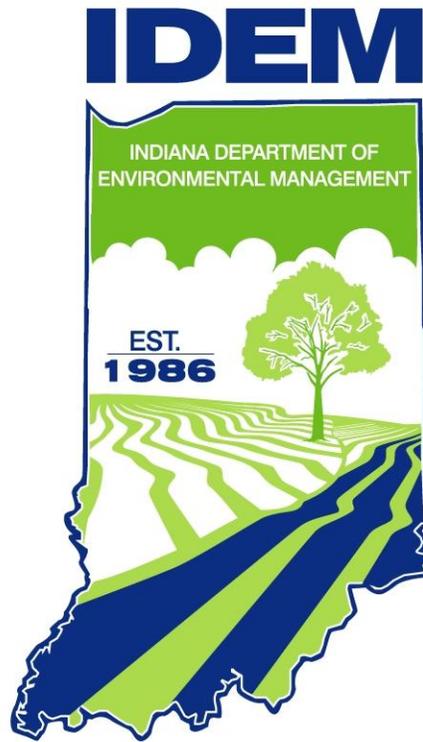


IDEM Agency Wide Quality Management Plan



2012

September 27, 2012

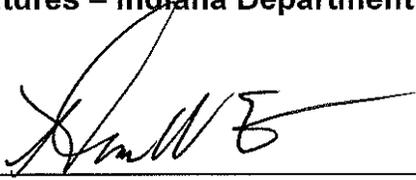
Indiana Department of Environmental Management

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

This page left blank intentionally

**Indiana Department of Environmental Management
2012 Quality Management Plan (QMP)**

Signatures – Indiana Department of Environmental Management



Thomas W. Easterly, Commissioner

9/27/2012

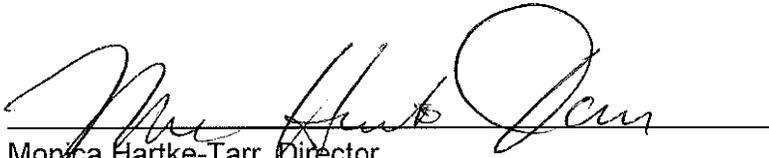
Date



Rick Bossingham, IDEM Quality Manager
and Assistant Commissioner,
Office of Compliance Support (OCS)

