes the agency's quality assurance activities of the previous year and identifies QA activities planned for the upcoming year.

2.2.3. *Quality Assurance Program Plans*

The agency currently has several programs that have planned, developed, and implemented Quality Assurance Program Plans (QAPPs). These QAPPs identify study parameters, personnel requirements, equipment and methods, implementation audits, data review, data acceptance evaluations, and final assessments prior to data use.

The agency currently has several programs that have approved QAPPs.

- Each of these three OLQ program QAPPs:
 - IDE�-U.S. EPA Region 5 PCB Inspection QAPP
 - Investigation of Underground Storage Tank Releases QAPP
 - Site Investigation Program QAPPreceives final approval from the EPA R5 office that retains approval authority. Although IDE� QA staff provides supporting reviews when each is updated, the three QAPPs are submitted directly to the appropriate approving EPA R5 divisional office by the respective IDE� program. Each is also uploaded into QA Track, where it is accessible to EPA R5 staff.
- The OPS Northwest Regional Office (NWRO) Lake Michigan Beaches Monitoring and Notification Program QAPP.
- The OWQ Watershed Assessment and Planning Program's 2017 Indiana Surface Water Quality Monitoring QAPP.

2.2.4.

Quality Assurance Manuals

The following agency programs maintain QA related manuals:

- The OAQ Air Monitoring Branch has developed and implemented a [Quality Assurance Manual](#) that serves as its program QAPP.
- The OAQ Air Programs Branch has developed and implemented a Modeling Guidance Document which outlines current IDEML air quality modeling policies providing the requirements for Major Source Prevention of Significant Deterioration (PSD), non-attainment New Source Review (NSR), and Hazardous Air Pollutants (HAPs) emissions modeling. EPA R5 staff review the guidance after each update.
- The OLQ uses the following [manuals and guides](#) to inform decision making based on the data gathered at contaminated sites:
 - The [Remediation Closure Guide](#) (RCG) documents the risk based criteria used by OLQ to support its cleanup related decisions.
 - The [Remediation Program Guide](#) (RPG), the companion manual to the Remediation Closure Guide, sets forth the policies and procedures applicable to all remediation programs, and specifically outlines the different processes and regulatory requirements for each.
 - Guidance Documents
- OLQ relies upon three groupings of guidance documents that provide additional tools for investigating and removing contamination in soil and ground water. They differ from the RCG in that they do not include rules or requirements.
 - [Site Characterization and Sampling Guidance](#) documents that explain how and where to investigate chemicals in soil and ground water, including what kind of contaminants could be found, and where and how they could migrate.
 - [Risk Evaluation](#) documents that identify what levels of contaminants could require further investigation, and how to determine levels of potential hazard.
 - [Remedy Selection and Implementation](#) documents explain how to choose the best cleanup plan for a site and how to maintain the site during long-term monitoring and restricted closures.
- The OWQ Watershed Assessment and Planning Branch is using a [Field Procedures Manual](#) that it is currently being converted into several technical SOPs which will take its place.
- The OWQ DWB uses SOPs to direct drinking water compliance rule activities, drinking water utility permitting, drinking water operator certification, source water monitoring, and wellhead protection activities. Management of the laboratory drinking water certification program is through a "Memorandum of Understanding" (MOU) with the Indiana State Department of Health. Current SOPs and the Drinking Water QAPP are being revised.
- The NWRO LAMP and RAP programs use Annex 2 of the 2012 Great Lakes Water Quality Agreement.

2.2.5. *Quality Assurance Project Plans*

The agency has in place active project specific QAPPs. Currently, the IDEM Northwest Regional Office (NWRO) has three active project QAPPs developed by NWRO staff. These project QAPPs are associated with, and funded by, federal Great Lakes Restoration Initiative (GLRI) grants:

- Aesthetics Monitoring in the Grand Calumet Area of Concern (AOC) GLRI Project
- Grand Calumet River AOC Project 1: Dune and Swale and GLLA Wetlands Restoration
- IDEM Lake Michigan Beach Monitoring and Notification

2.2.6. *Work Plans*

IDEML program areas have developed Work Plans, which the agency considers a subset of program QAPPs. Under this scenario, iterative projects are implemented following the requirements of a much more comprehensive program QAPP. Agency programs conducting essentially identical data operations to gather like data from sites that vary only by location, and/or time frame, opt to develop and to use these “sub-QAPPs”. These programs include:

- The OWQ Watershed Assessment and Planning Branch (WAPB), which annually targets rotating areas for specific types of water quality monitoring. Other monitoring projects may arise from OWQ program requests or commitments but with location being the only significant difference in work conducted. All OWQ WAPB Work Plans go through the same review and approval process as other quality documents.
- The OLQ has two programs that generate Work Plans. As with the OWQ, these OLQ work plans vary primarily by location. The programs are:
 - Underground Storage Tanks (USTs) Branch
 - Site Investigations

2.2.7. *Standard Operating Procedures (SOPs)*

IDEML relies on technical SOPs to document procedures directly associated with data operations. Complex non-technical SOPs are referred to as administrative SOPs. All agency SOPs are developed by program staff, and reviewed and approved by IDEML QA staff. SOPs are further discussed in Element 5, Documents and Records, of this document.

2.3. Program and Project-level Assessments

2.3.1 *Data Quality Assessments*

The following agency programs regularly engage in the assessment of laboratory data packets as part of assessing data prior to its usage. These and other project assessment practices, which are discussed in Element 9, Assessment and Response, include:

- OAQ Air Monitoring Branch evaluates the data it generates in the field and in its laboratories.

- OLQ Science Services Branch chemists perform data verification, validation, and assessment in response to requests for services from the various OLQ branches.
- OWQ DWB evaluates data generated from their contract laboratories' analyses.
- OWQ Watershed Assessment and Planning Branch (WAPB) staff evaluate lab data generated by contractors from the analysis of samples collected by WAPB field staff.
- NWRO evaluates data generated in accordance with the Grand Calumet AOC Aesthetics Monitoring QAPP and related SOPs, as well as *E. coli* enumeration and beach notification data entered into the BeachGuard database by entities participating in the Beaches Program. OWQ's WAPB staff evaluate much of the contract lab data generated through the RAP program.

2.3.2

Program Assessments

IDEM QA staff and program area staff rely on a number of approaches to conduct, and expand on program assessments within IDEM. These are discussed in greater detail in Element 9, Assessment and Response, including:

- Program reviews conducted by EPA R5 divisional staff.
- Annual QA inventories of program assessments as part of developing the QA Annual Report to EPA R5.
- QA document update cycles that improve individual documents and by extension, expand the QA culture of the programs.
- Internal program assessments.
- Individual annual performance assessments.

2.3.3

Performance Evaluations and Proficiency Testing

- OAQ Air Monitoring oversees the industrial monitoring networks operated by IDEM and tracks the Proficiency Testing program participation results for each source in the network.
- OLQ Science Services Branch (SSB) matches the sampling requests of staff from each of the various OLQ programs with the optimal OLQ contracted laboratory, develops the Scope of Work for those contracts and evaluates the technical competence of each facility during the contract period. This includes monitoring each contractor with respect to the maintenance of its quality system, its accreditations, and the results of any performance testing (PT) programs in which it participates.
- The OWQ DWB specifies independent accreditation and performance testing as part of its contract laboratory program. Laboratories operated by the Indiana State Department of Health (ISDH) or any other state entity are held to the same level of independent review.
- OWQ Watershed Assessment and Planning (WAPB) Branch tracks the laboratory accreditations and the results of a wide range of PT types used by its contractors.

2.3.4 *Evaluation of Contractor QA Competency*

IDEML relies on external laboratory contracts for a significant amount of the analysis performed in sampling. IDEML is responsible for ensuring the labs contracted to perform analysis and generate data for agency use meet the same quality system requirements that have to be met by IDEML staff.

- OAQ Monitoring Branch completes most of its own sample analysis while some external laboratory analysis is overseen by U.S. EPA.
- OLQ Science Services Branch, chemistry section staff drafts the Scope of Work that lays out contract laboratory requirements for the laboratory services hired by OLQ.
- The OWQ DWB specifies that all laboratories performing regulatory analyses have a valid ISDH certification for those analyses. For non-regulatory analyses as well as regulatory, contract laboratories are vetted during the laboratory contract phase. Contract laboratories must supply quality control manuals, method detection limit determinations, equipment and primary personnel lists, method SOP's and independent performance and accreditation results. All of which must meet minimum guidelines and performance criteria specified in the State's Request for Proposal (RFP).
- OWQ Watershed Assessment uses a number of contract laboratories, relies primarily on contractor third-party accreditations, and on each lab's successful participation in PT programs.
- The NWRO ensures labs generating *E. coli* enumeration data for the Lake Michigan Beaches Monitoring and Notification Program are certified to conduct such testing by a recognized body (e.g., the Indiana State Department of Health, IDEML).

IDEML technical staff must revisit the appropriateness (which can require the incorporation of graded approach QA principles) of existing environmental standards/decision making criteria in use. This component of any quality system can have a direct impact on the quality of the environmental decisions made by the agency. Such tasks would fall to IDEML staff that review and assess data, and work with assessing risks. When such re-evaluations and any associated changes to standards are justified, it likely will be in conjunction with U.S. EPA and other external experts.

2.4. Quality Assurance Training

IDEML management recommends all appropriate program staff attend QA related trainings made available to them by:

- EPA R5 QA managers, or
- QA presentations by EPA R5 divisional staff with whom program staff regularly interact. Such trainings are most likely to emphasize QA practices directly associated with the activities and topics most closely shared by IDEML staff and their respective U.S. EPA R5 counterparts.

As discussed in greater detail in Element 3, Personnel Qualifications and Training, IDEML QA staff provide the programs with:

- A wide variety of on demand QA training materials and associated U.S. EPA QA guidance on the agency Extranet, and
- In person QA training sessions, as requested.

3.0. PERSONNEL QUALIFICATIONS AND TRAINING

Purpose - To document the procedures for assuring that all personnel performing work for IDEM have the necessary skills to effectively accomplish their work.

Work done by IDEM staff requires a range of ongoing training and retraining. Training topics can include administrative protocols; health and safety; or technical skills associated with chemistry, biology, engineering, geology, toxicology, meteorology; and other ecologically related scientific discipline practiced by IDEM staff. Training in the application of QA standards and practices as they apply across the agency is the primary focus here.

3.1. IDEM QA Training Policy

As addressed in 1.1.4., a significant percentage of IDEM staff spend at least some portion of their overall work time completing tasks associated with environmental data operations, the central focus of the IDEM quality system. It is the expectation of IDEM senior management that all such agency staff participate in QA specific training to the level adequate to ensure that each understands, at minimum, the purpose for and the requirements of that part of the agency's quality system encompassed by their work. The more essential each staff is to gathering, using, or reporting environmental data, the greater their individual need for adequate QA training. Appropriate QA training topics could include, but are not limited to:

- The value of the quality system and its components
- Establishing data quality objectives
- Developing, reviewing, and or approving QAPPs, QAPP-related work plans, SOPs and TSOPs
- Implementing QAPPs, related work plans, SOPs and TSOPs
- Verifying, validating, and assessing data
- Evaluating the performance of QAPPs, work plans, SOPs and TSOPs types.
- Assessing quality system activities
- Tracking the QA compliance of entities acting on behalf of the agency

3.2. Training Processes, Roles, Responsibilities, and Authorities

Staff that perform environmental data operations require program specific technical training and the appropriate level of accompanying QA training. The technical training is guided by managers and more experienced staff within each respective program.

Materials used may include presentations, guidance documents, instruction manuals, technical SOPs, and other resources from a number of sources. U.S. EPA provides a number of training presentations via the internet, some of which U.S. EPA designed, and some of which originate from other scientifically respected organizations endorsed and made accessible by U.S. EPA. Some IDEM program areas may develop technically focused trainings in-house. Regardless of the source, some of these program area specific technical trainings may encompass QA related issues.

IDEML program area supervisors and management track, whether formally or informally, the training needs of staff reporting to them. Their ongoing interaction

with staff performing data operations informs management of the levels of individual staff program specific technical expertise, and the need for any additional trainings or retraining.

IDEML training to acquire or augment the QA skills needed to perform data operations is provided by agency QA staff. As with program area specific technical training, agency QA training includes presentations developed or endorsed by U.S. EPA, or by IDEML staff, and are made accessible to staff via webinar, in classroom settings, or in a document format. QA training is most often developed and presented from a generalized perspective. Because it can increase the effectiveness of the training, QA staff endeavors, whenever possible, to incorporate program related specifics to serve as real world examples. Nonetheless, QA principles remain applicable to any data operation.

The roles, responsibilities, and authorities of various levels of agency staff to provide or participate in QA training are as follows:

3.2.1 *Program Management QA Responsibilities:*

- Be knowledgeable of the practices and benefits of the IDEML quality system to the extent necessary to ensure reporting staff are adequately implementing those portions of the U.S. EPA required IDEML QA system encompassed by the program they manage.
- Ensure appropriate staff reporting to them participate in QA trainings provided by:
 - EPA R5 division level QA staff from the respective Air, Land and Chemical, Superfund, or Water Division that is the media specific counterpart of the program they manage.
 - EPA R5 QA management.
- Recommend staff participation in QA trainings provided by IDEML QA staff that is applicable to the work done by the program.
- Monitor the QA related training histories of staff reporting to them who perform QA related work. Such training information should be documented by those same staff, in the form of QA related personal resumes as described in 3.2.2.
- Incorporate QA components into individual staff's annual performance evaluation goals.

3.2.2 *Program Staff Involved with QA Tasks Are Responsible For:*

- Attending QA trainings required by management, especially those presented by:
 - EPA R5 division level QA staff.
 - EPA R5 QA management and staff.
- Attending QA trainings they identify as helpful, and are approved by their respective management staff.
- Maintaining a personal resume of their individual QA training histories. This self-maintained resume should be kept updated and should include QA-related:
 - Trainings, date attended, the source or sponsor of the materials presented (U.S. EPA, or U.S. EPA endorsed entities, scientific papers or journals, and other credible sources) including, but not limited to subjects such as:

- Project and/or sample planning
- QA document development
- Laboratory packet review
- Statistical data testing,
- Data assessment for decision making
- Associated certificates or other documentation that may have been provided to confirm participation in trainings.
- Listings of documents developed or work performed by the individual resulting in successful environmental projects or decisions.
- Other acknowledgements, awards, or achievements that similarly demonstrate the individual's understanding of QA principles and requirements.

3.2.3 IDEM QA Staff Training Responsibilities

The IDEM Quality Manager and QA staff are responsible for ensuring all agency staff required to complete QA training have the appropriate level of such training available to them. To meet this obligation QA staff must:

- Develop QA training materials from introductory to advanced levels.
- Assess agency QA training needs and apprise management of that assessment.
- Provide training as requested by program or agency management.
- Proactively promote the use by staff of the on-demand QA related training and guidance materials accessible via the IDEM Extranet.
- Arrange QA training presentations for agency staff by EPA R5 or other appropriate external entities.
- Provide a training resume template, if requested, to all agency staff required to track their individual QA training histories, as required in 3.2.2., and provide feedback and assistance to program area staff in completing that training template for their records.

3.2.4 Regarding Staff Maintaining Licenses and Professional Certifications

All IDEM staff are encouraged or even required to maintain licenses and professional certifications they may have acquired, such as attorneys' licenses, engineering registrations, and health and safety training certificates. Agency staff are responsible for providing such formal documentation upon justifiable request.

3.2.5 Regarding the Pending Application by U.S. EPA of QA Field Activities Procedures (QAFAP) Standards to the States

In 2010, the U.S. EPA's Regional Science and Technology (RST) organization first established and endorsed its Field Operational Guidelines (FOG) requirements to address that a more significant portion of environmental data error could be attributed to field error than to laboratory error. It is intended that the FOG address the most critical potential sources of in-the-field error.

In September 2014, the FOG was incorporated into the U.S. EPA QA Field Activities Procedure (QAFAP) under *EPA's Quality Policy (CIO 2105-P-02.0)*. The ten associated requirements were fully in place and audited

to ensure compliance by U.S. EPA field staff in 2017. Once U.S. EPA has determined its own staff are consistently compliant with the QAFAP requirements, it may look for similar levels of compliance by the states. At that point, IDEM QA staff will keep programs apprised of QAFAP requirements, and assist with training, if needed.

3.3. How QA Training Is Assessed

IDEML QA staff relies on several processes for determining the effectiveness of QA training, and program interest in additional training. For example:

- Each training session presented by agency QA staff ends with a survey that is then used by trainers to gauge the effectiveness of the presentation.
- The template distributed to agency branch chiefs for their input on the IDEM QA Annual Report to the EPA R5 QA manager:
 - Inventories management interest in QA training for branch staff regarding:
 - QA document development
 - QA document review
 - Sampling plan development
 - Field assessment/tracking to ensure plan is followed
 - Verification and validation of data packages
 - Verification and validation of existing data
 - Data assessment
 - Solicits input regarding improvements to U.S. EPA or IDEM QA guidance or training materials that could improve program data gathering or use.
- In August 2016, QA staff conducted a training survey that will be used to plan an agency training curriculum. The survey, which produced a significant amount of information, was randomly distributed to a statistically proportionate cross section of all agency staffing levels. It received a 54-percent response from the one quarter (222) of all agency staff that received the 18 part questionnaire. Results of the survey are being used to plan future training activities.

3.4. Identifying the Need for Retraining

Several features of the IDEM QA system suggest when retraining should be considered. They are:

- If there are changes to when or how a process is done, Element 5, Documents and Records (5.2.6.) requires that any existing SOP or technical SOP be updated.
- Program management assessments of work completed, either during annual performance reviews, during field audits, or the course of regularly occurring managerial surveillance and/or oversight of program activities, can identify activities or outcomes that may need to be remedied through retraining.
- The ongoing QA partnership maintained between the EPA R5 QA manager and IDEM QA staff often serves to alert QA staff and, subsequently, affected IDEM program staff of changes that could require retraining. The above discussion of potentially pending QAFAP requirements is an example of how this federal-state partnership could help identify the need for retraining.

3.5. Other Ways in Which IDEM Management Supports QA Training

IDEML utilizes the state's Pay-For-Performance based system for job training decisions and documentation. At the end of each calendar year staff are rated on the degree to which their overall performance conformed to the eight basic competencies for which all agency staff are held accountable. They also are evaluated regarding the manner in which they complete each of four or five other tasks they and their supervisor jointly agreed would be completed.

4.0. PROCUREMENT OF ITEMS AND SERVICES

Purpose - To document the procedures for purchased items and services that directly affect the quality of environmental decision making.

4.1. IDEM Purchasing Activities

The implementation of IDEM environmental data operations requires supplies, equipment, and professional services of appropriate quality. Procurement of these items follows a chain of review and approval that includes various levels of IDEM management, the Indiana Department of Administration (IDOA), and possibly the Office of Management and Budget (OMB) and/or the Indiana Office of Technology (IOT). Requisition amounts under \$2,000 can be approved by the purchasing director, amounts between \$2,000 and \$100,000 require the approval of the agency Chief Financial Officer, and a purchase of greater than \$100,000 must be approved by the Commissioner.

4.1.1. *Regarding the Purchase of Equipment and Supplies*

Program management responsible for the data operations authorize procurement staff to initiate requests for supplies and equipment, based on the specifications provided by technical staff. Once solicitations, or requests for proposals (RFPs) are posted publically, program staff evaluate the technical merits, guarantees and/or vendor technical support provided, and bids as the requests move through the PeopleSoft eProcurement module, receiving additional needs-based, technical, and budgetary scrutiny until final approval. Purchases may be based on bids from a list of agency and IDOA approved providers or from a sole source provider when necessary and with the appropriate waiver. All equipment and supplies are inspected by the purchasing program prior to payment and use. Equipment purchases may include service agreements. Unsatisfactory purchases (whether for technical, quality, reliability, or other reasons) may result in product returns and/or in the removal of the non-compliant supplier from approved vendors lists.

4.1.2. *Regarding Agency Contracting for Laboratory Analysis Services*

Because IDEM operates only some of the types of laboratories needed to validate the data it uses, agency programs must often solicit and rely on outside laboratory contractors. Programs contracting out laboratory services are required under IC 5-22-9, to draft a "Request for Proposal (RFP)," specifying the requested goods and/or services to be solicited for any contract valued at \$75,000 or more, although price is not the sole factor in awarding the contract.

Responses to RFPs are reviewed by appropriate program staff for technical and QA qualifications, services offered, support provided, client references, and other qualifications. Once providers are selected, resultant contracts include formal work proposals that identify the numbers of samples to be analyzed, describe procedures for chain-of-custody and sample preparation, specified method(s) of analysis, sensitivity or detection limit requirements, sample and laboratory specific quality control practices, data report formatting, and other criteria required in the Scope of Work.

Each contract and grant agreement undergoes the following internal review:

- The funding source is checked to ensure eligible funds are available.
- The goods and/or services to be provided must be justified to ensure such purchase meets the goals of the primary grant funding.
- Program area staff ensure the vendor meets the technical specifications for use by program staff working on the project.
- The program technical staff ensures the contractor can meet the same U.S. EPA recognized, ANSI/ASQ quality assurance and quality control standards that IDEML staff would be expected to meet were it to be performing that same work. When this includes third party documentation through accreditations or certifications, the expiration dates associated with such documents should run through the end of the contracting period. If accreditations or certifications must be renewed during the contracting period, no analyses or related data generation should be run on sample(s) provided by IDEML during the interim period when the laboratory is not accredited or certified. Entities sub-contracted by an IDEML contractor must be able to demonstrate the same level of QA competency as the primary contractor.
- Program technical staff and the IDEML OLC contracting attorney collaborate to ensure final contract language includes all necessary QA specifications. Program staff draft language, based on program needs and any applicable grant requirements, that establishes the technical and QA requirements for the RFP and subsequent contract. An attorney may sometimes assist with this process and will review the final contract language before forwarding the draft on to IDEML Business Services and Contracts, which assures that funding is available. Afterward, the contract must receive final approval from IDOA prior to being signed.
- When work begins, further review occurs. Regardless of the funding source used by IDEML (internal, grant, or cooperative agreement), as work proceeds:
 - Each invoice for reimbursement is reviewed to ensure each vendor meets the requirements of the contract.
 - Each sub-recipient proposal is reviewed and scored on how it meets the contract requirements. Funding is then approved for those contractors meeting the requirements.
 - When goods or services do not meet the terms and conditions of the contractor follow up, additional reviews are conducted to determine whether the vendor will be kept on the eligible vendors list for future consideration as a provider, or whether the agency will simply disqualify them from future participation in contracting opportunities.
- Program technical staff review the project deliverables and approve or deny payment.
 - If project deliverables are consistent with the requirements and objectives of the contract or other agreement, the invoice is approved for payment.

- If the request for payment is not approved, the appropriate program technical staff requests corrective action. Only after technical staff are satisfied that the work provided, or the corrections made meets requirements, is payment approved.

4.1.3.

Other Means of Determining Contractor Competency

In lieu of accreditation/certification, IDEM may rely on the following means of demonstrating competency:

- Results from on-going participation in proficiency testing or round-robin programs conducted by an external organization,
- Reports documenting technical and quality system assessments conducted by an external organization, or
- Quality documentation such as:
 - Laboratory quality manuals,
 - QMPs,
 - Detailed standard operating procedures (SOPs) or Technical SOPs that describe their organization's quality practices, and/or
 - Descriptions of applicable instrumentation, sampling, equipment, method sensitivities, reporting practices, capacity, experience, staffing (e.g., education, job experience, training), and demonstrations of successful past performance, consistent with [U.S. EPA's Forum on Environmental Measurements \(FEM\) Policy 2011-01, "Policy to Assure Competency of Organizations Generating Environmental Measurement Data Under Agency-Funded Acquisitions."](#)

4.2.

Ensuring QA Documentation Is Consistent With Contract Language

It is the responsibility of the IDEM program area initiating an environmental data operation to develop and/or provide a QAPP, or similarly appropriate QA documentation. This QAPP may be specifically referenced in the contract. The Office of Legal Counsel (OLC), which reviews the legality of the draft contract, ensures all the QA requirements identified by program technical staff, such as identification of the required methods, standards, techniques, and QC practices are adequately cited in the Scope of Work as contract deliverables.

IDEML programs strive to avoid inconsistencies between the QAPP and Scope of Work, or circumstances when the greater part of the required QA documentation is in the contract rather than the QAPP. Thorough referencing ensures participating program technical staff and other interested parties adequate access to all of the relevant details of technical and QA documentation associated with the project, particularly if it is not compiled into one source.

4.3.

Evaluating the Competency of Grantees or Volunteers Performing Sampling or Analysis on IDEM's Behalf

4.3.1.

Grantees (Entities receiving pass-through grants from IDEM)

Requirements for technical competence are proportional to the funding provided via the grant or assistance program, and to the environmental and public health impacts of the data generated. Currently only the OWQ WAPB nonpoint source grant program has staff that are evaluating the

QA planning of grant applicants, and stressing their adherence to volunteer monitoring protocols. Consistent with the graded approach, the more technical experience each grantee brings to the project, the better the quality of their QA work plan. As a result, less funding is needed for training and QA document development, and more is available for project implement, or for funding separate additional projects.

4.3.2.

Volunteer Organizations

Some IDEM program areas accept and use environmental data generated by volunteers. Those programs should have in place measures assuring that such voluntarily provided data is of sufficient quality to be included with other data the program generates and/or uses. For those voluntary organizations unable to provide third party accreditations, quality system documentation (QAPPs or SOPs followed), or other demonstrations of technical capability, the agency program areas involved should require, or provide a level of QA training consistent with the principles of the U.S. EPA-endorse graded approach, such as "[The Volunteer Monitor's Guide to Quality Assurance Project Plans](#)," U.S. EPA publication *EPA 841-B-96-003, September 1996*. The level of acceptable training and the confidence in the data voluntarily provided should be proportionate to the environmental and public health impacts of the decisions to be made using that data.

4.4.

Regarding IDEM Grant Activities

Once an IDEM program area determines that it will pursue a particular grant solicitation, staff develops an application package that includes a work plan describing in detail the proposed work to be done to fulfill the goals of the grant. The application package is evaluated by the grantor (generally a program within U.S. EPA) against the Request for Proposal (RFP) of the grant opportunity to ensure it follows the parameters necessary for funding.

Federal grant programs require competitive state applicants to have quality system documentation in place in the form of an approved QMP, or a comparable surrogate. The level of QA documentation required for each grant generally is established in the terms and conditions set by the grant. If data operations are involved, a project QAPP specific to the work proposed may be required, usually within 90 days of the grant award. Any contractual agreements associated with grant funding require the same level of justification as is required in the primary grant agreement, and any contractors must meet the same federal requirements as the grant awardee.

IDEML QA staff advise that even when a grant does not specifically require program area staff to perform onsite audits or review QA systems of the laboratory, staff still must make certain that contracted laboratories have in place, at minimum, third-party accreditation and/or other proof that they are qualified to competently complete the work for which they were hired with grant funding.

For projects closely paralleling work done under an existing agency or program QAPP, IDEML staff may instead opt to develop a sampling and analysis plan that provides project specific descriptors, locational information, and site conditions, but relies on the sampling and analysis methods and data assessment criteria

already established in that existing QAPP. This option allows for program compliance with grant QA documentation requirements while providing for consideration of the appropriate level of documentation required in proportion to the degree of threat to human health and the environment consistent with the graded approach.

4.5. Other Procurement Related Issues

4.5.1. *The Graded Approach*

Whatever the funding source, IDEM program technical and QA staff strive to use the graded approach to ensure the quality of data generated for use in agency decision making is as demonstrably accurate as possible, while also proportionately balancing the dollar costs associated with completing data operations and conducting the subsequent actions required. IDEM management maintains that a key benefit of a quality system is one that allows skillful use of the graded approach in a manner that both prevents adverse environmental conditions from harming, or further harming human health and the environment and at the same time avoids the wasteful spending of scarce resources on either inadequate or overly thorough action.

4.5.2. *Using QAPPs*

The lead IDEM program area doing or overseeing sampling, analysis, or other QA related task, is responsible for ensuring that a QAPP or other appropriate QA documentation is developed and approved prior to the start of any field or laboratory work.

5.0. DOCUMENTS AND RECORDS

Purpose - To document appropriate controls for quality-related documents and records determined to be important to the mission of IDEM.

The majority of all QA documents and records are developed by program area technical and/or administrative staff with oversight, review and approval from agency QA staff. QA documents applicable agency-wide are developed primarily by QA staff, with program input.

All IDEM QA documents and records are stored in SharePoint™ libraries or on the agency's internal Extranet site. QA maintains the same standards for quality, objectivity, utility, and integrity in the information used and disseminated by IDEM, as identified in the U.S. EPA Office of Environmental Information (OEI)'s October 2002, *Information Quality Guidelines*.

5.1. Process for Identifying QA Related Documents and Records

Any agency activity involving environmental data operations (the gathering, analysis, recording, or use of environmental data) is considered part of the IDEM quality system. Use of environmental data can include the design, construction, and operation of technologies to prevent contaminants from entering, or to remove them from, the environment. IDEM quality system QA documents include:

- All documents, templates, trainings, and other materials developed by agency QA staff for use in the QA system;
- All requirements or guidance documents developed or supported by U.S. EPA and used by the agency;
- All program documents associated with data operations that are submitted to agency QA staff for tracking, review, and approval; and
- All program documents associated with administrative processes that are submitted to agency QA staff for tracking, review, and approval.

Specific types of documents associated with agency quality system activities may include:

- The IDEM QMP;
- Quality Assurance Program Plans (QAPPs), or Quality Assurance Project Plans (QAPPs intended for repeated use on essentially identical projects);
- QAPP-related Work Plans/Sampling and Analysis Work Plans/ Sampling Plans;
- Standard operating procedures (SOPs) and technical SOPs (TSOPs);
- Forms (generated by program staff) used to record the implementation of data operations activities; and
- Related QA training materials.

5.2. Agency Documentation Requirements

The documents that inform agency staff of QA processes to be completed, and protocol and requirements to be met, are developed and managed as follows:

5.2.1.

Document Preparation

The QA Manager and staff are responsible for the development of QA documents that will be used agency-wide, or by multiple, but not all agency programs. Program management determines when their staff should develop QA documentation for operations within their respective programs. However, agency QA staff may suggest to program management additional QA documentation which might be useful or required.

When program managers determine that QA documentation is required, they assign staff that will be responsible for its development. It is recommended that staff follow the instructions in templates developed and/or approved by the agency QA manager. Each template includes information on the use of flowcharts, screenshots, schematic diagrams and other visual materials that may augment document text.

Generally, the type of QA documents prepared by program staff are QAPPs, work plans, or technical or administrative SOPs. They also generate work summaries for activities not needing a more formal SOP.

5.2.2.

Document Review

Once program management determines a draft QA document is ready, it is submitted for QA review through the agency SharePoint™ or e-mail systems. QA staff review the draft documents for:

- Formatting, grammar, and consistency with agency documentation and branding standards.
- The correct document number.
- Alignment with agency and U.S. EPA's ANSI/ASQ E-4 based expectations and requirements, or adequate explanation as to why they are not applicable.

The QA reviewer may insert suggested changes to the draft text that can be accepted or further modified by program staff. They may provide questions or comment about the technical content and logical flow of the document and/or the reasoning regarding the planning of the activities described. These questions or comments are intended to prompt further program consideration of how to increase document clarity and enhance adherence to quality standards.

The review process ensures the final revision is consistent with agency QA document standards and appropriately reflects technical procedures. At that time, the draft document is finalized and signed by program management and QA staff.

5.2.3.

Document Issuance and Control

Once a document is approved, QA staff posts it:

- On the agency QA Extranet page as a PDF file.
- In the agency's SharePoint™ QA documents library.

The posted copies are the official agency version, and may be accessed by all agency staff in a read-only format. The Word versions stored in SharePoint™ can be checked out by their respective program staff at some future date when further changes may be required.

5.2.4. *Document Maintenance*

The IDEM QA manager oversees the maintenance of the IDEM quality document management system, under which agency QA staff ensures each quality document:

- Is assigned a unique identification number.
- Is authorized for only a specific time period, identified in the table in 5.2.6.
- Is reauthorized at the conclusion of its effective period, as appropriate.
- Is removed from the active SharePoint™ and Extranet QA document libraries if it is obsolete.

QA specific training materials, templates, and support documents are maintained by the IDEM QA manager and staff.

5.2.5. *Document Use*

Program area management is responsible for ensuring that any work described by an authorized agency QA document is performed by program staff in a manner consistent with that document. QA staff may assist with field audits when requested.

5.2.6. *Document Revision*

If substantive changes occur to a statute, rule, method, or other resource upon which a quality document is based, that document should be immediately revised. A QA document under revision is subject to the same preparation, review, and issuance requirements as outlined above in 5.1.1., 5.1.2., and 5.1.3.

Agency QA documents are considered in effect consistent with the following schedule (See Figure 9), unless there are regulatory or process changes:

Figure 9

Effective Time Frames for IDEM QA Documents

QA Document	Maximum Authorization Period
Quality Management Plan	Five years, per U.S. EPA requirements, for the IDEM QMP
Standard Operating Procedures and Technical SOPs	Four Years
QA Project Plans, or Project QAPPs	Are in effect for the same time period as any associated funding or related contract or grant cycle, not to exceed one year without additional approval
QA Program Plans, or Program QAPPs	Should be reviewed each year, and revised to accommodate changes to technical and legal requirements, project goals, or funding cycles; but should never be in effect for more than five years
Sampling plans/Work plans (time or location specific data gathering done under an existing QAPP)	End of the field season, (unless up to one additional season, following the same parameters, is approved by QA staff)

Policies	Should be reviewed annually for consistency with federal, state, and agency requirements; and revised and re-approved as appropriate.
State Air Monitoring Manual	Three years, per the cycle established by the EPA R5 Air Division

5.3. Agency Record Requirements

As listed in 5.1., the forms used to record the implementation of data operations activities may be considered QA documents. These forms generally are generated by the program areas and with appropriate state forms management oversight, when required. They are for use during the conduct of work planned in QAPPs and other QA planning documents. Many of these forms such as field sheets, chain of custody forms, and bench notes (on forms developed by the labs), are of the type used during data operations (or QAPP) implementation and they record:

- When, where, how, and by whom work was done;
- Conditions in which it was done;
- Techniques employed for sampling;
- Methods of analysis used;
- Irregularities associated with completion of the work;
- How samples were transported;
- How samples were prepared for analysis; and
- Who had custody of the samples at each stage of the process.

5.3.1. *When Documents Become Records*

Once a data operation has begun, the plan of how the operation was to be conducted, and the related attached forms for recording how and under what circumstance the plan was carried out, become records. The QA document implemented as written and the associated, and now completed forms, may no longer be altered except if the approved QA plan (QAPP) was subsequently revised prior to continued use during the completion of that same project, in which case each version used to implement the project becomes part of the record for that project, and requires preservation. In addition, if the QAPP in question is a program QAPP, it can be reused for any number of additional similar, but separate project(s), becoming part of the permanent record for each project for which it is used.

5.3.2. *Ensuring Records and Documents Reflect Work Completed*

Element 8, Implementation of Work Processes, documents IDEM measures in place to ensure agency work completed reflects agency planning. That, as stated in 5.3.1., the QAPP or other QA planning document followed and the associated completed forms each immediately become unalterable records, ensures that data operation planning and recorded actions are frozen in time. Field forms which must be completed in ink or in a waterproof medium when necessary, log books completed only in ink and/or the use of electronic tablets and software that cannot be altered once data is entered, all ensure that

IDE�'s final records of environmental data operations accurately reflect the work done.

QAPPs, technical and administrative SOPs, and other QA planning documents remain dynamic in that they may be used again for additional, similar, future projects. However, that the agency properly controls and limits access to all previously used versions of planning documents, and only allows access to currently effective versions of planning documents and forms further ensures that agency records of data operations accurately reflect work completed.

5.3.3.

Records Management

Record management practices are driven by the Indiana Access to Public Records Act (APRA) (IC 5-14-3), under which a public record is "any writing, paper, report, study, map, photograph, book, card, tape recording, or other material that is created, received, retained, maintained, or filed by or with a public agency and which is generated on paper, paper substitutes, photographic media, chemically based media, magnetic or machine readable media, electronically stored data, or any other material, regardless of form or characteristics." IDE� manages its records in a manner consistent with the requirements of the Indiana Archives and Records Administration (IARA) in 60 IAC and with related agency policies.

IDE� specific policies on data, documents, and record management include:

- The Records Management Policy applies to all IDE� staff regarding the management, storage, and disposition of records including papers, electronic documents, e-mails, videos, films, and photographs. That policy adopts agency-wide records retention policies, provides for records disposition schedule training, and provides guidance on compliance with state and federal records management and confidentiality laws and rules. It also ensures that the agency's records are microfilmed or are uploaded into the Virtual File Cabinet (VFC), the IDE� electronic digital image document repository, in which electronic document files received or created by the various agency programs are stored and accessible in part or in full to agency staff and the public for the proper length of time, and are destroyed only when it is appropriate to do so.
- The E-Mail Management Policy sets requirements for managing e-mail for evidentiary purposes and labeling and handling confidential e-mails.
- The Records Request Policy ensures a timely and complete response to public record requests.
- The Litigation Hold Policy (Federal Rule of Civil Procedure 34, Indiana Trial Rule 34) ensures documents relevant to pending or reasonably anticipated litigation are preserved consistently with applicable state and federal trial rules.
- The Posting Public and/or Legal Notices on the Agency Websites Policy sets the approval process for posting agency documents.

- The Personal Identifying Information Disclosure, Prevention, and Response Policy and the Social Security Numbers Confidentiality Policy protect the personal information of IDEML staff and the public.
- The Forms Management Policy ensures all IDEML forms meet Americans with Disabilities Act formatting standards, are consistently applicable with state regulations, and are authorized by the state forms management office.

5.3.4.

IDEML Record Storage

All state and agency records are subject to record retention schedules approved and maintained by IARA. These schedules ensure records are retained for as long as legally required, and provide time tables for determining when certain obsolete records may be destroyed or deleted. The IDEML Office of Legal Counsel reviews draft records retention schedules before they are sent to the IARA for approval to verify that all applicable state and federal record keeping requirements are met. Electronic, and any paper agency records that may exist, are retained based on IARA retention schedules while records in the VFC are currently maintained indefinitely.

5.4.

Chain of Custody Practices

Each agency program involved with collecting samples has chain of custody practices in place that include:

- Individually-labelled custody seals on sample containers,
- Adequate preservation and packaging of samples,
- Appropriate holding time requirements to preserve sample representativeness, and
- Custody forms that accompany samples from the sampling site to the laboratory to ensure against holding time exceedance or tampering with collected samples. The forms record the chain of all persons who had legal possession of the sample(s) during the transport processing.

Program specific IDEML chain of custody practices:

- OAQ
 - Air Monitoring Branch chain of custody procedures are outlined in Chapter 2 of the [IDEML OAQ Quality Assurance Manual](#).
- OLQ
 - The Science Services Branch (SSB), which provides the sampling setup packets for OLQ Remediation Services, Inspections, and Emergency Response, follows the SW-846 chain of custody protocol identified in the SSB Chemistry Support Field Documentation SOP.
 - Remediation Services federal programs follows U.S. EPA chain of custody requirements.
- OWQ
 - Drinking Water Branch relies on the chain of custody process employed under the Drinking Water Certification Program.
- OPS - NWRO

- Water samples collected for *E. coli* enumeration as part of the Lake Michigan Beaches Monitoring and Notification Program employ chain of custody procedures as documented in the program QAPP and associated SOP.