9/27/12

Date



Monica Hartke-Tarr, Director
Office of Planning and Assessment, OCS

9-27-12

Date

This page left blank intentionally

**Indiana Department of Environmental Management
2012 Quality Management Plan (QMP)**

Signatures – U.S. Environmental Protection Agency Region 5



Susan Hedman, Regional Administrator, Region 5

2-28-13

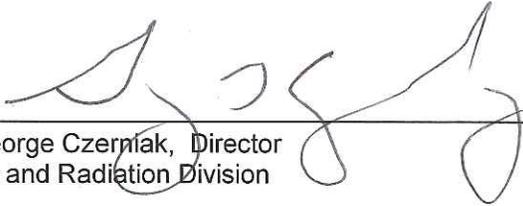
Date



Kevin Bolger, Regional Quality Assurance Manager

02/20/13

Date



George Czerniak, Director
Air and Radiation Division

2/22/13

Date



Cheryl Newton, Assistant Administrator
Resources Management

2/28/13

Date



Richard Karl, Director
Superfund Division

2-22-13

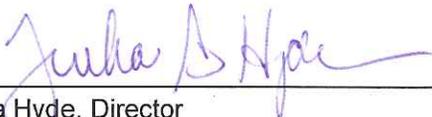
Date



Margaret Guerriero, Director
Land and Chemical Division

2/28/2013

Date



Tinka Hyde, Director
Water Division

2/26/13

Date

This page left blank intentionally

Table of Contents

Signatures – Indiana Department of Environmental Management... **Error! Bookmark not defined.**3
 Table of Contents..... 7
 Key Acronyms and Definitions 10
 Introduction..... 13
 1. Management and Organization..... 15
 1.1. Quality Assurance System Policy 15
 1.1.1. Agency quality system policy statement 15
 1.1.2. The role of the IDEM quality manager 15
 1.1.3. Importance of the agency quality system 16
 1.1.4. QA goals and objectives..... 16
 1.1.5. Commitment to staffing the agency QA initiative..... 18
 1.2. Quality System Organizational Chart..... 19
 1.3. Programs Covered by QA System/Technical Programs Subject to QA/QC21
 1.3.1. Technical activities or programs that require QA management 21
 1.3.2. Oversight of delegated or extramural programs 22
 1.3.3. Coordination between IDEM and other organizations 22
 1.3.4. Allocations for travel funds and personnel 22
 1.3.5. How management assures understanding and implementation of QA..... 22
 1.3.6. Resolving QA-related disputes..... 22
 2. Quality System Components 25
 2.1. Description of the IDEM Quality System 25
 2.1.1. History 25
 2.1.2. A change in approach..... 27
 2.2. Quality System Components 29
 2.2.1. Quality system documentation 29
 2.2.2. IDEM QA staff and its role in the quality system 30
 2.2.3. Program area office staff roles in the quality system 31
 2.3. Tools for Implementing Each Component 32
 2.4. Incorporating QA Responsibilities into Performance Standards..... 32
 3. Qualification and Training 34
 3.1. Description of Training Policy 34
 3.2. Future Training 35
 4. Procurement of Items and Services 36
 4.1. Regarding IDEM Grant Activities 36
 4.2. Regarding the Ability of IDEM to Make Timely Draws Against a Grant Award 36
 4.3. Contractual Grant or CA Sub Agreements 37
 4.4. The Grant Review Process..... 37
 4.5. Delegation of QAPP Review..... 38
 5. Documents and Records..... 39
 5.1. IDEM’s Commitment to Information Quality 39
 5.2. Identifying Records and QA-related Documents Important to the Agency Mission 39

- 5.3. IDEM Quality System Documents 40
 - 5.3.1. Managing QA documents..... 40
 - 5.3.2. Summary of responsibilities for developing and maintaining QA documents 40
- 5.4. Agency Records 42
 - 5.4.1. Managing IDEM records..... 42
 - 5.4.2. Responsibility for managing IDEM records 43
 - 5.4.3. Record retention schedules 43
- 5.5. Document and Record Handling Processes 44
 - 5.5.1. Handling agency QA documents 44
 - 5.5.2. Handling agency records 44
- 5.6. Ensuring Documents and Records Accurately Reflect Completed Work..... 44
- 5.7. Document and Record Maintenance Processes..... 44
 - 5.7.1. Maintenance of agency QA documents..... 45
 - 5.7.2. Maintenance of agency records..... 45
- 5.8. Compliance with Statutory/EPA Recordkeeping Requirements 45
- 5.9. Procedures for Implementing Chain-of-Custody for Evidentiary Records..... 46
- 6. Computer Hardware and Software 47
 - 6.1. Interacting with Agency and State Procurement Staff and Policies 48
 - 6.1.1. Processes associated with software/hardware testing..... 48
 - 6.1.2. Processes associated with software/hardware use 48
 - 6.1.3. Processes associated with software/hardware maintenance..... 48
 - 6.1.4. Processes associated with software/hardware control..... 49
 - 6.1.5. Documentation associated with hardware/software 49
 - 6.2. Hardware/Software Usage Assessment and Documentation 49
 - 6.3. Hardware/Software Evaluation..... 49
 - 6.4. Data QA/QC Standards..... 50
- 7. Planning..... 51
 - 7.1. Systematic Planning Process Description..... 51
 - 7.2. IDEM QAPPs 52
 - 7.2.1. QAPP format..... 53
 - 7.2.2. QAPP development..... 53
 - 7.2.3. QAPP review and approval..... 54
 - 7.2.4. QAPP responsibilities 55
 - 7.2.5. Using an approved QAPP..... 55
 - 7.3. Existing Data 56
 - 7.4. QAPPs – A New Direction 57
 - 7.5. Quality Assurance as a Team Effort..... 57
- 8. Implementation of Work Processes..... 59
 - 8.1. Implementing QAPPs 59
 - 8.2. Developing and Implementing SOPs 60
 - 8.2.1. When an SOP is needed..... 60
 - 8.2.2. IDEM requirements for SOPs..... 60

8.2.3. SOP development and review process..... 61

8.2.4. Responsibility for managing SOPs 62

9. Assessment and response..... 63

9.1. Assessing the Adequacy of the IDEM Quality System..... 63

9.1.1. Assessment tools 63

9.1.2. Future Assessments 66

9.1.3. Frequency of assessments 67

9.1.4. Selection of assessment processes and personnel..... 68

9.2. Response..... 68

9.2.1. Corrective actions..... 68

9.2.2. Dispute resolution..... 68

9.3. Current Assessment Goal: Training 69

10. Quality Improvement..... 70

10.1. Identifying Process Improvement Opportunities..... 70

10.2. Working with Groups to Build Ownership 70

10.3. Rooting Out Conditions Adverse to Quality..... 71

10.4. Promoting Continuous Improvement..... 72

Appendices..... 73

Appendix A: IDEM Senior Management Team’s Fiscal Year 2012 Goals and Objectives..... 73

Appendix B: IDEM Program Area and Support Office Organizational Charts 75

Appendix C: IDEM Program Office Activities and Corresponding Federal Authorization 80

Key Acronyms and Definitions

AC – Assistant Commissioner: The management position within IDEM just beneath Commissioner, charged with leading a program area office comprised of branches, some of which are made up of several sections.