5.5. Agency Roles and Responsibilities Regarding QA Documents

5.5.1. ***IDEML Management Shall:***

- Authorize agency QA documents.
- Ensure, through the use of field audits, supervisory surveillance, or other QA associated oversight, that staff follow QA planning documents as written.
- Designate program staff to acquire the training to develop and implement needed program QA documentation.
- Ensure QA documentation under development is not reviewed and approved by the same staff that are developing it.
- Ensure the review of existing program QA documents.

5.5.2. ***IDEML Program Staff Shall:***

When working with agency QA staff to develop a QA document:

- Utilize only authorized versions of quality documents.
- Implement QA documentation as written, recording the implementation on the appropriate forms identified in the planning document.
- Record on the provided forms any deviation to implementation that may occur, along with the reason for and conditions under which the deviation occurred.
- Track their individual QA qualifications as required in 3.2.3.

5.5.3. ***Agency QA Staff Shall:***

- Maintain convenient staff access to all agency QA documents.
- Advise program staff of documents requiring review or update.
- Develop and maintain access to templates, training, and other resources required by staff tasked with QA document development.
- Review all new and updated program QA documents submitted, and approve as appropriate.
- Upload to EPA R5 QA Track all IDEML self-approved QAPPs and other QA documents that may be submitted in that manner.
- Maintain an up to date archive of past QA documents.

6.0. COMPUTER HARDWARE AND SOFTWARE

Purpose - To document how IDEM will ensure that computer hardware and software satisfy the organization's requirements.

Responsibility for the deployment, operation, maintenance, and control of IDEM computer hardware and software resources is shared between IDEM's Office of Information Services (IS) and the Indiana Office of Technology (IOT).

6.1. Processes For Maintaining Computer Hardware and Software

The responsibility for processes associated with the development, installation, testing (including verification and validation), use, maintenance, and documentation regarding computer hardware and software used by IDEM rests in [IOT](#). Under Title 4, Article 13.1 of the Indiana Code, IOT has consolidated the electronic data and information infrastructure of all state executive branch offices under its control. In that role it provides the following services to IDEM:

- Application development services.
- Hardware, software, and security for desktop, laptop, tablet, and network devices as well as desktop/PC refresh and support.
- Database services including database hosting and administration.
- Enterprise shared services, including SharePoint™, Oracle application server, and Citrix (remote access services).
- Field operations, including PC, printer, network and remote-server support.
- GIS Services that enable coordination with federal, state, and local governmental units.
- Mainframe system administration.
- Network maintenance and management, including voice and cellular phone services, network connectivity, adds, moves, and virtual private network (VPN) remote access.
- Professionalize project management partnering with IOT's customers.
- Server administration and infrastructure support.
- Service Management: Implement Information Technology Infrastructure Library (ITIL) "best practices."
- Tier 3 Services: Global changes, security, software installation, Windows administrative tasks, and troubleshooting desktops/laptops.

IDEML's IS program addresses agency specific electronic data and information issues such as:

- Preparing and expediting requisitions for hardware,
- Controlling the purchase and management of licenses for commercially available software,
- Managing agency application data,
- Supporting in-house and third-party development of software applications,
- Managing, developing, and supporting in-house application development,
- Controlling access to agency electronic resources, and
- Interacting with agency and state procurement staff.

In 2015, the Indiana Office of Technology received a Special Achievement in GIS award at the Environmental Systems Research Institute (ESRI) Users Conference in recognition of Indiana's Data Sharing Initiative.

6.2. Assessing and Adjusting to the Impact of Changing User Requirements

Agency hardware and software is selected specific to user requirements. When there is a change in user requirements, the IS director ensures the necessary changes are made to the hardware or software capabilities. These changes are facilitated by in-house:

- Business Systems Consultants (BSCs) who:
 - Serve as the point of contact with agency programs.
 - Establish application requirements and draft user documentation.
 - Provide training to users.
- Project managers (PMs) who play a central role in developing medium to large, complex, multi-program area enterprise application projects; providing developers with background information on the software applications.
- The Applications Development Team, whose members include BSCs and PMs, create and manage IDEML-specific application software. In that capacity they:
 - Prepare and expedite requisitions.
 - Manage and interact with contracted third party software developers.
 - Create/develop, test, and manage IDEML-specific application software.
 - Perform database administration, security, installation/configuration, back-up, and recovery.

6.3. Evaluating Hardware and Software

- IDEML IS evaluates hardware and software in conjunction with program management and staff to ensure it meets program needs.
- IDEML IS also is approved to use commercial off-the-shelf or U.S. EPA Central Data Exchange Services (CDX), Shared Cross Media Electronic Report Rule (CROMERR) electronic reporting approaches for software such as its:
 - National Network Discharge Monitoring Report System (National NetDMR), and
 - Electronic Sample Entry Verify (eSE Verify) used by the IDEML water program, and
 - Electronic Authentication System (eAuth), which is used by each of the IDEML offices; air, land, and water.
- Commercial off-the-shelf software (e.g., ESRI-ArcGIS) testing is done through IS (Procurement is handled in conjunction with IOT and IDOA).
- Procedures and enterprise software such as Microsoft Office or McAfee Virus procurements are under IOT control.
- In-house software development (e.g., National Environmental Information Exchange Network (NEIEN) Node 2.0 and Data Flows for moving data from IDEML to U.S. EPA) testing is done according to the following:
 - Software Development Life Cycle (SDLC).
 - Data Standards (DS) (EDSC/Security, etc.).
 - IDEML's testing procedures – First, unit testing by developers to make sure requirements or scope or deliverables are met. Then, a second unit User Acceptance Testing via plan by project managers.

- Third-party created software (e.g., Air Compliance and Enforcement (ACES)) testing is done through IDOA contracting/procurement policies and procedures and the above-listed SDLC, DS, and IDEM testing procedures.
 - Desktop hardware testing is done through IOT and adheres to State Quantity Purchase Agreements and the Exception Process.
 - Server hardware and network environment hardware testing processes and are controlled by IOT.

6.4. Ensuring Data Meets Applicable Standards

Protecting the integrity of its environmental data is essential to establishing and maintaining the agency's culture of quality. Working together to serve the electronic data and communications needs of the agency, IOT and IDEM's IS provide the equipment, services, procedures, and policies necessary to achieve that goal. The support they provide ensures compliance with the following categories of standards and practices:

6.4.1. ***Data Standards***

IDEML uses the following data standards, which can be applied to any site or contact information:

Database Standards Guide
[TEMPO360 Data Standards Guide](#)
[TEMPO360 Data Standards USPS Appendices](#)

6.4.2. ***Standards for Ensuring the Quality of Data Uploaded to U.S. EPA***

IDEML programs that collect data subsequently shared with U.S. EPA to populate its publicly used searchable databases, such as Envirofacts or Enforcement and Compliance History Online (ECHO) work closely with their U.S. EPA counterparts to provide data consistent with U.S. EPA standards intended to facilitate environmental information sharing between that agency and the states, tribes, and other U.S. EPA partners.

These databases include:

- Facility Registry System (FRS)
- Integrated Compliance Information System (ICIS)
- Toxic Release Inventory (TRI)

IDEML internal database:

- Multimedia Enforcement Tracking System (METS)
- TEMPO

OAQ

- Air Compliance and Enforcement System (ACES)
- Leading Environmental Analysis of Data System (LEADS)

OAQ internal databases:

- Hazardous Air Pollutants (HAPs)
- ToxWatch Monitoring
- Meteorological Data

OLQ

- Resource Conservation and Recovery Act Information (RCRA Info)
- Solid Waste Management Information System (SWIMS)
- Geographic Information System (GIS) Data

- Global Positioning System (GPS) Data

OLQ internal databases:

- Sampling Database (SampDB)

OWQ

- Assessment Information Management System (AIMS)
- Safe Drinking Water Information System (SDWIS)
- Federal Integrated Compliance Information System (ICIS)

OPS/NWRO

- BeachGuard Monitoring and Notification Database data is processed into an XML file and uploaded to an IDEM Exchange website

6.4.3. *Ensuring Intra-IDE� Data Transfers Protect Data Integrity*

Indiana Extranet is a browser driven network composed of informational web sites and services. It provides secure connectivity to internal applications and data for state employees and business partners located outside of the main campus, as well as those working at field offices and remote sites. Among the services it provides are several that facilitate the safe transmission of secure material and data among IDEM staff around the state. These include:

- Citrix – A centralized application management and delivery mechanism.
- Secure File Transfer (SFTP) – Secure FTP is a program that uses a secure shell cryptographic network protocol to transfer files and encrypts both commands and data.
- Virtual Private Network – Secure method of transporting data from a remote location over the Internet.

6.4.4. *Data Security Standards*

The following components ensure protection of the integrity of IDEM electronically managed data:

- IOT put into place a Removable Media Policy on August 21, 2017, to further reduce the risks of data loss or theft as a result of viruses or malware introduced or spread through the state system by the use of external drives like USB flash drives, external hard drives, or camera cards. They worked with agency management to identify all staff that need read/write access to external drives.
- Office 365, a Microsoft (MS) service procured by IOT, includes access to Office Suite and SharePoint™ and is enabled via cloud services. Its certifications include:
 - FISMA/FedRamp, which provides provisional authority to operate for the Federal Risk and Authorization Management Program (FedRAMP), mandatory for cloud services used by federal agencies, and
 - Federal Information Process Standard Publication (FIPS) 140-2 compliance by way of underlying cryptographic modules used in Microsoft products.
- IOT Information Security Framework (ISF) is an information security network developed and supported by IOT that applies to all Indiana

state agencies. It sets policy, establishes control objectives, and references standards that secure Indiana government information assets. ISF's National Institute of Standards and Technology (NIST) Cyber Security Framework (CSF) Policy and Standards encompass the following:

- [Security Policy Overview](#)
The principles advanced by the IOT Security policy:
 - Ensure confidentiality, integrity and availability of sensitive information.
 - Provide for the protection of proprietary information.
 - Ensure agency staff accountability for information assets and resources entrusted to them.
 - Ensure compliance with legal and regulatory requirements.
 - Minimize risk to the state's information resources.
- [Review and Evaluation of State Policy](#)
All new State-Wide IOT policies and standards must first be reviewed by a policy management committee and approved by the State's Chief Information Officer (CIO).
- [Compliance with the State's Policy and Standards](#)
Demonstrating compliance provides assurance that information is appropriately protected. State agencies not completing annual compliance evaluations are considered out of compliance.
- [Acceptable Use Policy \(Information Resources Use Agreement\)](#)
All executive branch personnel, state employees, and long term contractors (greater than 30 days) are required to electronically acknowledge that they understand and will comply with the IRUA, which establishes information resources use requirement and limits, and makes clear the consequences of non-compliance.
- [Exceptions](#)
Any request for exceptions must be signed by a state Information Technology or Management Information System Director, or above.
- [Security Mentor, Inc.](#) ensures all IDEM staff participate in mandatory, contractor provided security training addressing all electronic media that could provide vectors into the agency data management and storage system.

7.0 PLANNING

Purpose - To document how individual data operations will be planned within IDEM to ensure that data or information collected are of the needed and expected quality for their desired use.

7.1. Planning environmental data operations using a systematic planning process

7.1.1. **Agency Reliance on Systematic Planning**

IDEML programs that may require the systematic planning of environmental data operations include:

- The cooperative IDEML-EPA Performance Partnership Agreement
- The Clean Air Act required State Implementation Plan (SIP) development
- IDEML issued permits (may require evaluation of effectiveness)
- The National Priorities List of contaminated sites within the state
- Remediation programs to facilitate the productive ongoing use or reuse of properties
- The Indiana Water Quality Monitoring Strategy
- The terms and conditions of funding grants received by IDEML

These and other programs regularly implemented by agency staff involve, and rely upon, the acquisition and use of reliably accurate data. The accuracy of any data is always subject to some degree of error; be it sampling error, laboratory error, or assessment error.

When there is a high degree of certainty the data generated by a particular measurement correctly reflects real world conditions, there can be a similar level of confidence in the environmental decision made using that data. Conversely, when there is a reduced probability that a measurement is correct, there should be a similarly lower level of confidence in that data.

7.1.2. **Details of the IDEML Systematic Planning Process**

The tool most central to ensuring the success of an environmental data operation is the planning process used to organize it. As stated in 2.2., each IDEML program is required to incorporate the principles of systematic planning when organizing data operations. Consistent with the actions outlined in the *U.S. EPA Guidance for the Data Quality Objectives Process (QA/G-4)*, staff responsible for planning an environmental data operation should adequately address the following:

- **Scoping** – What are the right questions to be asked and answered at the conclusion of the operation to identify how the data collected will be used to solve the problem. That is:
 - What are the conditions to be evaluated (what, when, where, how, why, and to what extent or affect)?
 - How will the evaluated conditions be compared to the baseline conditions to determine:
 - The extent of risk posed to human health and the environment, and

- The degree to which it will be necessary to restore conditions, or limit or prevent additional changes?
- **Organizing** – Which stakeholders, land owners, suppliers, laboratories, or others need to be involved, and what is expected of, and needed from, each?
- **Staffing** – Which staff will be involved in the operation, and what are their roles, responsibilities, and associated training needs?
- **Scheduling** – Determine what resources are required versus what resources are available (make a budget). Identify scheduling options to counter interferences like lack of access, weather, or factors that could be reasonably anticipated to impact the study. Schedule field checks or audits to ensure the plan is producing the desired results (data), or to prompt necessary mid-project adjustments.
- **Measuring** – Identify what should be measured and why the chosen target is the correct one (product vs. by-product, precursor vs. result, presence of a compound or nutrient vs. biotic impact). Identify the field procedures, any equipment needed to take such measurements, and any associated technical considerations.
- **Determining a confidence level** – To ensure the data collected is appropriate for the decision; to establish the numbers and types of quality control samples to be collected, and why those are the appropriate types of control samples; and to identify what criteria the sampling results should meet to ensure an adequate confidence interval or percent chance of error.
- **Sampling parameters** – Where and when will samples will be collected, how will the sampling locations or sources (for existing data) be determined, what sampling activities need to be recorded, what are the holding time limits, what are the appropriate sample preservation requirements, and are there adequate chain of custody procedures to protect sample integrity?
- **Sample analysis** – Describe sample analysis methods and requirements (either in the field or the laboratory) to be used, and how the resulting data (or the acquired existing data) will be verified, validated, tested against pre-established performance criteria, and assessed against its intended use.

7.2. IDEML Office Specific QA Planning Processes

Some of the most extensively developed and frequently used products of the systematic planning process generated by agency staff are those QA inclusive processes intended for use as part of an environmental data operation. Especially those QA processes and associated tools required to conduct field sampling and analysis.

7.2.1. **QA Planning Within the Office of Air Quality (OAQ)**

The Air Monitoring Branch (AMB) develops, and maintains:

- A program QAPP, the OAQ Quality Assurance Manual.
- Technical SOPs

- A Strategic Plan

The branch also relies on the [U.S. EPA Quality Assurance Handbook for Air Pollution Measurement Systems](#).

7.2.2.

QA Planning Within the Office of Land Quality (OLQ)

The Science Services Branch (SSB) contracts with various environmental laboratories to provide analysis of samples collected from air, soils, sediments, water, wastes, and soil gas. In lieu of each OLQ field project manager (PM) having to individually conduct a systematic planning process for each site assigned to them, they contact OLQ SSB staff using the OLQ Analytical Services Guide (See Appendix F) to conduct the planning process.

SSB staff use the information provided by the PM to make all the necessary arrangements for the sampling event. They prepare a full sampling kit for field use and schedule the required sample analysis at the properly accredited contract laboratory.

Once the raw data has been returned from the laboratory, it is verified, validated, and assessed by OLQ SSB chemists. The PM then follows the systematic approach outlined in the OLG Remediation Program Guide (RPG) and Remediation Closure Guide (RCG) to determine the need for additional action.

7.2.3.

QA Planning Within the Office of Water Quality (OWQ)

The two primary planning tools used by the OWQ Watershed Assessment and Planning Branch (WAPB), which gathers Indiana surface water data are:

- [2017 QAPP for IN Surface Water Quality Monitoring](#)
- [Indiana Surface Water Quality Monitoring Strategy](#)

All WAPB monitoring projects are evaluated through the Water Quality Monitoring Strategy review process to determine if they continue to meet OWQ and IDEM level objectives. Projects are reviewed and discussed for potential outcomes, value, and use of resulting data. The planning process in the IDEM OWQ Monitoring Strategy includes:

- Staffing
- Existing and needed equipment
- Funding sources
- Coordination with other ongoing projects
- External resources and assistance, including partnering or outsourcing
- Training needs
- Data storage, management, and usability

7.2.4.

Other “Embedded” QA Processes

QA practices are also incorporated, or built into what are primarily thought of as technical processes. Such “embedded” QA practices can be found in technical processes developed by either IDEM or U.S. EPA.

For example, permitting programs generally implement a pre-application process, especially for larger or more complex projects, during which they

may meet with stakeholders to discuss differing interpretations of permit rules, the appropriate assessment of applicant submitted data, or which calculations should be employed to predict impacts or establish permit limits. These discussions resolve the same types of issues as the systematic planning process. They only change when there are changes to the standards or associated processes.

7.3. **Documenting Planned Environmental Data Operations**

Consistent with the IDEM culture of quality, documenting data operations planning, and the review and approval processes associated with it, are the central feature of the IDEM QA system.

7.3.1. ***Planning Documents***

QAPPs are a central focus of the IDEM QA system, including:

- Project QAPPs document individual, single location, single issue, one time only studies of one environmental problem. Several current program QAPPs are identified in 2.2.5.
- Program QAPPs (See 2.2.3.) detail repetitive data operations following the same approach to planning as a project QAPP, except that the same type of study is done repeatedly, with only the study location changing.
- QAPP related work plans, a hybrid QA document also described in 2.2.6.
- SOPs and technical SOPs reflect program level, consensus based processes, best practices generally encompassing the same principles central to the systematic planning process.
- In some instances, the QA planning component already is established by statute or rule. For example, the Indiana drinking water program, overseen by IDEM and the Indiana State Department of Health, requires that each public water system demonstrate compliance by ensuring samples collected by a competent person are analyzed by a certified laboratory using Safe Drinking Water Act approved methods.

7.3.2. ***IDEM QA Review of Systematic Planning Documentation***

IDEM QA staff reviews and approves any new or revised QAPP. Work described in a QAPP should not be started before that QAPP has been reviewed and is approved by QA staff.

7.4. **Evaluating and Qualifying Data**

The following IDEM programs evaluate and qualify data:

- OAQ monitoring employs the procedures established in the EPA R5 Air and Radiation approved Quality Assurance Manual (See 7.2.1.)
- OLQ staff review and prepare reports on the laboratory data used by PMs and management to make decisions consistent with the RPG and RCG OLQ program guidance described in 2.2.4.
- OWQ DWB staff review laboratory contract data for suitability of use.
- OWQ WAPB staff review and characterize the quality of laboratory data, consistent with the 2017 QAPP for Surface Water Quality Monitoring.

IDEML QA staff intend to emphasize training for appropriate data operations staff, in the evaluation for use of both laboratory packets and existing data using materials including, but not limited to:

- [U.S. EPA \(QA/G-5\) Guidance for Quality Assurance Project Plans](#)
- [U.S. EPA \(QA/G-4\) Guidance for the Data Quality Objectives Process](#), which includes U.S. EPA's Elements for Systematic Planning (See Appendix E)
- [U.S. EPA \(QA/G-8\) Guidance on Environmental Data Verification and Data Validation](#)
- Training videos from the GLNPO QA Track Resources Training Library:
 - Reviewing Project-level Quality Documentation
 - Preparing Project-level Quality Documentation
 - Systematic Planning and Statistical Sampling Design
 - Systematic Planning and Quality Documentation for Projects Using Existing Data
 - Quality Assurance Strategies for the Use of Existing Data

7.4.1. *The Value of Existing Data*

Per 7.1.2., the final step of the IDEML systematic planning process includes identifying how data, whether acquired as a result of recent field sampling and laboratory analysis or is existing or secondary data; is to be verified, validated, tested against pre-established performance criteria, and assessed against its intended use. Because it requires fewer resources to use existing data, evaluation of that option always should be part of the planning of any data operation. For existing data to be its most useful, it is vital that it be accompanied by adequate information on how it was generated, what its purpose was, what field and laboratory methods were used to gather and analyze it, and whether there are adequate reporting on how the final data was verified, validated, and assessed for use. The successful implementation of a well-planned data operation can facilitate reuse, or additional other use of data, allowing the agency to:

- Avoid the costs of additional sampling and analysis
- Gain additional value from data operations already paid for

7.4.2. *IDEML Programs That May Use Existing Data*

Some IDEML programs evaluate applicant or permittee provided data as part of regulatory functions. However, the interest here is in those IDEML programs that incorporate existing data into predictive or comparative models to evaluate potential outcomes, and then use the data generated to support adjustments to regulatory requirements or identify measurably achievable potential environmental goals. Such agency programs include:

- Permitting and compliance programs that use data reported to the agency.
- OAQ Programs Branch, which uses secondary data in the following processes:
 - Photochemical Modeling
 - PSD Air Quality Modeling
 - Mobile Source Modeling
- OWQ Watershed Assessment and Planning Branch, which may use secondary data submitted through the External Data Framework in the following processes:

- Clean Water Act (CWA) Section 305(b)/303(d) assessment and listing decisions.
- CWA Section 314 lakes assessments of trend and trophic state.
- Water quality modeling for total maximum daily load development.
- Demonstrating effectiveness of watershed restoration efforts funded by OWQ's Nonpoint Source (NPS) Program.
- Demonstrating the effectiveness of watershed management plan and/or TMDL implementation over time (incremental improvements that meet U.S. EPA performance measures).
- Supplementary information for use in planning and prioritizing OWQ monitoring efforts for TMDL development, MS4 program development and prioritization, watershed characterization studies and other projects.
- Determining representative background conditions for the purpose of developing National Pollutant Discharge Elimination System (NPDES) permits.
- Classifying waters for the purpose of determining the necessary requirements new permittees must meet to comply with antidegradation rules in Indiana's Water Quality Standards.
- IDEM's NWRO may utilize secondary data collected by other projects as inputs to beach predictive models, or to evaluate ecological conditions in the Grand Calumet River AOC and the Lake Michigan basin.

8.0 IMPLEMENTATION OF WORK PROCESSES

Purpose - To document how work processes will be implemented within IDEM to ensure that data or information collected are of the needed and expected quality for their desired use.

The IDEM quality system ensures the repeatability of IDEM data operations. Peers from the scientific community challenging or using data generated by IDEM programs following the same QA documentation used by IDEM staff will get the same results from the same location. The QA culture being fostered by IDEM promotes the adequate planning, documentation, implementation, and recording necessary for the future review of data operations by interested internal and external peers.

8.1. Ensuring Work Is Performed As Planned

IDEML programs have a number of measures in place to promote and support the thorough and accurate implementation of planned activities including:

8.1.1. *Regular Calibrations of Field Equipment*

To ensure the ongoing and consistent accuracy of field equipment, each program has in place requirements and processes, documented in technical SOPS and equipment manuals that address equipment calibration. Each program also maintains logs documenting calibration activities.

- OAQ

The AMB has a QA Section that maintain standards instruments used to certify the transfer standards agency field staff uses to calibrate the instruments at each of the field stations in the Indiana air monitoring network. It similarly certifies the transfer standards used by other public entities as well as some owned by permittees required to perform self-monitoring as a condition of their permit. Items which cannot be certified in-house are sent to an accredited laboratory for a NIST traceable certification.

- OLQ

The Emergency Response, Leaking Underground Storage Tanks, and Federal Site Investigations programs are the primary OLQ users of equipment requiring calibration. The Electronics Technician 1 position, embedded in the Office of Emergency Response, is responsible for the in-house calibration of dissolved oxygen meters, 4-gas photo ionization detectors, and multi-meters using NIST traceable gases. Equipment that cannot be correctly calibrated in-house is contracted to certified vendors.

- OWQ

The WAPB, the primary water program for gathering field data, performs or contracts regular calibrations of its field Hydrolab, data sondes, pH meters, flowmeters, turbidimeters, and other field equipment as described in the OWQ Field Procedure Manual.

8.1.2. *Use of Technical SOPs*

IDEML maintains a library of technical SOPs documenting field activities on equipment operation, sample collection, data logging of electronic sampling, packaging of samples collected, recordkeeping associated with field activities, and other processes relevant to the gathering of field data. The review and approval process is outlined in 5.2. In addition OAQ AMB and OWQ WAPB also maintain quality and field manuals documenting technical procedures associated with data operations.

8.1.3. *Supervisory Review*

Most data operations performed by IDEML staff include some degree of supervisory oversight, surveillance, or review. This reinforces and further contributes to the implementation of activities as they were planned. Oversight is consistent with long standing agency management practices, and is often incorporated into staff performance evaluations as a work goal.

8.1.4. *Adequate Training and Planning*

IDEML QAPPs and related work plans are required to include sections on training for involved staff. IDEML QA staff review each such document before work may commence, and may require additional training requirements, or further clarification of training materials used.

8.1.5. *Commitment to U.S. EPA QA Field Activities Procedures*

As stated in 3.2.5., IDEML QA staff are ready to coordinate with EPA R5 QA staff to assist with the expanded implementation of Quality Assurance Field Activities Procedures (QAFAP) once U.S. EPA is prepared to expand its field operations guidance program to require greater adherence by state environmental organizations.

8.1.6. *Field Audits*

Some IDEML programs conduct audits during their QA plan implementation to further ensure and record that work is being completed as stated in the approved planning document.

- OAQ monitoring performs QA audits to ensure planning documents or standards requirements were followed at sample sites, for evaluating data, or for certifying equipment in the AMB QA standards laboratories.
- OLQ maintains a field guidance used during their data operations.
- OWQ WAPB performs field audits of staff during sample gathering.
- IDEML's NWRO conducts field audits of habitat restoration and monitoring efforts, as well as beach monitoring and notification activities, performed by contractors or grantees.

8.1.7. *Documentation of Field Activities*

As described in 5.1. and 5.3.2., each IDEML program collecting field data has developed forms (paper or electronic) that must be completed by program staff in the field. Some agency programs use forms provided by U.S. EPA contract labs. These forms, also described as field sheets or logs, match the sampling container identification numbers, and provide specific sample collection details.

Per 5.3.2., once completed, these forms serve as records of sample collection activities and conditions.

8.1.8. *Verification and Validation Activities*

As addressed in 7.4., IDEM staff not otherwise associated with the planning or implementation of environmental data operations or the use of the resultant data verify and validate the data from the laboratory by reviewing field sheets and laboratory bench notes. This ensures chain of custody forms, sample identification numbers, sample receipts, instrument logs, worksheets, and the information regarding sampling locations, numbers of samples collected, laboratory methods used are consistent with the specifications established in the QAPP.

8.2. Standard Procedures

SOPs and technical SOPs are most useful for documenting processes that must be completed many times over and in the same manner each time. Once written and approved, they can be referenced in multiple QA documents that use the same process. This makes SOPs and technical SOPs the building blocks of the IDEM quality system. IDEM processes used in conjunction with implementation of environmental data operations, or QAPPs, are required to be documented in technical SOPs. Additional requirements for when a SOP is required are outlined in [Whether to Develop a SOP, or a More Informal Work Summary](#). Requirements for the preparation, review, approval, revision, and withdrawal of SOPs from the QA system are fully outlined in 5.2.

IDEML uses two different levels of SOPs:

- The [Technical SOPs](#) template is more formal, and more reflective of the [U.S. EPA QA/G-6 Guidance for Preparing Standard Operating Procedures](#). TSOPs require flowcharts, written procedural steps, and information on health and safety, cautions, interferences, calibrations, and trouble shooting. They also require descriptions of staff roles, needed forms and equipment, definitions, quality assurance and quality control requirements, information on managing and preserving the work product generated, and references and appendices as appropriate.
- The [Administrative SOPs](#) template is streamlined to require only procedural steps, any training requirements; management of the work product generated, references, and appropriate definitions.

8.3. Managing Plan Changes

If work begins, or continues once it is determined that a change to the QA documentation is needed, any data generated might not be consistent with data needs established by the final plan. In addition, it could skew study results or adversely impact the project budget if data prematurely gathered is unusable. Conventional quality system principles require that work should be halted whenever conditions prevent the QAPP from being implemented as written or if it is determined the data being generated by the QAPP is not of the type or quality needed to address the issue(s) for which the QAPP was written. Either scenario could also skew results and/or waste resources.

Because individual data operations vary in complexity, decisions to halt the implementation of, and/or to change a QAPP are best made by agency management and staff most closely involved. They are the most informed regarding key factors like costs; the importance of data confidence proportionate to the potential impacts of study results; the importance of extenuating circumstances regarding time, staff, equipment, or laboratory availability; or even options to employ correction factors to improve the usability of the data.

Any changes that might be made to the QAPP will have different impacts, some more substantial or potentially disruptive than others. The key factor, consistent with use of the graded approach, is that all changes made to the manner in which the approved QAPP was conducted are adequately documented so those implementing it, verifying, validating, or assessing the value of the data it generates; intending to use that data for decision making; and, any peers from the scientific community that may have a future interest in the data, will each be able to adequately determine all the circumstances associated with the environmental data collected. To maintain the value of the data generated, IDEM requires that any changes that could impact the understanding of the data generated should also be documented in the QAPP or the accompanying field records, as appropriate.

Like the agency processes for SOP development, the staff roles and requirements for QAPP development, revision, approval, withdrawal from staff access, and archiving are discussed in 5.2.

9.0 ASSESSMENT AND RESPONSE

Purpose - To document how IDEM will determine the suitability and effectiveness of the implemented quality system and the quality performance of the environmental programs to which the quality system applies.

Ensuring data quality through the use of effective and accurate planning, implementation, and assessment of the results obtained from project level environmental data operations is the primary purpose of, and benefit from, the IDEM quality system.

Since the last system wide assessment, IDEM programs have substantially expanded the numbers and refined the quality of QA planning documents (technical SOPs and QAPPs, see review cycles at 5.2.6.). As is stated in the IDEM QA annual reports, the assessment and evaluation of project level data has improved as agency programs have escalated their scrutiny of the QA competency of the laboratory contractors and are also relying on increasing numbers and types of internal self-assessment processes.

These advances have subsequently elevated the need for more systematic evaluation of the IDEM quality system. Resultant agency planning to more fully assess the overall IDEM quality system has driven project level QA successes, as described below.

9.1 Agency-wide Quality System Assessments

Some IDEM programs have implemented internal, or undergone external technical systems audits to evaluate equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system. For example, EPA R5 Air and Radiation Division performs such audits on the QAQ monitoring branch every three years, often in conjunction with updates to the branch QA manual (see 7.2.1.). OWQ WAPB has conducted internal technical audits of its Fixed Station Monitoring Program as well as technical audits of branch field staff activities. Each audit noted compliance with planned activities and QA practices and identified opportunities for process improvements.

The 2005 Management System Review at IDEM was conducted by the EPA R5. IDEM responded by improving its agency document storage and retrieval capabilities.

9.2 Agency Assessment Planning

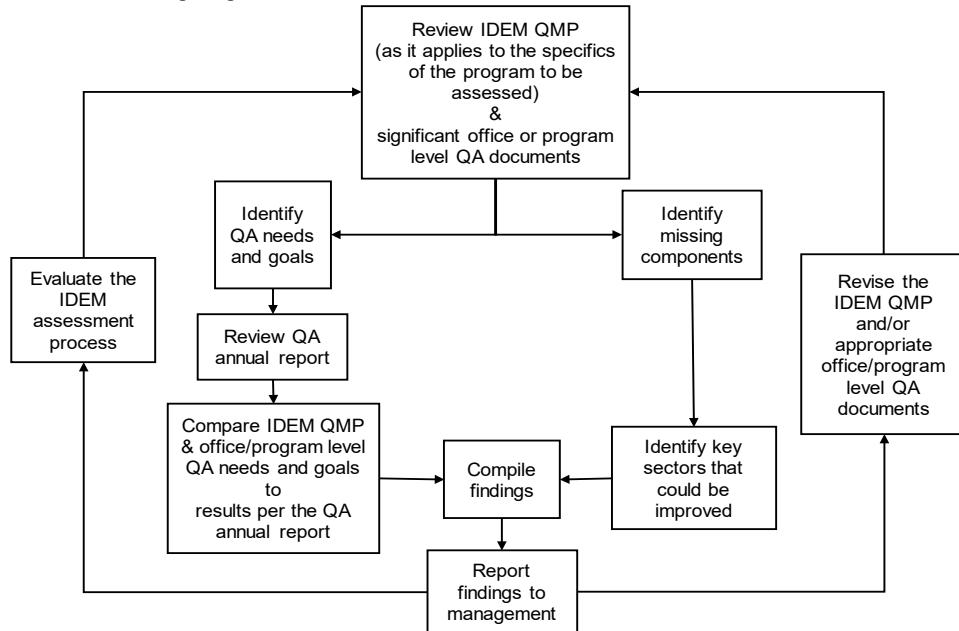
IDEML has developed an initial plan to conduct quality system audits (see Figure 10) using some of the processes outlined in [U.S. EPA QA/G-3 Guidance on Assessing Quality Systems](#). The intent is to objectively verify that applicable elements of the quality system are in place and being effectively implemented throughout the agency. The goal is to identify any key sectors of the QA system requiring additional QA improvement.

Assessment staff (IDEML QA staff, and possibly staff from offices other than those being assessed) will first meet with program management to identify assessment goals. Managers and assessors may each propose topics of interest, but all finalized assessment topics must be mutually supported. Assessments will focus on the quality of program QA documentation, its alignment with QA annual

reporting, and interviews with management and staff.

Figure 10

IDEML Quality System Assessment Plan



Beginning with document review, assessors will first identify those processes and goals in the agency QMP most applicable to the QA activities of the program being assessed. During the second phase of document review, assessors will evaluate significant office or program level QA documents to similarly identify any specific QA procedures that may need more emphasis. Comparing QMP goals to accomplishments, noted in the IDEM QA Annual Report and Work Plan to EPA R5, will make up the third phase of the documentation assessment.

Assessors will then conduct interviews with appropriate staff to assess their understanding of the importance and proper implementation of QA procedures. Finally, assessment findings will be shared with management. QA staff may also assist, as appropriate, with the implementation of any subsequent recommendations. These assessments will, in turn, engage each agency office in a rotation to be completed once during each QMP cycle.

9.2.1. **How Assessment Should Benefit the IDEM Quality System**

Strengthening the IDEM QA assessment process will:

- Drive further improvement of the agency quality system and strengthen the IDEM culture of quality.
- More closely align the QMP with the QA Annual Report.
- Increase the utility of the QMP as a reference for planning and QA guidance.

9.2.2. **Important Characteristics Needed For QA Assessment Staff**

Staff participating in QA assessments should:

- Adequately document:
 - The assessment plan,
 - Document review findings,

- Staff interview summaries (protecting staff anonymity as appropriate and agreed to), and
- Assessment findings and recommendations.
- Be technically competent, in that they have a strong understanding of:
 - ANSI/ASQ and U.S. EPA required endorsed quality system tools and requirements, including: how to use those tools to comply with QA requirements and why their successful implementation is important to data quality; and,
 - The fundamental understanding of the technical aspects of the program (and associated activities) being assessed, including: program goals, primary processes involved, the specifications and function of any equipment, supplies, forms, or software used, any potential pitfalls to be avoided, and an appreciation for the ramifications of the decision(s) to be made with the data generated.
- Have no conflicts of interest in the form of assessment responsibilities that may overlap with their current work assignments.
- Have the support of appropriate management, both external and internal to the program being assessed, and their authorization to implement the assessment as planned and report any findings.
- Be free to track any changes made to a program or related process in response to assessment findings in order to determine the effectiveness of the assessment itself and its impact on the subsequent quality of work product(s).

9.3 Assessment Follow Up

Once an assessment has been completed, the assessors will report their findings and recommendations to management. Management may simply accept the report, or further discuss the findings. If they concur with any recommended changes, they can require QA staff input regarding:

- Identification of possible causes for the QA problem(s) noted.
- Implementing and or measuring any improvements resulting from changes precipitated by the assessment.
- Suggesting steps to avoid reoccurrence of the problem or to prevent backsliding once corrective measures are put in place.

IDEML is in the formative stages of regular program level quality system assessments, therefore, any additional annual assessment follow up steps will be developed and included in a future revision of the IDEML QMP.

9.4 Project Level Assessments

- **Peer reviews** of program planning documents and reviews, performed in the OLQ SSB, OAQ monitoring and programs development branches in OWQ WAPB, and by QA staff that review QAPPs, QAPP-subordinate QA work plans, and technical SOPs.
- **Technical reviews** of specific, in the field data operations conducted, and reported to EPA R5 in QA annual reports. Although performed in-house, program staff remain motivated by knowing the data they generated is reliable for responsible decision making.

- **Surveillance**, or the frequent monitoring and verification by management of the proper implementation of QA planning and subsequent data assessment to ensure requirements are being adequately fulfilled, is a significant part of the IDEM quality system, which has traditionally relied on a chain of review and approval by managers and more experienced staff.
- **Performance evaluation** is perhaps one of the most regularly used tools to ensure the quality of data generated by contracted laboratories and internally operated agency labs.
- **Data quality assessment** is used as necessary to evaluate the suitability of data used for agency decision making.

10.0 QUALITY IMPROVEMENT

Purpose - To document how IDEM will improve the organization's quality system.

10.1 Ensuring the Promotion of the IDEM Culture of Quality

The decisions made by IDEM, using data generated by environmental data operations, are frequently of the type necessary to protect human health and the Hoosier natural environment. As a result, agency management, QA staff, and all IDEM program staff engaged in environmental data operations have some responsibility toward furthering the culture of quality. Though a limited number of IDEM staff sign or authorize agency decision documents, each group of agency staff, mentioned above, has some collective ownership of the data upon which IDEM decisions are based, and so similarly has a stake in the quality of the data used to make decisions.

Each environmental data operation should be undertaken in accordance with, and benefit from, the safeguards against risky and presumptive thinking, that are built into the plan, do, check, act (PDCA) cycle. These four actions, or steps, represent the iterative cycle on which upon which ANSI/ASQ and U.S. EPA quality system requirements are based. Notably, they also reflect the titles and/or purposes of the last four of the ten elements of this QMP:

- Plan – Analyze the situation, develop solutions
QMP Element 7 – Planning
- Do – Implement the planned solutions
QMP Element 8 – Implementation and Work Processes
- Check – Assess the results of the implementation
QMP Element 9 – Assessment and Response
- Act – Take corrective action after assessment
QMP Element 10 – Quality Improvement

As stated in various places throughout this QMP, IDEM strives to ensure the data it uses to make decisions is always of a quality (accuracy and correctness) appropriately proportionate to any adverse risk posed by the consequences of an incorrect environmental decision. Agency management provides QA resources and direction, while QA staff must advise staff of requirements, manage QA documentation, provide training, assessment implementation, and otherwise support agency QA efforts. Program staff engaged in data operations should participate in QA training commensurate with their roles in data operations, adequately document that training, and regularly impart their QA knowhow into assigned work.