Branch – An organizational level within IDEM, a branch is a subunit of a program area office.

CA – Cooperative Agreement

CI – Continuous Improvement

EnPPA – Environmental Performance Partnership Agreement

GLNPO – Great Lakes National Program Office, located at U.S. EPA Region 5 offices.

GLRI – Great Lakes Restoration Initiative, implemented by GLNPO.

IDEM – Indiana Department of Environmental Management

IDOA – Indiana Department of Administration

NELAC – National Environmental Laboratory Accreditation Conference

NPD – Nonrule policy document: an explanation issued under the authority of Indiana Code 13-14-1-11.5, and intended to clarify for the public IDEM's interpretation of an environmental statute or rule. It does not have the authority of law or rule.

NWRO – Northwest Regional Office located in Merrillville, IN, in IDEM OCS.

OAQ – Office of Air Quality, in IDEM.

OCS – Office of Compliance Support, which includes the Office of Pollution Prevention and Technical Assistance, Health and Safety, the Public Records Office, the Office of Planning and Assessment (which includes the agency QA and continuous improvement staff), and the four IDEM regional offices (Merrillville, South Bend, Petersburg, and Brownstown, IN), in IDEM.

OLQ – Office of Land Quality, in IDEM.

OPA – Office of Planning and Assessment, in IDEM OCS.

OPPTA – Office of Pollution Prevention and Technical Assistance, in IDEM OCS.

OWQ – Office of Water Quality, in IDEM.

PRO – Public Records Office, in IDEM OCS.

Program area office – A level of organization within IDEM that includes the offices of air, land, and water quality, as well as OPPTA within OCS.

QA – Quality Assurance: 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.

QAAR – Quality Assurance Annual Report: The U.S. EPA-required Quality Assurance Annual Report and Work Plan that IDEM annually submits to the U.S. EPA Region 5 quality manager.

QC – Quality control: The overall system of technical activities that measures 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; operational techniques and activities that are used to fulfill requirements for quality. In other words, QC involves measuring the "thing produced" against a standard to ensure it is a quality product that meets the identified need.

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

SharePoint – Software program in which IDEM QA staff maintains QA documents.

VFC – Virtual File Cabinet: 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.

This page left blank intentionally

Introduction

For the past 25 years, the Indiana Department of Environmental Management (IDEM) has been responsible for implementing federal and state regulations to protect human health and the environment while allowing the environmentally sound operations of industrial, agricultural, commercial and government activities vital to a prosperous economy. Like environmental programs in other states, IDEM relies in part on funding from the federal government, represented by the United States Environmental Protection Agency (U.S. EPA), to assist in accomplishing that core mission.

Because IDEM receives some federal funding, it is subject to the requirements for financial assistance to state governments per 40 CFR 35, and the “Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments,” per 40 CFR 31. IDEM also is subject to the *EPA Requirements for Quality Management Plans, EPA QA/R-2*, reissued May 2006, that are based on the American National Standards Institute (ANSI) American Society for Quality (ASQ) E4-2004 quality system requirements for environmental data and technology programs.

However, it is not federal funding requirements alone that drive the agency to maintain a continually improving environmental quality system. IDEM values any systemic improvement that helps it to provide its customers – the Indiana public and the regulated community, as well as IDEM staff – with environmental decisions that are based on accurate data, and that are speedy (timely), predictable (consistent), and fair (transparent). The agency recognizes that a good quality system helps ensure data gathering is done effectively, so that all data used in the decision-making process – as well as the resulting decisions themselves – are reliable, defensible and if need be, repeatable by others. Because IDEM values these benefits of a robust quality system, the agency has made significant strides in recent years to bring its quality system more in line with U.S. EPA requirements, especially those that add the most value to those tasks that are part of the agency’s core mission.

There is another dynamic to be considered by government in 2012. These are among the leanest times ever for government operations. As a result, IDEM senior staff has been forced to adopt a graded approach toward any activities that are not part of its core mission. As stated in the IDEM Senior Management Team’s FY 2012 Goals and Objectives, IDEM’s Office of Compliance Support shall “Re-purpose our quality system toward simplification and an orientation towards improvement rather than simply instituting rigid standards.”

Accordingly, those quality assurance (QA) activities that contribute most to the quality of the work products of the core mission shall merit the greatest focus and resources, while those QA activities which contribute less to the quality of core mission work products may merit less focus, and fewer resources. In this climate of limited financial resources and correspondingly limited governmental resources, IDEM shall endeavor to continue to develop its quality system. IDEM commits to:

- Continue to develop and promote our quality system by simplifying agency quality assurance (QA) requirements and practices, and by facilitating the expansion of the QA culture among IDEM staff, whose primary responsibility remains the fulfillment of the agency’s core mission.
- Focus on data quality at the project level.
- Document what we do, and do what we document.
- Meet U.S. EPA quality system requirements in proportion to their applicability and value to our overall agency mission.