10.2 Sustaining the IDEM quality system

To preserve the quality system improvements built up over time, each IDEM staff should:

- Exercise vigilance against conditions adverse to quality by:
 - Never making assumptions. Staff that do not remember what to do next, or what to record; should double-check, rather than assume.
 - Communicate clearly. Staff developing QA documents or recording field conditions should review what they wrote and ask themselves whether their audience will know what was meant.

- Question situations or results inconsistent with their understanding of proper quality practices and discuss with their managers, colleagues, or technical staff any uncertainties they may have.
- Avoid the temptation to take shortcuts regarding such things as:
 - Preparing planning documents without verifying all references, or otherwise being overly reliant on the reuse of a previous copy of an “almost the same” version of a QA document.
 - Skipping practice runs or refresher trainings.
 - Ensuring up to date instrument calibrations.
 - Not performing repetitive processes uniformly, thereby risking inconsistencies that could potentially affect data outcomes.
 - Recording field notes accurately.
- Identify process improvement opportunities or propose solutions for problems to prevent reoccurrences after problems are noted or corrective actions taken
- Always go to the shared QA Library when QA documents are needed rather than store them elsewhere in a manner that could result in the use of an expired version.
- Request training or clarification when proper procedures have changes, or are unclear.

10.3 Inviting the Participation of Others

Agency offices, programs, and staff invite input on QA issues from sources external to their own program. Because QA principles are applicable across environmental media (air, land, or water) issues, suggestions from those who may not be doing the same work but who are sufficiently cognizant of similar types of work, whether from within IDEML, U.S. EPA, other R5 states, accrediting organizations, or the broader scientific community, can always offer a fresh perspective. Comparing in-house QA processes with those of other entities practicing QA is another avenue for ideas to move QA forward.

To that end, IDEML QA staff will, during the effective period of this 2018 QMP, try to bring new ideas into the agency QA system by:

- Reviewing available QA related guidance materials to gain new insight into how to better meet ANSI/ASQ required/U.S. EPA endorsed QA standards.
- Increasing interaction of other R5 states, all of which also comply with the same U.S. EPA QA requirements as does IDEML.
- Continuing inner-agency interaction through ongoing IDEML QA Committee meetings and workshops, as mentioned in 1.3.2. Role of IDEML QA Manager and Staff.
- Strengthening QA interaction with the EPA R5 QA management, and with EPA R5 Divisional QA leaders.
- Making use of existing and future EPA R5 sponsored data enterprise management systems to access and review QMPs, QAPPs, and other QA documentation developed by the R5 states in order to contrast and compare various ways of accomplishing QA goals with those of IDEML in order to implement best practices to meet IDEML specific program needs.

APPENDIX A. IDEM Quality Documentation Policy

DEPARTMENT OF ENVIRONMENTAL MANAGEMENT	COVERAGE: Agency wide	POLICY NUMBER: A-050-AW-18-P-R2
AGENCY POLICY	AUTHORIZED: Bruno L. Pigott, Commissioner	
SUBJECT:	SUPERCEDES: A-050-OEA-09-P-R1	OFFICE: Office of the Commissioner
QUALITY ASSURANCE DOCUMENTATION	EFFECTIVE: February 15, 2007	REVISED: March 16, 2018

1.0 PURPOSE

This policy addresses the development, review, approval, and management of agency quality assurance (QA) documents that enhance the implementation of the Indiana Department of Environmental Management (IDEM) Quality Management Plan (QMP).

2.0 SCOPE

This policy applies to all agency staff developing or approving QA documents.

3.0 SUMMARY

This policy establishes:

- 3.1. Requirements for the content, development, review, and approval of agency QA documents.
- 3.2. Staff responsibilities associated with the development, review, and approval of QA documents.

4.0 DEFINITIONS

- 4.1. "Agency staff" – Any employee or representative of the IDEM including regular employees, temporary employees, contractors, and interns.
- 4.2. "Agency quality assurance (QA) staff" – Agency staff within the Office of Program Support (OPS) responsible for the implementation and maintenance of IDEM's QA system.
- 4.3. "Authorized" – Ordered and/or approved by agency management.
- 4.4. "Data" – A collection of numeric and/or non-numeric information from which conclusions may be drawn.
- 4.5. "Deliberative" – Involved in or characterized by deliberation, discussion, and examination pursuant to IC 5-14-3-4(b)(6).
- 4.6. "Environmental technology (as defined in U.S. EPA Order 5360.1 and U.S. EPA QA/R-2)" – An all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from, or prevent them from entering the environment. Usually, this term applies to hardware-based systems; however, it also applies to methods or techniques used for pollution prevention, pollutant reduction, or containment of

contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

- 4.7. “Procedure” – A specified set of steps detailing how to perform an activity.
- 4.8. “Project” – A temporary endeavor undertaken to create a unique product, data set, or service.
- 4.9. “Quality assurance (QA)” – An integrated system of management activities involving planning, implementation, documentation, assessment, reporting and quality improvement to ensure that a process, item, data set, or service is of the type and quality needed and expected by the client.
- 4.10. “Quality assurance (QA) document” – Any document associated with the agency quality system such as the IDEML QMP or any agency policy, SOP, or QAPP developed and authorized to ensure data operations and other agency business is conducted in a consistent, effective, efficient, and transparent manner.
- 4.11. “Quality assurance (QA) library” – A centralized collection of agency QA documents in which the IDEML QMP and agency policies, SOPs, QAPPs, and related QA documents are stored, archived and made accessible for use by agency staff and stakeholders.
- 4.12. “Quality assurance project plan (QAPP)” – A document describing the activities of an environmental data operations project involving the acquisition of environmental information whether generated from direct measurement activities, collected from other sources, or compiled from computerized databases and informational systems. A QAPP may reference one or more standard operating procedure or other QA documentation. A QAPP:
 - A. Documents the results of the technical planning process that should precede implementation of an environmental data operations project.
 - B. Identifies the goal(s), boundaries, scope, and the quality objectives of a project, or multi-project program.
 - C. Identifies key project personnel and their responsibilities for implementing the project.
- 4.13. “Quality control (QC)” – The overall system of technical activities that measure the attributes and performance of a process, item, data set, or service against established standards to verify that they meet the level of quality required to adequately support any decision made based on that data.
- 4.14. “Quality Management Plan (QMP)” – A document that describes the IDEML quality system in terms of its organizational structure, policies and procedures, management and staff responsibilities, lines of authority, and the required interfaces between those planning, implementing, documenting and assessing data operations and related activities. The QMP serves as an umbrella document under which policies, SOPs and QAPPs are developed, maintained, stored, distributed and implemented to ensure that all agency decision-making processes and related work products benefit from sound QA practices.
- 4.15. “Quality system” – A structured and documented system for ensuring the quality of agency work processes, products (items), data sets, and services.
- 4.16. “Standard operating procedure (SOP)” – The method for operation, analysis or action with prescribed techniques and steps. An SOP is the approved method for

performing a specific routine function or repetitive task. SOPs are developed in consultation with staff who regularly perform the work.

4.17. "Supervisor" – The manager to whom the agency staff reports.

5.0 ROLES

- 5.1. The commissioner, or designee, may authorize the development and/or approval of any agency QA document.
- 5.2. An assistant commissioner (AC) or designee(s) shall:
 - A. Ensure that program areas within their respective offices are developing and using the necessary QA documents.
 - B. Designate program area staff to draft, review, or sign QA documents developed for use within their respective program area.
- 5.3. Supervisory staff shall:
 - A. Lead policy development.
 - B. Manage the development and use of QA documents within their program area.
 - C. Ensure staff have knowledge of, access to, and comply with all applicable agency QA documents.
 - D. Review, and when designated by the AC, authorize program QA documents by signature.
 - E. Designate staff to develop QA documents or to assist with policy development.
 - F. Ensure that an electronic copy of each draft QA document is submitted to agency QA staff for review, comment, approval, and maintenance within the agency QA library.
 - G. Ensure all program QA documents are reviewed and, if necessary, updated, consistent with the time frames shown in the table in 6.5.
 - H. Ensure appropriate program management and technical staff have the opportunity to review QA documents under development.
 - I. Request when appropriate, that agency QA staff archive out-of-date program area QA documents.
- 5.4. The agency QA staff shall:
 - A. Develop and maintain the IDEM QMP and its components.
 - B. Promote and track the development and completion of program area QA documents by:
 1. Developing agency specific quality system-related policies, templates, checklists, and training materials that meet accepted scientific standards.
 2. Assigning a unique ID number to each QA document to facilitate tracking it during development and approval, and accessing it during storage and use.
 3. Reviewing each draft QA document for formatting and logical content.
 - C. Approve a QA document that meets all agency QA standards.
 - D. Post each authorized QA document in the QA library.
 - E. Maintain the agency QA document library.
 - F. Archive agency QA documents no longer in effect.
 - G. Submit to the U.S. EPA R5 QA manager:
 1. The IDEM QMP and, as a condition of sustaining R5 approval of that QMP,
 2. A QA annual report, and
 3. All IDEM self-approved QAPPs and QAPP related work plans.
 - H. Provide agency staff with the training needed to develop QA documents.

- 5.5. Agency program area staff shall:
 - A. Participate in available QA document development and implementation trainings provided by IDEM, U.S. EPA QA staff, or equivalent sources.
 - B. Coordinate as assigned with agency QA staff, to develop and obtain approval of the QA documentation required to meet IDEM, U.S. EPA, and accepted scientific standards.
 - C. Comply with the document formatting and content requirements established herein.
 - D. Ensure that any project contractors or sub-grant recipients they oversee, comply as required with associated QA documentation and implementation requirements.
 - E. Notify agency QA staff of all ongoing and new QA or QAPP agreements they reach with their U.S. EPA counterparts.
- 5.6. The IDEM grants coordinator shall monitor agency program grant recipients to confirm, in conjunction with agency QA staff, that grant related QA documentation and implementation requirements are met and reported to the awarding entity.

6.0 POLICY

- 6.1. The agency will demonstrate its commitment to scientifically defensible and transparent decision making by:
 - A. Recording its QA practices and requirements in standardized QA documents; and
 - B. Reviewing, approving, and systematically maintaining access to QA documents for use by agency staff and others, as requested.
- 6.2. QA documents will be developed using the appropriate agency standardized template, or other format approved by the agency or by U.S. EPA.
- 6.3. Agency QA documents are applicable as follows:
 - A. Policies are management directives to agency staff that relate to internal operations and shall be documented in a standard policy template. A policy shall not conflict with, or supersede a policy approved at a higher organizational level.
 - B. Standard operating procedures (SOPs) prescribe orderly steps in a routine or repetitive process. There are two types of SOPs:
 1. Administrative SOPs developed for procedures associated with the administration or implementation of a task not associated with the gathering or use of environmental data.
 2. Technical SOPs for procedures that involve the collection, evaluation, use, or reporting of environmental data, or that involve the design, construction and operation of environmental technology based upon that data.
 - C. Quality assurance project plans (QAPPs) capture the planning, implementation, assessment, and reporting associated with the environmental data operations required to gather new or use existing data to design, construct, or operate environmental technology to prevent the pending, or remediate the past release of constituents potentially detrimental to human health or the environment.
 1. There are two types of QAPPs:
 - a. A project QAPP; describing a data operation meant for one time implementation, at a specific location and time.
 - b. A program QAPP; describing data operations meant to be implemented multiple times, at multiple locations, and/or during multiple time frames, but always in the same manner.

2. A QAPP may be required of agency staff as part of a federally funded grant.
3. The agency may similarly require that a QAPP be included as a component of contracts or other agreements involving the collection of environmental data by parties representing IDEM.

6.4. Regarding the authorization of QA documents:

- A. Each QA document must be authorized by the appropriate level of management within the hierarchy of the agency's organizational structure, such that:
 1. The commissioner, or a designee, shall sign any document applicable agency wide.
 2. The appropriate supervisor, or a designee, shall sign program specific documents.
 3. A supervisor or designee representing each affected program area shall sign any document applicable to multiple programs.
- B. An unauthorized QA document is considered under development, not in effect, and therefore deliberative and exempt from public disclosure under IC 5-14-3-4(b)(6).
- C. Most QA documents may not be developed and approved by the same individual staff. However, policies are management directives and may therefore be developed and approved by the same manager(s).
- D. Each QA document authorized or reauthorized through the signature process shall be posted and maintained in the QA library.
- E. Authorization of a new or revised QA document requires that:
 1. Staff listed on the signature page must each sign the same version of the pending QA document. If a document is revised after the signature process has begun, it must be re-signed by each approving staff.
 2. To facilitate posting in the agency QA library, program area staff must provide agency QA staff with an electronic copy of the same version of the signed document.
- F. A QAPP must be signed by all staff with oversight of its implementation, before any work may begin. A QAPP that is subsequently revised must be re-signed by those same staff before work may resume.
- G. The time frames during which various types of authorized QA documents are in effect, appears in the following table:

Time frames during which QA documents are in effect (as established in 5.2.6. of the IDEM QMP).

QA Document	Maximum Authorization Period *
Standard Operating Procedures and Technical SOPs	Four Years
QA Project Plans (QAPPs)	Project QAPPs are in affect for the same time period as any associated funding or related contract or grant cycle, not to exceed one year without additional approval
QA Program Plans (QAPPs)	Should be reviewed each year and revised to accommodate changes to technical and legal requirements, project goals, or funding cycles; but should never be in effect for more than five years

Sampling plans/Work plans (time or location specific data gathering projects done under an existing program QAPP)	End of the field season, (unless approved by QA staff for up to one additional season, following the same parameters)
Policies	Should be reviewed annually for consistency with federal, state, and agency requirements; and revised and re-approved as appropriate.

* Except when there is a change to the processes, methods, or regulations on which a QA document is based, in which case it should be immediately revised to reflect those changes.

6.5. Program areas using QA documents containing confidential information shall maintain control of those documents, and agency QA staff may only review them at the discretion of the controlling program.

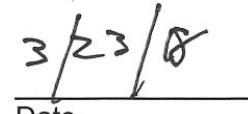
7.0 REFERENCES

- 7.1. [CIO 2105.0 Policy and Program Requirements for the Mandatory Agency-Wide Quality System \(formerly, U.S. EPA Order 5360.1 A2, May 2000\)](#)
- 7.2. [CIO 2106.0 U.S. EPA Quality Policy](#)
- 7.3. [CIO 2106-P-01.0 U.S. EPA Procedure for Quality](#)
- 7.4. [U.S. EPA Requirements for Quality Assurance Project Plans \(QA/R-5\)](#)
- 7.5. [U.S. EPA Guidance for Preparing Standard Operating Procedures \(QA/G-6\)](#)
- 7.6. [IDEML Quality Management Plan](#)

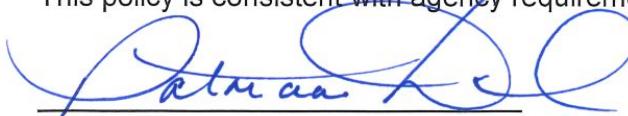
8.0 SIGNATURES



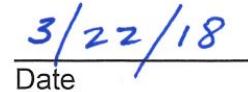
Bruno L. Pigott, Commissioner
Indiana Department of Environmental Management


Date

This policy is consistent with agency requirements.



Quality Assurance Staff
Office of Program Support


Date

APPENDIX B. Calculation of IDEM Fulltime Equivalent (FTE) Quality Assurance (QA) Staff

The numbers of full-time equivalent (FTE) IDEM staff reported above in section “A.1.2. Staff Resources Dedicated to Quality Assurance” was calculated by multiplying the numbers of staff doing QA-related tasks by the estimated percentage of work time each spent on that task, then adding those products to find the total full-time equivalent (FTE) of QA-related work done. For example, if one staff person is doing 80-percent QA-related tasks (0.8 FTE) and four other staff are each doing 33-percent QA (0.33 FTE each, or 1.33 total FTE QA), then those five staff would be counted as doing QA work equivalent to 2.13 FTE staff.

IDEM Office-level FTE QA Totals (rounded up to the nearest 0.1 from Appendix C totals)	Program Area	FTE Program Staff Engaged in QA Activities (See details in Appendix C)
Air Quality = 18.4 FTE	Air Monitoring	15.35
	Compliance and Enforcement	2.75
	Permits	None reported
	Programs	0.3
Land Quality = 21.4 FTE	Compliance and Response	1.9
	Permits	None reported
	Remediation Services	3.3
	Science Services	11.71
	Natural Resources Defense (NRD) (Calumet River ACC)	0
	Underground Storage Tanks	7.8
Water Quality = 19.8 FTE	Compliance	5.45
	Drinking Water	5.84
	Surface Water, Operations and Enforcement	None reported
	Permits	None reported
	Watershed Assessment and Planning	8.49
Program Support = 3.6 FTE	IDEM quality assurance (QA) staff	2.8
	Northwest Regional Office (NWRO) GLNPO grants program staff	
	• Lakewide Action and Management Plan (LAMP) Remedial Action Plan (RAP) Coordination	0.25
	• Lake Michigan Beaches Monitoring and Notification Program	0.55
Agency Total = 63.2 FTE		

*** From section A.1.2., page 7, of the 2017 IDEM QA Annual Report to be submitted to EPA R5 before February 1, 2018. There were 63.2 full-time equivalent (FTE) IDEM staff positions (7.7 percent of the approximately 819 total agency staff) engaged in QA-related work during 2017.

APPENDIX C. Technical Activities and Programs Supported by the IDEM Quality System

Office of Air Quality (OAQ) Technical Activities and Programs

Monitoring Branch (MB)

- Field Monitoring – site selection, site setup, ongoing operations
- Laboratory analytical analysis of samples
- Data Processing – Collection, evaluation, corrections, submittal, etc.
- Standards laboratory – comparisons

Technical Program	Environmental Activity
Field Monitoring	Sample acquisition Sample transport Site information Sampler/analyzer/equipment setup Monitoring plan development
Laboratory analysis of samples	Sample preparation Sample analysis
Data Processing	Data analysis QA documentation Data transmission
Standards laboratory – comparisons	Sampler/analyzer/equipment performance evaluation
Laboratory and office operations	Maintenance and cleaning of monitoring and analysis equipment Safety training and implementation QA personnel documentation QA operations policy Equipment tracking Training equipment operations Administrative operations

Programs Branch (PB)

The Programs Branch has the following technical programs:

- Development of the State Implementation Plan (SIP)
- Data analysis projects
- Rule development
- Oversight of the Inspection and Maintenance (I/M) program,
- Transportation Conformity
- Mobile source modeling
- Diesel Wise On-Road Mobile Source Inventory
- Photochemical Modeling
- PSD Air Quality Modeling
- Emission Statement Review, Correction, and Coordination with Reporting
- ToxWatch Screening
- Criteria pollutant and air toxics emission inventory development

- RAPIDS Inventory – QAPP: Indiana Point Source Hazardous Air Pollutants Inventory Quality Assurance Plan
- Lake Shore Screening Analysis for Air Toxics
- Southwest Indianapolis Air Toxics Study – QAPP: Quality Assurance Project Plan – Southwest Indianapolis Neighborhood Air Toxics Study

Compliance and Enforcement Branch (CEB)

- Inspections
- Stack test and CEMS/COMS observations
- Review of compliance documents (e.g. quarterly reports, annual compliance certifications, stack test reports, stack test protocols, CEMS/COMS reports)
- Complaint response
- Data input and tracking
- Sampling and monitoring
- NOx/CAIR/CSAPR allowance calculations

Permits Branch (PB)

The primary role of OAQ Permits Branch is to prepare and review air permit applications utilizing data prepared and analyzed by the applicant, Programs Branch, Compliance and Enforcement Branch, and U.S. EPA permit construction and operating requirements. The review of permit applications and the issuance of appropriate levels of permits based on technical data and emission factors provided by others is a principally administrative action best implemented through the development and use of standard operating procedures (SOPs) as the primary quality assurance planning tools.

Office of Land Quality (OLQ) Technical Activities and Programs

Science Services Branch (SSB)

The Science Services Branch (SSB) assists the Office of Land Quality with their processes. The SSB sections and the senior risk assessors provide technical information, advice and guidance to the decision-makers in the other branches of the Office of Land Quality. Subsequently, the Quality Assurance components of the SSB also benefit the OLQ programs being assisted by SSB. The work product consists of a technical memo which contains the document name, location, site number and any other identifying information. The standardized format for these memos is available upon request. The memo sections consist of the site history, the specific comments and the conclusion with any recommendations about how to proceed with the site. The following table illustrates the SSB section, the program they assist and the associated expectation:

Science Services Branch (SSB)

Program/Section	Assistance	Work Product
Hazardous Waste Program	Review and evaluate various permit types Review and evaluate delisting petitions; Provide sampling assistance	Technical memo
Solid Waste Program	Review and evaluate various permit types; Review and evaluate waste determinations; Provide sampling assistance	Technical memo

Leaking Underground Storage Tanks Section	Review and evaluate work plans, Corrective Action Plans (CAP)s, other plans; Provide sampling assistance	Technical memo
State Clean Up Section	Review and evaluate work plans sampling plans Provide sampling assistance	Technical memo
Federal Programs Section including Defense Restoration Program and Superfund	Review and evaluate work plans, other plans	Technical memo
Voluntary Cleanup Program Section	Review and evaluate remediation work plans, other plans Provide sampling assistance	Technical memo
Excess Liability Trust Fund Technical Section	Review and evaluate work plans, other plans	Technical memo
Site Investigations	Review and evaluate work plans, other plans; Provide sampling assistance	Technical memo
Indiana Brownfields Program Technical Section	Review and evaluate work plans, other plans	Technical memo

Geological Services Branch (GSB)

Program/Section	Assistance	Work Product
Leaking Underground Storage Tanks Section	Review and evaluate work plans, CAPs, other plans; Provide sampling assistance	Technical memo
State Clean Up Section	Review and evaluate work plans, other plans Provide sampling assistance	Technical memo
Federal Programs Section including Defense Restoration Program and Superfund	Review and evaluate work plans, other plans	Technical memo
Voluntary Remediation Program Section	Review and evaluate work plans, other plans Provide sampling assistance	Technical memo
Excess Liability Trust Fund Technical Section	Review and evaluate work plans, other plans	Technical memo
Site Investigations	Review and evaluate work plans, other plans Provide sampling assistance	Technical memo

Engineering and GIS Section (EGS)

Program/Section	Assistance	Work Product
Hazardous Waste Program	Groundwater data import into database Review and evaluate work plans	Technical data memos and maps
Solid Waste Program	Groundwater data import into database; Provide GPS/GIS assistance	Data and maps
Leaking Underground Storage Tanks Section	Review and evaluate work plans, Caps, other plans; Provide GPS/GIS assistance; Groundwater data import into database	Technical memos and maps
State Clean Up Section	Review and evaluate work plans, other plans; Provide GPS/GIS assistance	Technical memos and maps
Federal Programs Section including Defense Restoration Program and Superfund	Review and evaluate work plans, other plans; Provide GPS/GIS assistance	Technical memos and maps
Voluntary Remediation Program Section	Review and evaluate work plans, other plans; Provide GPS/GIS assistance	Technical memos and maps
Excess Liability Trust Fund Technical Section	Review and evaluate work plans, other plans; Provide GPS/GIS assistance	Technical memos and maps
Site Investigations	Review and evaluate work plans, other plans; Provide GPS/GIS assistance	Technical memos and maps
Indiana Brownfields Program - Technical Section	Review and evaluate work plans, other plans; Provide GPS/GIS assistance	Technical memos and maps
Natural Resources Defense Program	Provide GPS/GIS assistance	Technical memos and maps
Federal Programs Section including Defense Restoration Program and Superfund	Review and evaluate work plans, other plans Provide GPS/GIS assistance	Technical memos and maps
Voluntary Remediation Program Section	Review and evaluate work plans, other plans; Provide GPS/GIS assistance	Technical memos and maps
Excess Liability Trust Fund Technical Section	Review and evaluate work plans, other plans; Provide GPS/GIS assistance	Technical memos and maps
Indiana Brownfields Program - Technical Section	Review and evaluate work plans, other plans; Provide GPS/GIS assistance	Technical memos and maps
Natural Resources Defense Program	Provide GPS/GIS assistance	Technical memos and maps

Regulatory Reporting Section (DSS)

Program/Section	Assistance	Work Product
Hazardous Waste Program	Receive data, quality check data, import into database, generate reports	Data
Solid Waste Program	Receive data, quality check data, import into database, generate reports	Data
Leaking Underground Storage Tanks Section	Maintain database	Data
State Clean Up Section	Maintain database	Data
Federal Programs Section including Defense Restoration Program and Superfund	Maintain database	Data
Voluntary Remediation Program Section	Maintain database	Data
Excess Liability Trust Fund Technical Section	Maintain database	Data
Site Investigations	Maintain database	Data
Indiana Brownfields Program Technical Section	Maintain database	Data
Community-right –to-know program	Quality check data, generate reports	Data

Risk Services Section and Senior Risk Assessors (E7s) (RSS and SRR)

Program/Section	Assistance	Work Product
Hazardous Waste Program	Review and evaluate work plans	Technical memo
Leaking Underground Storage Tanks Section	Review and evaluate work plans, Caps, other plans;	Technical memo
State Clean Up Section	Review and evaluate work plans, other plans	Technical memo
Federal Programs Section including Defense Restoration Program and Superfund	Review and evaluate work plans, other plans	Technical memo
Voluntary Remediation Program Section	Review and evaluate work plans, other plans	Technical memo
Excess Liability Trust Fund Technical Section	Review and evaluate work plans, other plans	Technical memo
Site Investigations	Review and evaluate work plans, other plans	Technical memo
Indiana Brownfields Program Technical Section	Review and evaluate work plans, other plans	Technical memo

In addition, a senior level SSB position provides information on, and audits contract laboratory services used by, OLQ, and a senior level data coordinator provides information regarding data management systems.

Remediation Services Branch (RSB) focuses on the identification, investigation, and remediation of hazardous substance and petroleum releases in the State of Indiana. These environmental activities are performed under the regulatory authorities of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Resource Conservation and Recovery Act (RCRA). The RSB manages various programs for site investigation, immediate removals, risk evaluation, long-term remedial actions, and cost

recovery (where applicable) activities. The RSB programs are organized within the following sections:

- State Cleanup Section (SCU)

The State Cleanup Section manages short-term to long-term remediation (*i.e. cleanup*) of uncontrolled or abandoned hazardous waste sites that may not qualify for cleanup under the federal Superfund Program. The majority of sites are referred to the SCU Section via the Emergency Response (ER) Section in IDEM's Office of Land Quality. The ER Section addresses environmental emergencies but has no mechanism for long-term remedial oversight. The State Cleanup Section coordinates and manages waste tire dump cleanups and sites requiring immediate removals due to imminent threat. Although the SCU is modeled after the Federal Superfund Program, it differs from the Superfund program in several respects. Hazardous substance sites are prioritized with the Indiana Scoring Model (ISM) as prescribed by 329 IAC 7. Unlike Superfund, the SCU Section has the authority to respond to petroleum releases in addition to releases of hazardous substances. As a planned quality improvement initiative, the SCU Section is proposing modifications to existing legislation to replace the current ISM with a more streamlined prioritization process.

- Federal Programs

Congress passed the CERCLA, also known as Superfund, in 1980. CERCLA requires the identification, investigation, and cleanup of sites contaminated by past releases of hazardous substances. Within OLQ, the Federal Programs Section manages and coordinates remediation at facilities that: 1) are listed on the National Priorities List (NPL); are non-NPL sites managed by the Superfund program; or 3) are under the Defense Environmental Restoration Program (DERP).

The Federal Programs Section receives program and site-specific federal grants that provide the majority of the section's funding. The terms of the federal grants are documented in site-specific project narratives. By federal law, IDEM works in a highly structured partnership with the U.S. EPA, the Department of Defense (DOD), and the Army Corp of Engineers in which the roles of the respective agencies are dictated in site specific project narratives rolled into Cooperative Agreements.

- Site Investigation

This section administers the federal Site Investigation program, following the statutory requirements of the National Contingency Plan, CERCLA, and the Superfund Amendments and Reauthorization Act (SARA). Funding is provided from U.S. EPA, with program expectations outlined in a Cooperative Agreement with EPA R5.

Activities conducted with grant funds include site discoveries, site screening, preliminary assessments, site inspections, integrated assessments, Hazard Ranking System scoring packages, and, when necessary, site reassessments. These activities are conducted to determine if sites require immediate response actions, should be referred to the SCU Section, or ultimately qualify as federal Superfund sites.

- Voluntary Remediation Program (VRP)

The VRP provides a mechanism for property owners, operators, or potential buyers to voluntarily address environmental liability issues associated with buying, selling, or developing contaminated property. The VRP provides oversight of site investigations and any necessary remediation to ensure that health-protective closures are achieved. Upon successful completion of a project, IDEM issues a Certificate of Completion, and the Indiana Governor's office issues a Covenant Not to Sue (CANTS) to the VRP participant for the property. In addition, IDEM has a Memorandum of Agreement (MOA)

with the U.S. EPA that provides assurance that they will not pursue enforcement action if a site is addressed within the VRP.

The VRP is primarily self-funded by recovering costs for administrative and technical oversight from program applicants. Costs for staff time that cannot be directly recovered from participants (program development, staff training, etc.) are provided through a U.S. EPA Cooperative Agreement.

- Indiana Brownfields Program [Administered by the Indiana Finance Authority (IFA)]

The Indiana Brownfields Program offers educational, financial, technical and legal assistance to eligible entities involved in brownfields redevelopment. The Remediation Services Branch provides technical oversight and review for all projects receiving State financial assistance, as well as projects receiving U.S. EPA brownfield grants.

The Indiana Brownfields Program was created by 2005 Indiana legislation that merged the brownfield financial and technical review programs into one program, thereby combining existing brownfield resources to better assist communities with brownfields redevelopment. The Indiana Brownfields Program works in partnership with U.S. EPA and other Indiana agencies to assist communities in making productive use of their brownfield properties.

The SCU, LUST, ELTF, VRP, and Indiana Brownfields Programs utilize IDEML OLQ's Remediation Closure Guide and Remediation Program Guide, companion manuals that set out risk-based criteria for deciding how to address contaminated sites. The guides provide flexible closure options for conducting site assessments, cleanup alternatives, and consistent closure goals. The Federal Programs Section and Site Investigations Section follow investigative and remediation guidance established by U.S. EPA or DOD. For more information, including links to U.S. EPA guidance documents, visit the [U.S. EPA Superfund Cleanup website](#).

Each of these programs performs, or oversees the performance of, site-specific environmental investigations regarding the actual or potential release of hazardous substances or petroleum. All environmental data collection, project planning, data collection, data analysis, data verification and validation, and determinations for action, based upon the environmental data that was collected, are subject to independent QA review by entities outside of the RSB. The primary review function is provided by either the OLQ Science Services Branch or environmental consultants.

Compliance Branch (CB) technical activities subject to quality assurance/quality control practices:

- Program inspection planning – Each Compliance Program has its own criteria addressed in "Neutral Selection Policy" listed in Agency QA library and under Section 2 of this QMP.
- Sampling (both field and real time)
- Determinations for corrective action associated with program violations.
- Compliance Program Inspections including the PCB program

PCB inspections will be conducted in accordance with the IDEML-U.S. EPA Region 5 PCB QAPP. This document was signed by Larisa Leonova, U.S. EPA QA Manager LCD; Kendall Moore, U.S. EPA Technical Contact, Pesticide & Toxics Compliance Section, LCD; David Star, U.S. EPA Chief, Pesticide & Toxics Compliance Section, LCD; and Mardi Kievs, U.S. EPA Chief, Chemical Management Branch, LCD. This document directs all OLQ contract lab procedures relating to PCB sampling and analysis. SSB chemists review all the data deliverable as outlined in the QAPP.

Permits Branch (PB) technical activities subject to quality assurance/quality control practices:

Activity	Section	QA Staff Resources	Tools, SOPs, Standards Used
Record reviews of submitted ground water, surface water, soil, methane gas data, groundwater flow maps, statistical analyses, statistical exception notices.	Geology	Geologists Supervisor	Protocol for Documenting the Review of Ground Water Monitoring Reports, OLQ SampDB Database and its Correspondence Module Entries, Digital Data Submission Requirements, Non-Rule Policy Document on Methane Monitoring Program, Indiana Ground Water Standards, NPDES Standards, Great Lakes Initiative Protection Standards, RISC Default Closure Levels, Indiana Drinking Water Standards, Prescribed Methane Gas Limits, Drinking Water Equivalent Levels, Removal Action Levels, Region IX Preliminary Remediation Goals, & Health Effects Assessment Summary Tables
Collection of ground water, surface water, soil & methane gas data.	Geology	Geologists Supervisor (Done in conjunction with Chemists from Science Services as needed)	Facility Specific Sampling/Analysis Plans; Geology's Ground Water Sampling and Analysis Plan Preparation Guidance; OLQ Generic Health and Safety Plans; Non-Rule Policy Document on Methane Monitoring Program; Field Instrumentation Procedures; Abandoned Landfill Generic SAP; EPA's Ground Water Sampling Guidelines for Superfund & RCRA Project Managers
Collection of GPS data	Geology	Geologists Supervisor	GPS Training Manuals and GPS Specific Library Templates
Ground Water Program Inspections	Geology	Geologists Supervisor	Comprehensive Monitoring Evaluation; Operations & Maintenance Evaluation; Monitoring Well System Inspection Checklists (New SOP in final draft stage); Ground Water Sampling Inspection (Proposed); Monitoring Well Installation Observations; EPA & State Guidance Documents and Narratives
Evaluation of Submitted Sampling and Analysis Plans	Geology	Geologists Supervisor	Geology's Ground Water Sampling and Analysis Plan Preparation Guidance; EPA & State Guidance Documents & Rules
Evaluation of Submitted Statistical Evaluation Plans	Geology	Geologists Supervisor	EPA & State Guidance Documents and Rules, Commercial Statistical Programs and Training; Stats Workgroup SOP (to be revised)
Evaluation of Submitted Methane Monitoring Plans	Geology	Geologists Supervisor	Non-Rule Policy Document on Methane Monitoring Program; EPA & State Guidance Documents and Rules; Proposed SOP on Review of Methane Monitoring Plans
Evaluation of Ground Water Monitoring/ Network Plans	Geology	Geologists Supervisor	EPA & State Guidance Documents and Rules, Indiana Well Construction and Abandonment Rules, Well Installation Observations

Activity	Section	QA Staff Resources	Tools, SOPs, Standards Used
Enforcement Oversight	Geology	Geologists Supervisor	Section SOP on making Enforcement Referrals, Economic Costs of Benefits, Enforcement Sections' SOPs & Guidance Documents, SEP Policy; EPA & State Guidance Documents and Rules
Tracking and Evaluation of Leachate and Leachate Recirculation Reports	Engineering	1 Engineer 1 Engineering Supervisor	Solid Waste Rules, Guidance Documents and Permit Conditions
Evaluation of Landfill Gas Collection and Control Systems and Coordination with Office of Air Quality	Engineering	1 Engineer 1 Engineering Supervisor (OAQ Staff as well)	Solid Waste and Air Pollution Control Rules, Guidance Documents and Permit Conditions
Evaluation and Analyses of Construction installation, tank leak tests, action leakage rate exceedances, as built design, site conditions, slope stability, hydraulic conductivity, operational and maintenance plan and monitoring data	Engineering	12 Engineers 1 Engineering Supervisor	Solid and Hazardous Waste and CFO Rules, Guidance Documents and Permit Requirements
Financial Assurance Documents	Engineering Hazardous Waste (HW) Permitting	1 Engineer 1 Financial Assurance Officer 1 Engineering Supervisor	Solid and Hazardous Waste Rules, Proposed SOP on Financial Assurance Review, Guidance Documents and Permit Requirements

Activity	Section	QA Staff Resources	Tools, SOPs, Standards Used
Evaluation of Work Plans and Reports	HW Permit Solid Waste (SW) Permit Engineering Geology	Project Managers. Engineers, Geologists, Supervisors/ Managers	Solid and Hazardous Waste Rules, Proposed SOPs, Guidance Documents and Permit Requirements
Issuance of Enforcement Actions	HW Permit	Project Managers	Hazardous Waste Rules, Proposed SOPs, Guidance Documents and Permit Requirements
Photo/Video Documentation	HW Permit SW Permit; Engineering Geology	Project Managers. Engineers, Geologists, Supervisors/ Managers	Preservation of Film Photographs, Digital Photographs, Video & Audio Recordings For Evidentiary Purposes Policy
Permits	Hazardous Waste (HW) Permit Solid Waste (SW) Permit, Geology, Engineering	Permit Managers Engineers Geologists Managers	SOPs, Rules, NPDs, Statutes and Guidance
Closure Plans	HW Permit SW Permit Geology Engineering	Permit Managers Engineers Geologists Managers	SOPs, Rules, NPDs, Statutes and Guidance
Corrective Action	HW Permit SW Permit Geology Engineering	Permit Managers Engineers Geologists Managers	SOPs, Rules, NPDs, Statutes and Guidance
Compliance, Enforcement and Rules Support	HW Permit SW Permit Geology Engineering	Permit Managers Engineers Geologists Managers	SOPs, Rules, NPDs, Statutes and Guidance
Compliance (Geology)	Geology	Geologist	SOPs, Rules, NPDs, Statutes and Guidance

Underground Storage Tanks (UST) Branch technical activities subject to quality assurance/quality control practices:

- Leaking Underground Storage Tanks (LUST) Program
The LUST program oversees the investigation and remediation of suspected and confirmed releases of regulated substances (petroleum and hazardous substances) from regulated underground storage tank (UST) systems. LUST program responsibilities have been delegated to IDEM through a cooperative agreement with the U.S. EPA. The primary program elements of this cooperative agreement are:

1. Program Administration – Provide management, supervisory and support services in order to develop grant applications, clean up contaminated sites, and report financial and performance measures to the EPA R5.
2. Corrective Action – Receive release reports, evaluate and prioritize sites, mitigate immediate threats to human health and the environment, and investigate and remediate releases of petroleum and regulated substances from regulated USTs.
3. Enforcement/Cost Recovery – Compel owners and operators to conduct appropriate responses to LUST incidents including mitigation, site characterization and corrective action or to recover costs for state funded responses.

- Excess Liability Trust Fund (ELTF) Program
The Excess Liability Trust Fund (ELTF) program provides a mechanism for the reimbursement of monies spent by UST owners and operators on the cleanup of petroleum released from USTs. This section is integrally linked with the LUST Program, and provides technical oversight of LUST report submittals for sites seeking reimbursement from the ELTF.

Office of Water Quality (OWQ) Technical Activities and Programs

Watershed Assessment and Planning Branch (WAPB)

Virtually all of WAPB's programs involve the collection or analysis of quantitative data.

Technical Programs Subject to Quality Assurance/Quality Control Processes
Fixed Station Monitoring
Probabilistic Monitoring Program
Baseline Monitoring for Watershed Planning
Monitoring to Identify Improvements (Performance Measures) in Water Quality
Monitoring to Support TMDL Development
• Special Studies / Compliance Evaluations Inspections Program
• Monitoring to Support development of Public Health Advisories
❖ Fish Tissues and Sediment Contaminants Monitoring Program for Fish Consumption Advisories
❖ Cyanobacteria and Microcystin Monitoring
Lakes Monitoring
319/205(j) Project Monitoring

Compliance Branch (CB)

The following Compliance Branch activities involve QA/QC processes:

- Review of Discharge Monitoring Report (DMR), Monthly Report of Operation (MRO) and Monthly Monitoring Report (MMR).
- Data collection, entry and maintenance.
- Providing compliance assistance and outreach.
- Inspection protocol.
- Complaint Response protocol.
- Evaluation of operator certification applicants and trainers.

Permits Branch (PB)

The following Permits Branch activities involve QA/QC processes:

- Sewer construction.
- Industrial NPDES Permits.
- General Industrial Permits.
- Municipal NPDES permits (and semi-publics).
- Industrial pretreatment program.
- Wastewater facility construction permitting.
- Waste load allocations/TMDL reviews.
- Long Term Control Plans.

Drinking Water Branch (DWB)

The following DWB activities involve QA/QC processes:

- Construction permit application review.
- Rules development.
- Data collection, entry and maintenance.
- Providing compliance assistance and outreach.
- Inspection protocol.
- Complaint Response protocol.
- Sampling protocol.
- Evaluation of operator certification applicants and trainers.

Surfacewater Operations and Enforcement Branch (SWOEB)

The following Branch activities involve QA/QC processes:

- Stormwater run-off plan review.
- Construction stormwater inspection.
- Wetland mitigation plan review.
- OWQ budget and spending plans.
- OWQ Contract and Grant development.
- Enforcement Case management.
- Enforcement Case penalty calculations.

Office of Program Support (OPS) Technical Activities and Programs

Northwest Regional Office (NWRO)

The following NWRO activities involve QA/QC processes:

- AOC Aesthetics monitoring data collection and evaluation
- Field audits of habitat restoration and monitoring activities
- Field audits of beach water sample collection and notification.
- Review of *E. coli* enumeration data against notification decisions and quarterly reports.
- Review of invoices submitted by contractors working on AOC or Beach Program projects.
- Evaluation of monitoring data for use in Beneficial Use Impairment removal and Area of Concern delisting decisions.
- Review of Lake Michigan basin water quality and ecosystem data against the General, Substance, and Lake Ecosystem Objectives specified in Annex 2 of the 2012 Great Lakes Water Quality Agreement or developed pursuant to that Annex.
- Development of Lake Michigan Lake Ecosystem Objectives.

APPENDIX D: Oversight of Contracted, Delegated, or Extramural Programs

Office of Air Quality (OAQ) Oversight of Contracted, Delegated, or Extramural Programs

Monitoring Branch (MB)

Some laboratory analysis are done by contract laboratories. Local agencies perform some environmental monitoring under agreement with IDEM. Some industries are required to monitor for various reasons. While this monitoring is not delegated to them they are subject to QA/QC requirements and oversight by the AMB.

Contract/Extramural entity	Data or Service provided	Means of oversight
Eastern Research Group (ERG)	Analysis – Carbonyls, PAMS PM _{2.5} Speciation	U.S. EPA contract Lab – U.S. EPA provides QA/QC QAPP is written for analysis by the contactor ERG prior to EPA awarding a contract. QA/QC of performance evaluation is done in comparison to QAPP requirements. EPA QAPP/Contract oversight is provided by Ms. Motria Caudill.
Contract/Extramural entity	Data or Service provided	Means of oversight
Industries – Each is a Primary Quality Assurance Organization required to have its own QMP		
Duke Energy	Monitoring, QA and QC of SO ₂ SO ₂ and Meteorology	Monitoring/QA plan - outlines the QA/QC requirements to assure the quality of data submitted. Systems Evaluation by OAQ QA (Annually) provides an external audit of the QA/QC procedures. Quarterly QA data submittal review by AMB staff to provide oversight on all data submitted.
ArcelorMittal	SO ₂ and Meteorology	Same as above
IPL (AES)	Monitoring, QA and QC of SO ₂ and Meteorology	Same as above
Northern Indiana Power and Service Company (NIPSCO)	Monitoring, QA and QC of SO ₂ and Meteorology	Same as above

Programs Branch (PB)

The Branch reviews the QMP of potential contractors prior to receiving bids on contracts. It reviews the QAPPs of potential contractors before contracts are awarded.

Contract/Extramural entity	Data or Service provided	Means of oversight
BP Amoco/ South Shore Clean Cities	Rebates to municipalities for alt fueled vehicles Conversions Rebates to individuals for alt fueled vehicles Idle Reduction Education Program	IDE� staff refers to exhibits contained in specific contracts, which outline the scope of work, the timeline for each step of the project and the associated costs, and monitors that all parameters are met. This review is conducted in order to ensure that Quality Assurance requirements are met on any project that provides a service or data to the department.
BP Amoco /NW Indiana Diesel Grant Program	Diesel retrofits	
Hammond Department of Environmental Management (BP Amoco)	Idle Reduction Education Program	
Merrillville School Corp (Ispat/Inland)	Diesel retrofits	
Envirotest Systems	Operation of the inspection and maintenance program	

Compliance and Enforcement Branch (CEB)

The Compliance and Enforcement Branch is only using one contractor at this time.

The Compliance and Enforcement Branch contracts out Coke Oven Battery 303 Inspections that are subject to QA/QC activities:

- Maintenance and revisions to the Air Compliance and Enforcement System (ACES)

Contract/Extramural entity	Data or Service provided	Means of oversight
Air Compliance and Enforcement System	Computer data system maintenance	Review of biweekly invoices Periodic testing of revised data system Review of maintenance status report and signoff in the Tracking Performance System

Office of Land Quality (OLQ) Oversight of Contracted, Delegated, or Extramural Programs

Science Services Branch (SSB)

Science Services Branch conducts oversight of contractors.

- Contracted Laboratory Analysis
Laboratory analysis is performed for the Office of Land Quality by private laboratories under contract to the state. As part of the contract process, the laboratories are required to have a documented Quality Control System (QCS). The QCS criteria are outlined in the Laboratory Services Request for Proposals 9-34. All prospective vendors were audited for QCS criteria prior to award.
- Laboratory Analyses
Laboratory analyses are either performed by IDEM Contract Laboratories, or are performed by U.S. EPA laboratories. IDEM Contract Laboratories are required to have a documented QCS in place. Details regarding acceptable laboratory QCS criteria can be referenced in the contracts to provide analytical laboratory services A305-9-291 thru A305-9-293 *Broad Agency Announcement 2-003 for Laboratory Services* or in the following OLQ contract *RFP 5-102 for Laboratory Services*. Prior to awarding any laboratory contract, the SSB conducts a laboratory audit of their respective QCS to ensure IDEM's quality criteria are met.
- Consultant/Services Contracts
When needed, the RSB generally procures services for sampling, risk assessment preparation, remedial or construction oversight, and technical review services under one of two contracts (referred to as Master Agreements) for Services including:
 - Field Response Services

Remediation Services Branch (RSB)

These Master Agreements are currently in the revision process and their scope has not been completed yet. Contractual oversight is provided through project manager (PM) and technical staff review of plans and or reports or through direct observation of environmental data collection or remediation. Payment of invoices for work performed is contingent upon the signature of the RSB project manager to signify approval of the work performed. General RSB Contracts: Occasionally, RSB procures contracts for specialized supplies, training, or other miscellaneous services. Procurements are defined in writing via Scope of Work, requests for proposals, or requests for quotations. These documents individually specify tasks, deliverables, quality assurance, and other requirements as determined by the RSB PM. As with the Master Agreement contracts, the RSB PM must approve adequate work performance prior to invoice payment.

The remediation of the majority of sites in the RSB programs are funded by responsible parties (RPs) that conduct site investigations and remediation activities with oversight from RSB project managers who review and validate the quality of the data upon which remediation activities are based.

RSB program specific information:

- State Cleanup (SCU)

On sites where an imminent threat to human health or the environment has been identified, State Cleanup Section staff may conduct limited environmental investigation and/or conduct immediate removal actions. Any IDEM-lead investigation will follow the appropriate U.S. EPA and IDEM Remediation Closure Guide (RCG) or risk guidelines and typically utilize one or more of the existing Master Agreement for Services contracts.

- Federal Programs

As part of the federal grant process, IDEM and U.S. EPA enter into Cooperative Agreements that include Scopes of Work that detail the work, and quality system components, expected to meet annual and long-term goals. Work products undergo technical review by either internal SSB staff or external contracted consultants. In accordance with Cooperative Agreement and grant requirements, Federal Programs staff submit quarterly and semi-annual reports to EPA R5 detailing performance results, and meet with them twice a year to discuss relevant issues. PMs evaluate contracted work products for adherence to the appropriate U.S. EPA guidance. Superfund and Department of Defense sites utilize Quality Assurance Project Plans.

- Site Investigation

Site Investigation program staff conduct their own environmental investigations, following the appropriate U.S. EPA guidance, the SI Program QAPP, and site-specific Work Plans. Laboratory analyses are performed by U.S. EPA laboratories (CLP/CRL/SAS).

- Voluntary Remediation Program (VRP)

Documentation (Investigation Reports, Remediation Work Plans, QAPPS, Health and Safety Plans, etc) submitted to IDEM is subject to review and evaluation for technical sufficiency. The VRP PM, or his/her designated technical representative, may perform direct oversight during field work activities. In addition, the VRP PM, or his/her designated technical representative, collects split-samples for all project closures as a verification that conditions meet closure criteria.

- Indiana Brownfields Program (Administered by the Indiana Finance Authority)

Site assessment and petroleum or hazardous substance remediation activities conducted with IFA grants must be performed consistent with IDEM RCG. Specific assessment activities must receive Indiana Brownfields Program approval prior to implementation. PM staff perform oversight at all grant-funded site assessments to ensure quality of work.

Compliance Branch (CB) conducts oversight of contractors as following:

Sampling and laboratory analyses (performed by IDEM Contract Laboratories under the oversight of Science Services).

Contract/Extramural entity	Data or Service provided	Means of oversight
Emergency procurement Contracts	Spill containment removal, characterization and disposal	On-site coordinator oversight & review of expenses with assistance from Science Service Branch for review of lab QA/QC results
Sampling and laboratory analyses	OLQ Science Services Branch review of lab QA/QC results	OLQ Science Services Branch Quality Manager

Permits Branch (PB) does not work with contractors and so does no oversight.

All data analyzed by the OLQ contract laboratories is subject to an independent data verification and validation review by the Chemistry Services Section. The data package is assigned by the Environmental Chemist Section Chief (ECSC) to an Environmental Chemist (EC) to be reviewed after it has been logged in as stated in the "Data Package/Field Documentation Receipt" SOP. The EC reviews the data in accordance with the "Data Verification and Validation" SOP. The data review is conducted independently of the Project Manager, who uses the data for project decisions. A Verification, Validation and Project Assessment memo is written, peer reviewed

and sent through the ECSC to the Project Manager. Any data quality disputes are handled by the Quality Assurance Officer (QAO), a senior level chemist who specializes in laboratory analytical methods and the contract specifications. Both the ECSC and the QAO report to the Science Services Branch Chief. This ensures independence and authority for these reviews.

UST Branch

As part of the federal grant process, IDEM and U.S. EPA enter into Cooperative Agreements that include Scopes of Work that detail the work, and quality system components, expected to meet annual and long-term goals. Work products undergo technical review by internal SSB staff. LUST Program staff submit quarterly and semi-annual reports to U.S. EPA detailing performance results, and meet twice a year with U.S. EPA to discuss relevant issues. PMs evaluate contracted work products or those submitted to IDEM for review for adherence to the RCG or risk based guidelines.

Office of Water Quality (OWQ) Oversight of Contracted, Delegated, or Extramural Programs

Watershed Assessment and Planning Branch (WAPB)

Environmental samples, collected from different matrices (water, sediments, and fish tissues) are sent to contract laboratories for chemical analyses. All contracts with laboratories require that a U.S. EPA approved QA/QC system is in place and acceptable to IDEM. A copy of the current quality assurance manual of each contracted laboratory is reviewed and kept in the contract manager's files. Additionally, assessment activities in the field may be conducted in cooperation with non-IDEML groups such as U.S. Geological Survey (USGS), Indiana University School of Public and Environmental Affairs (IU SPEA), or volunteer monitoring groups. Lakes assessments may be conducted by IU SPEA.

All contract labs are prequalified by IDEM which reviews and approves their Quality Management Plans, SOPs, and other technical documents in response to IDEM Requests for Proposals (RFPs). Labs submitting bid responses to IDEM also include details about each facility, staffing, staff qualifications, and lab audit reports performed by other groups or organizations as well as state or federal accreditations. Consequently, IDEM does not require a site visit or audit of any contract lab. Site visits may occur to resolve laboratory quality assurance problems that may occur or to verify that the proper corrective action has been taken.

The WAPB performs a vigorous quality check of data provided to IDEM by contract laboratories. Each lab data set is checked for compliance against the IDEM WAPB QAPP and contract requirements for QA/QC. Contract labs also submit data in electronic format which is reviewed for accuracy and completeness and assigned to a specific level of data quality assessment (DQA) indicating the quality of data and its usefulness in water quality assessments which are suitable for regulatory decision-making.

319 and 205(j) grant project managers in the Watershed Planning and Restoration Section are responsible for review of tasks, deliverables, and schedules during quarterly site visits with contractors or grant sponsors. The contractors or grant sponsors are required to submit progress reports with every invoice, or at least quarterly progress reports if they don't invoice as often. The project managers review reports and invoices to ensure all tasks are on schedule, expenses and match are eligible, and deliverables are acceptable. Invoices are signed by the senior project manager or section chief for submittal to the accounting office.

Contract/Extramural entity	Data or Service provided	Means of oversight
Pace Analytical Services Indianapolis, IN	<p>Provides analytical services for water and sediment samples collected by IDEM. Analyses may include general chemistries, nutrients, metals, and organic parameters. These services support multiple WAPB Projects including the Probabilistic and Watershed Characterization Programs, Source ID, TMDL development, and special projects.</p>	<p>Data Reports / Packages are reviewed for QA/QC in compliance to a template check list developed for project specific Water Quality Monitoring Programs. This QA/QC template has been designed to be consistent with IDEM RFP and WAPB QAPP requirements so that each QA/QC review is consistent with agency standards.</p>
TestAmerica, Inc. University Park, IL.	<p>Provides analytical services for water samples collected by IDEM. Samples may be analyzed for general chemistries, nutrients, metals, organic, and bacteriological parameter. These services support IDEM's Probabilistic and Watershed Characterization Programs, TMDL development, and special projects.</p>	<p>Data reports/packages are reviewed for QA/QC in compliance to a template check list developed for project specific Water Quality Monitoring Programs. This QA/QC template has been designed to be consistent with IDEM RFP and WAPB QAPP requirements so that each QA/QC review is consistent with agency standards.</p>
Eurofins Eaton Analytical South Bend, IN	<p>Provides analytical services for water samples collected by IDEM. Samples may be analyzed for general chemistries, nutrients, metals, organic, and bacteriological parameter. These services support IDEM's Probabilistic and Watershed Characterization Programs, TMDL development, and special projects.</p>	<p>Data reports/packages are reviewed for QA/QC in compliance to a template check list developed for project specific Water Quality Monitoring Programs. This QA/QC template has been designed to be consistent with IDEM RFP and WAPB QAPP requirements so that each QA/QC review is consistent with agency standards.</p>
Indiana State Department of Health (ISDH) Environmental Laboratory Indianapolis, IN	<p>Provides analytical services for water samples collected by IDEM. Analyses may include metals, inorganic chemicals, organic chemicals, physical properties, and <i>E. coli</i> bacteria. These services support IDEM's Fixed Station and Watershed Characterization Programs, TMDL Development, and special projects.</p>	<p>Data Reports/Packages are reviewed for QA/QC in compliance to a template check list developed for project specific Water Quality Monitoring programs. This QA/QC template has been designed to be consistent with IDEM RFP and WAPB QAPP requirements, so that each QA/QC review is consistent with agency standards.</p>

Contract/Extramural entity	Data or Service provided	Means of oversight
Pace Analytical Services, Madison, WI and Minneapolis, MN	Provides analytical services for fish tissues and sediment samples collected by IDEM staff. Samples are analyzed for general chemistry, nutrients, and organic parameters in support of Fish Tissues and Sediments Contaminants Monitoring Project, Fish Consumption Advisories, and special projects.	Data reports / packages are reviewed for QA/QC in compliance to a template check list developed for project specific Water Quality Monitoring programs. This QA/QC template has been designed to be consistent with IDEM RFP and WAPB QAPP requirements, so that each QA/QC review is consistent with agency standards.
U.S. Geological Survey Indiana Water Science Center 5957 Lakeside Blvd. Indianapolis, IN 46278-1996	Conducts analyses of chlorophyll for nutrient criteria development using data collected by IDEM monitoring staff and conducts sampling and analysis for mercury using ultra clean techniques.	Data reports/packages are reviewed for QA/QC in compliance to a template check list developed for project specific Water Quality Monitoring programs. This QA/QC template is consistent with IDEM RFP and WAPB QAPP requirements so each QA/QC review is consistent with agency standards.
IU SPEA	Conducts water quality monitoring in lakes and reservoirs through the Clean Lakes Program. Implements a volunteer monitoring program which provides more limited data. Clean Lakes Program data is submitted to IDEM for use in Clean Water Act Assessments, and volunteer data is submitted for potential use in these processes. Contractor also conducts data analyses, submitting the results in a report to IDEM annually.	Data reviewed by IU SPEA for compliance to 319 IDEM approved QAPP. Only qualified data are submitted to IDEM. Data which would be assessed as rejected are maintained according to the IU retention schedule by IU SPEA. Data undergo internal QA review in accordance with the approved QAPP prior to reporting to IDEM. IU SPEA submits a QA to IDEM report annually.

Contract/Extramural entity	Data or Service provided	Means of oversight
319/205(j) Grantees	Environmental sampling and analyses. Nature and scope of monitoring efforts vary from project to project but may include biological, bacteriological, and chemical parameters. Grantees conduct outreach, develop watershed management plans, including watershed characterization, source identification of pollutants, and information on cause and effect relationships. Grantees install and may monitor best management practice with the goal of improving water quality.	<ul style="list-style-type: none"> • Quarterly site visits by project managers • Progress reports with every invoice submitted or at least quarterly • Quality assurance project plan submission and approval required before sample collection can begin • Any changes to the monitoring plan must be approved prior to their implementation. Data submission with final project report for final review and evaluation

Compliance Branch (CB)

Laboratory technical assistance with NPDES approved test methods or with other laboratory issues, is available. The Branch assists U.S. EPA in the administration of the DMR-QA program.

Permits Branch (PB)

Permits does not delegate or contract out any work.

Drinking Water Branch (DWB)

Environmental samples, collected from different matrices (ground water, surface water, and finished drinking water) are sent to contract laboratories for chemical analyses. All contracts with laboratories require an IDEM acceptable QA/QC system. A copy of the current quality assurance manual of each contracted laboratory is reviewed and kept in the contract manager's files.

All contract labs are prequalified by IDEM which reviews and approves their Quality Management Plans, SOPs, and other technical documents in response to IDEM Requests for Proposals (RFPs). Labs submitting bid responses to IDEM also include details about each facility, staffing, staff qualifications, and lab audit reports performed by other groups or organizations, as well as state or federal accreditations.

IDEML works with other state and federal agencies through a Memorandum of Understanding (MOU) system. Typically, MOU's are for a one year period. QA/QC is managed in the same manner as with commercial labs and require an acceptable IDEM approved QA/QC system.

Contract/Extramural entity	Data or Service provided	Means of oversight
Pace Analytical Services Indianapolis, IN	Provides analytical services for water and sediment samples collected by IDEM. Analyses may include general chemistry, nutrient, metal, and organic parameters.	Data Reports are minimally set to receive analytical quality control results accompanying sample results. QA/QC data is reviewed for suitability of use. Enforcement level data includes additional bench and analytical run data for a more in depth review.

Contract/Extramural entity	Data or Service provided	Means of oversight
Eurofins Eaton Analytical South Bend, IN	Provides analytical services for water and sediment samples collected by IDEM. Analyses may include biological, general chemistry, nutrient, metal, and organic parameters.	Data Reports are minimally set to receive analytical quality control results accompanying sample results. QA/QC data is reviewed for suitability of use. Enforcement level data includes additional bench and analytical run data for a more in depth review.
Indiana State Department of Health (ISDH) Environmental Laboratory Indianapolis, IN	Provides analytical services for water and sediment samples collected by IDEM. Analyses may include biological, general chemistry, nutrient, metal, and organic parameters.	Data Reports are minimally set to receive analytical quality control results accompanying sample results. QA/QC data is reviewed for suitability of use. Enforcement level data includes additional bench and analytical run data for a more in depth review.

Surfacewater, Operations and Enforcement Branch (SWOEB)

- Mapping and GIS services
- Mobile Application Development

Office of Program Support (OPS) Oversight of Contracted, Delegated, or Extramural Programs

Northwest Regional Office (NWRO)

The NWRO conducts oversight of contractors involved in habitat restoration or monitoring efforts in the Grand Calumet River Area of Concern, as well as data collection and support of IDEM's Lake Michigan Beaches Monitoring and Notification Program.

Contract/Extramural entity	Data or Services provided	Means of oversight
Indiana Department of Natural Resources (IDNR)	<ul style="list-style-type: none">Monitors restoration work conducted under the Dune and Swale GLRI Direct Funding Grant (GLE001506).Provides/oversees habitat restoration crews and equipment purchases pursuant to Dune & Swale Grant for 13 sites.Develops natural resource plans and administers contracts on IDNR properties.Provides Clean Marina Program Support.Plans and chairs Septic Coordination Workgroup Meetings.Attends LAMP/RAP related meetings.Supports LAMP Conference Planning.Coordinates IDNR portion of LAMP implementation, including nonpoint source and SepticSmart Week initiatives.Represents Indiana at Great Lakes Fisheries Commission meetings.Develops invasive species control programs for IN Dunes State Park.Provides Lake Michigan interpretative presentations at IN Dunes State Park.Lake Michigan Water Program Coordination & Urban Waters support.	<ul style="list-style-type: none">Quarterly reimbursement requests and backup documentation reviewed against MOA specifications.Site visits and audits of restoration work conducted at least annually.Review of quarterly progress reports.Review of habitat monitoring data submitted by IDNR.
Lake County Parks and Recreation Department	<ul style="list-style-type: none">Monitors restoration work conducted under the Dune and Swale GLRI Direct Funding Grant (GLE001506).Provides/oversees habitat restoration crews and equipment purchases pursuant to Dune & Swale Grant for 2 sites.	<ul style="list-style-type: none">Invoices and backup documentation reviewed against contract specifications.Site visits and audits of restoration work conducted at least annually.Review of quarterly progress reports.

Contract/Extramural entity	Data or Services provided	Means of oversight
Wild Goose Chase, Inc.	<ul style="list-style-type: none"> • Patrols beaches managed by the City of East Chicago May 1- August 31(sunrise to sunset), preventing shorebird nesting, roosting, and foraging activities. • Collects data on bird counts, weather conditions, beach events, etc., at both Jeorse Park and Whihala beaches and distributes to IDEM. • Conducts public outreach on hand-feeding of nuisance shorebirds. 	<ul style="list-style-type: none"> • Invoices and backup documentation reviewed against contract specifications. • Periodic site visits a conducted. • Review of progress reports.
<p>Beach Contractors:</p> <ul style="list-style-type: none"> • Indiana DNR • Hammond Port Authority • City of Whiting • East Chicago Health Dept. • City of Gary • Town of Ogden Dunes • Town of Beverly Shores • City of Michigan City • LaPorte County Health Dept. 	<ul style="list-style-type: none"> • <i>E. coli</i> sample collection and analysis • Beach notification action reporting of <i>E.coli</i> monitoring results into BeachGuard and posting of appropriate signage at the beaches. 	<ul style="list-style-type: none"> • Invoices and backup documentation reviewed against contract specifications. • Periodic site visits conducted. • Review of progress reports and final reports. • Daily review of BeachGuard monitoring and notification entries

APPENDIX E. The Systematic Planning Process

From: [U.S. EPA QA/G-4 Guidance on Systematic Planning Using the Data Quality Objectives Process](#)

Table 1. Elements of Systematic Planning	
Elements	
Organization:	Identification and involvement of the project manager, sponsoring organization and responsible official, project personnel, stakeholders, scientific experts, etc. (e.g., all customers and suppliers).
Project Goal:	Description of the project goal, objectives, and study questions and issues.
Schedule:	Identification of project schedule, resources (including budget), milestones, and any applicable requirements (e.g., regulatory requirements, contractual requirements).
Data Needs:	Identification of the type of data needed and how the data will be used to support the project's objectives.
Criteria:	Determination of the quantity of data needed and specification of performance criteria for measuring quality.
Data Collection:	Description of how and where the data will be obtained (including existing data) and identification of any constraints on data collection.
Quality Assurance (QA):	Specification of needed QA and quality control (QC) activities to assess the quality performance criteria (e.g., QC samples for both field and laboratory, audits, technical assessments, performance evaluations, etc.).
Analysis:	Description of how the acquired data will be analyzed (either in the field or the laboratory), evaluated (i.e., QA review/verification/validation), and assessed against its intended use and the quality performance criteria.

APPENDIX F. The OLQ Analytical Services Guide

A guide used by OLQ staff to communicate sampling information to SSB staff:

OLQ Analytical Services Guide

Requesting Lab Services from Contracted Labs for Analyses

Office of Land Quality (OLQ) staff collects various samples of different matrices such as air, soils, sediments, water, wastes, and soil gas to identify the concentration of potential hazardous contamination. Staff from any section or branch within OLQ may request analyses set up and sampling assistance.

You're Going Sampling. What's next?

You need to determine what constituents need to be analyzed in the various matrices at your site or facility. OLQ contracts with various environmental laboratories to provide analyses of your samples collected from your site or facility.

Consult with the site chemist or Environmental Chemistry Technical Specialist (Chemist E7) regarding the objective of the sampling event and sample analyses. The Chemist E7 also serves as the Sampling Gatekeeper (SG).

To obtain the sample containers with subsequent analyses, you will need to determine the type of analyses and complete the Sample Request Sheet (SRS) which is available on the OLQ Chemistry Services SharePoint Site.

Sample Request Sheet – Fill out the turquoise colored portions of the SRS. The turn-around-time (TAT) is generally 30 days to complete the analyses and return the data.

Note: Remember to include Quality Control samples such as duplicates, equipment blanks, and trip blanks, on the SRS. Matrix spike/matrix spike duplicates are automatically accounted for and do not need to be included on the SRS. Also, allow enough time for the SG to complete the cost estimation, determine contract laboratory, and to set up sampling kit.

After you have consulted with a chemist and completed the SRS, then e-mail or take the completed SRS to the SG for cost estimation and determination of the contracted laboratory that will provide sample containers and analyze your samples. The SG will return the SRS with assigned sample identification numbers to you to review and finalize the details of the sampling event (ensure that Item 11 on the SRS will meet your expectations). Next, have your supervisor sign the SRS, make a copy for your records, and then return the original signed SRS to the SG. If you are in the UST Branch or the Federal Programs Section, see Attachment 1 for additional information.

The following field documentation sheets are delivered with the sampling kit and are also available on the OLQ Chemistry Services SharePoint Site.

- Site Information Sheet - You will need this sheet to document site conditions and basic site information.
- Sample Field Sheet - You will need this sheet for each sample location.
- Chain-of-Custody Form – You will need this three page carbonless State of Indiana form (IDEM COC form) to account for samples relinquished to the laboratory. The laboratory keeps two, the white and the yellow copy. You keep one copy, the pink form, and return it to the SG.

Additional information regarding Quality Control samples is provided in Attachment 2 and sample forms are in Attachment 3.

I have placed my request. Now what happens?

You should allow time for the SG to consult and communicate with the lab, to order the sample kit set-up, and delivery and transfer of the sampling kit within IDEML OLQ. Please allow a minimum of a week for this process. The sample kit, consisting of cooler(s) with the appropriate matrix containers, will be delivered to you with the following field documentation: site information sheet per site, sample field sheets per sample location, and the IDEML COC form. When the sampling kit arrives from the lab, the SG will check to ensure you received what you ordered. Let the SG know right away if you experience problems with items in the sampling kit.

Complete the site information sheet in pen (black or blue ink only).

Complete sample field sheets during the sampling event - **one sample field sheet per sample location will be included with the sampling kit.**

Note: You may be able to complete some information on the field documentation sheets prior to the sampling event.

After completing the sampling event, return the sampling kit that contains sampled materials to the assigned contracted laboratory identified on the SRS. After you complete the IDEML COC form, both you and the laboratory technician will sign and date the IDEML COC form at the laboratory to relinquish sampled materials to the laboratory. You give the laboratory the white and yellow copies of the IDEML COC form and keep the pink copy.

Return the completed field documentation sheets (SRS, site information sheet, sample field sheets, the pink copy of the IDEML COC form, and statement of container cleanliness sheet(s) to the SG. This is an important step because it will ensure a timely and thorough evaluation of your data.

How Long Do I Wait For the Data?

The laboratory will generally take 30 days (See SRS) to analyze and process your samples. If you need the data sooner be sure to discuss this with the SG during the consultation phase prior to your sampling event. When the data package arrives, the SG documents the receipt of the data and sends the data package and your documentation to the OLQ Chemistry Services Section.

The site chemist will be assigned to review the data package for verification, validation, and interpretation. The site chemist will check that the laboratory performed the applicable analyses.

You will receive a Data Summary Sheet, a Data Verification and Validation Memo, and a Data Interpretation Memo from the site chemist that performed the evaluation of your sampling data. Your Administrative Assistant will ensure that these memos are placed in Virtual Filing Cabinet (VFC).

Attachment 1

Quality Assurance Project Plan

The Tanks Branch, Site Investigation (SI) program, and Compliance Branch (PCB sampling) use a QAPP format when sampling in the field. Tanks Branch, SI program, and Compliance Branch staff should read and be familiar with all aspects of the respective program QAPPs which can be found at:

[Tanks Branch QAPP \(2014\)](#)

[Site Investigation program QAPP \(2014\)](#)

[Compliance Branch PCB QAPP \(2015\)](#)

A general QAPP guidance (2015) is available on OLQ Chemistry's webpage [here](#).

Attachment 2

Additional Information

Quality Control

Quality control measures are those activities one undertakes to demonstrate the accuracy (how close to the real result one is) and precision (how reproducible the results are) of the analysis. Quality Control (QC) consists of field and laboratory steps one will take to determine the validity of specific sampling and analytical procedures. Terms with which the sampler should be familiar relative to the sampling event are listed below.

Quality Control Definitions

- *Field Blanks* - A trip blank (also known as a field blank), ambient blank, and equipment/rinsate blank use deionized water which is treated as a sample. They are used to identify errors or contamination in sample collection and analysis.
- *Field Duplicates or Co-located Samples* - A field duplicate is a split sample of the original field sample collected by the same team or by another sampler or team at the same place, at the same time. A co-located sample is collected in the same place as the duplicate. It is not a split. These samples are used to estimate sampling and laboratory analysis precision.
- *Temperature Blank* - For each cooler that is shipped or transported to an analytical laboratory 40 ml Volatile Organic Analyte (VOA) vial will be included that is marked "temperature blank." This will be used by the laboratory custodian to check the temperature of samples upon receipt at the laboratory.
- *Matrix Spike Samples* – A sample of the same matrix (e.g., water, soil, sediment, waste) per every twenty samples being analyzed for the same constituents may be associated with a single matrix spike (MS) sample or a matrix spike/matrix spike duplicate (MS/MSD) pair.

Special Considerations

The Emergency Response (ER) Section obtains approximately 100 sample numbers (designated as RI numbers) and provides samples to the Indiana State Department of Health (ISDH). These samples are analyzed by the ISDH using the EPA 500 analyses series. This is a drinking water series of analyses and is primarily used to determine if the matrix may be contaminated with hazardous materials as described in the RCRA or Superfund programs.

Site Investigations Section, a Federal Programs gatekeeper process, may use the laboratory contracts for requests to:

- Provide Derived Waste disposal,
- Provide rental of sampling equipment, or
- Provide Site Investigation screening analyses.

Attachment 3

Sample Forms

<i>OLQ Sample Request</i>		1. Date 2/27/2015	Sample Numbers	
2. Site Name		3. Site ID Numbers (Old)	(New)	4. Grant Code
5. Street Address		6. City	7. County	
8. Person Requesting Samples		Branch/Section	Phone	
9. Sampler(s)		Branch/Section	Phone	
10. Site Manager / Facility Contact		Phone		
11. Reason for Sampling: Briefly describe the problem <u>sampling and analysis</u> should resolve.		<input type="checkbox"/> Electronic Copy <input type="checkbox"/> Yes		
12. DQO:		13. Protocol:		
14. Matrix Type:		15. Dedicated Equipment?		
16. <u>This section for Air Analysis only:</u> 16 A. Six (6) Liter Summa Certification (Includes vacuum and pressure gauge):				
16 B. Flow Controller:				
17. Analysis:				
18. Samples:				
Duplicates:				
Trip Blanks:				
Equipment Blanks:				
Total:				
19. Projected Sample Date(s)	20. Projected Date(s) to Lab	21. Turnaround Time	22. Cooler Arrival	
Lab Assigned	Lab Contact	Lab Contact Date	Projected Cost	
Actual Date to Lab	Data Package Due	Preliminary Results Received	Package Received	
Sampling Gatekeeper				
Section Chief		Branch Chief		
Assistant Commissioner		Assistant Commissioner of OMBA		
\$0-\$10,000 - Section Chief \$20,001-\$40,000 - Add Assistant Commissioner of OLQ		\$10,001-\$20,000 - Add Branch Chief Over \$40,000 - Add Assistant Commissioner of OMBA		

5/13 Revision

SAMPLE REQUEST SHEET INSTRUCTIONS

Please complete only the numbered items on the form.

1. Date – Today's Date (Filled in automatically).

Items 2-7 are facts about the site being sampled.

8. Person Requesting Samples – Assuming you are filling out this form, that would be you.

9. Sampler(s) – Person(s) who will be in the field, collecting the samples.

10. Site Manager/Facility Contact – Non-IDEML contact person for the site or facility (if applicable).

11. Reason for Sampling – Briefly describe the problem sampling and analysis should resolve.

Identify thresholds or action levels for decision criteria. For site characterization identify the sampling locations by map, site document, or descriptive sampling points. **Electronic Copy – Always Yes.**

12. Data Quality Objectives – The adjoining turquoise cell contains the following drop-down categories: Preliminary/Screen, Waste ID/Characterization, RISC-ISC, RISC-Monitoring, RISC-N&E, RISC-Closure, VRP (grandfathered), UST/LUST (grandfathered), Other, Multiple, thus varies by use of data. All contract laboratory data packages are enforceable. Highlight the best category that best describes your objective and either click your mouse or hit enter.

13. Protocol – The adjoining turquoise cell contains the following drop-down categories: SW846, Drinking Water, CLP, and Special Analytical Services (SAS). SW-846 should be suitable for most purposes. Drinking water methods should only be used on drinking water samples. CLP use is program and site specific. Highlight the category that best describes your protocol and either click your mouse or hit enter. Please note, if you are utilizing a SAS, Mr. David Harrison (Chemist E7) must sign the sample request.

14. Matrix Type – The adjoining turquoise cell contains the following drop-down categories: Air, Soil, Sludge, Other Waste, Surface Water, Ground Water, Waste Water, Wipe, Other. Please submit one form for each matrix being sampled. This should reduce confusion about the appropriate number of duplicates and matrix spikes to obtain. Highlight the category that best describes your matrix and either click your mouse or hit enter.

15. Dedicated Equipment – The adjoining turquoise cell contains the following drop-down categories: Yes or No. In other words, is the sampling equipment you will be using going to be dedicated (single use) or will it have to be decontaminated between uses? Highlight the category that describes your use of sampling equipment and either click your mouse or hit enter.

16. Analysis – The adjoining turquoise cells contain the following drop-down categories: See #11, BTEX, BTEX/MtBE, Cyanide, Lead, Metals-A, Metals-B, Metals-C, Metals-D, Metals-E, VOCs, SVOCs, PAHs, PCB, Pest, Pest/PCBs, TPH-Gas, TPH-Diesel, TPH-Oil, TPH-ALL, % Solids. The pull down menu contains only the most common parameter lists. If you need another parameter, please choose "See #11" and indicate the needed parameters in Item 11 above. Highlight the category that describes the requested analysis and either click your mouse or hit enter. Please select one analysis per cell.

17. Samples – Enter the number of samples.

18. **Projected Sample Date(s)** – Enter the date or dates on which you expect to collect the samples. Please try to avoid collecting on Saturdays unless you can get the samples to the laboratory by the end of the day.

19. **Projected Date(s) to Lab** – We ask for this information because the laboratories like to know what to expect. If your plans change, please let the SG know as soon as possible. Samples should be submitted to the laboratory as soon as practicable, generally within 48 hours of collection. Some analyses (e.g. hexavalent Chromium) may require more rapid submittal to allow the laboratory to do the analysis within holding times. Extended sampling events may require multiple submissions to the laboratory. Try to avoid delivery to the laboratory on Saturdays – labs are sometimes closed on weekends, or charge us high "emergency" response fees to have someone on hand to accept weekend deliveries.

20. **Turn-a-round Time** – The turquoise cell below contains the following drop-down categories: 90 Days, 60 Days, 30 Days, 21 days, 14 Days, 7 Days, 2 Days, Other. Highlight the category that describes the requested turn-around time and either click your mouse or hit enter. The laboratory has to submit the full data package to IDEM. Ordinarily 30 days. Faster turn-a-round times can be requested at **rapidly** escalating expense. In some cases we are able to obtain preliminary faxed or electronic results; ask the SG for these if you need them.

21. **Cooler Arrival** – Enter the date for either cooler arrival (out-state labs) or when you would like to pick up the cooler (in-state Labs). Please note: If you do not need coolers or bottles type: NA.

INDIANA DEPARTMENT OF ENVIRONMENTAL
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SITE INFORMATION *

IDEML Sample #s: _____	Sampling Date(s): _____	
Site Name: _____	Site ID #: _____	
Street Address: _____	City: _____	County: _____

Site Representative(s): _____ Company: _____
IDEML Samplers: _____ Laboratory: _____

Weather Conditions: Sky _____ Ground _____ Wind _____ Temp _____ Humidity _____

Sample Types (check all applicable): Mon. Well Res. Well Creek Leachate Ditch
 Drainage Tile Lagoon Pond Sludge Sediment Industrial Waste
 Waste Pile Soil Truck Drummed Waste Waste Liquid Oil
 Solvent Sand Ash Other _____

Sample Choice (check): Grab Composite Statistical Random Judgmental

Sampling Equipment Used: _____
Decontamination Procedures: _____

Field Test Equipment Used: _____
Calibration Notes: _____

Container Source: _____ Sample Preservative Source: _____
Blank Water Source: _____ Decontamination Water Source: _____

Program Area (check): RCRA CERCLA Solid Waste DOD LUST/UST VRP
 State Cleanup Emergency Response Other _____

Purpose (check): Complaint Compliance Enforcement Other _____

Constituents Expected: _____ Handling Precaution: Yes No

Photos Taken? Yes No Send analytical data review to: _____ Phone: _____

Other Notes or Deviations from Sampling Plan: _____

Revised 09-11-00

Sampler Signature: _____ Date: _____

* This form is for general use in OLQ sampling projects.

SAMPLE CUSTODY CHAIN - IDEM OFFICE OF LAND QUALITY

State Form 42091