The Structure of the IDEM Quality Management Plan

The IDEM 2012 Quality Management Plan (QMP) consists of an overarching, agency wide QMP accompanied by program area office-level QMPs for the Offices of Air Quality (OAQ), Land Quality (OLQ), Water Quality (OWQ), and Pollution Prevention and Technical Assistance (OPPTA). The 2012 IDEM QMP also is accompanied by appendices that include additional details about the program area office QMPs, and a “mini-QMP” from the Northwest Regional

Office (NWRO), because a number of area-specific grant projects (including the Great Lakes National Program Office (GLNPO) grants to IDEM) are administered solely by the NWRO.

This multi-tiered structure is a continuation and refinement of the approach from IDEM's 2007 QMP, which was intended to include an agency wide QMP and numerous branch-level QMPs (several from each program area office). In 2007, U.S. EPA approved the overarching agency wide IDEM QMP. During the next few years, drafts were developed for each of the various branch-level QMPs, but the drafts were not requested, reviewed, or approved by U.S. EPA.

IDEM began revisions to the QMP in July 2011, in anticipation of the current agency QMP expiring on April 16, 2012. Due to changes to the organizational structure of the agency, and because program area office managers had suggested that office-level QMPs might be more appropriate because of the overlap between branches within each program area office, it was decided that the draft branch QMPs would be merged into office-level QMPs. The end result is four office-level QMPs written by program area office staff, each identifying how their particular office complies with the requirements of *U.S. EPA Requirements for Quality Management Plans QA/R-2*.

IDEM management feels strongly that this approach to the QMP will help the agency to develop and promote a QA culture within the various program area offices. For program area office staff to truly embrace QA practices and a culture of quality, it MUST be something that they do, that they take responsibility for, and that they own. So long as QA is something the program area office staff feels is being imposed upon them by U.S. EPA and IDEM QA staff, there will be little motivation for the programs to develop a culture of quality.

Because the office-level QMPs have been written by the offices, they will have ownership. The responsibility for QA program development now has been taken on by the program area office assistant commissioners, instead of QA staff. This change also should promote ownership of the QA system by the program area offices. Meanwhile, QA staff now assists program area office management and staff with meeting U.S. EPA quality system requirements, instead of driving that agenda.

The IDEM program area offices' (OAQ, OLQ, OWQ, and OPPTA) management and staff realize that the QA requirements, as documented in *U.S. EPA Requirements for Quality Management Plans QA/R-2* and *U.S. EPA Requirements for QA Project Plans QA/R-5*, (and in subsequent U.S. EPA revisions of these documents, anticipated in 2012) not only must be met, but in many instances are also practices that can add value to both the work processes they execute, and the work they produce. As IDEM program area offices already are extremely busy completing those core functions, they need to maximize the use of any time spent cultivating their quality system. That is why IDEM QA staff has been focused on providing assistance to them.

1. Management and Organization

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

1.1. *Quality Assurance System Policy*

1.1.1. **Agency quality system policy statement**

It is the policy of the Indiana Department of Environmental Management (IDEM) that it shall continue to improve its system of quality assurance practices, consistent with the guidance and requirements posted by the U.S. Environmental Protection Agency (U.S. EPA) on the Internet at “[EPA Quality System: Agency-wide Quality System Documents](#).” IDEM shall in particular strive to meet the U.S. EPA requirement that all work funded by U.S. EPA that involves the acquisition and/or use of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized databases and information systems shall be implemented in accordance with an approved quality assurance project plan (QAPP) that meets U.S. EPA standards. In addition, IDEM shall require 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 QAPP.

The Assistant Commissioner (AC) of the Office of Compliance Support (OCS) shall serve as the agency quality manager, and shall be assisted by the IDEM Quality Assurance (QA) staff in the OCS, Office of Planning and Assessment. The remaining agency Assistant Commissioners and Deputy Assistant Commissioners and their designees shall be responsible for driving the ongoing improvement of the agency quality system within their respective program area offices, assisted by the IDEM QA staff.

The QA staff, who shall report to the quality manager through the Director of the Office of Planning and Assessment, is responsible to provide to the IDEM program area offices quality system development tools, input, and other QA-related support as requested. IDEM QA staff functions independently of program area office staff and leadership, and any input they provide to improve program area office quality system activities will be based solely on promoting quality assurance practices and goals.

In addition, QA staff is responsible for revising the agency QMP as necessary, and to submit the required Quality Assurance Annual Report and Work Plan to U.S. EPA Region 5. Agency QA staff is also responsible for managing all agency QA-related documents and making them accessible to agency management and staff via the Extranet (the IDEM internal website) or SharePoint.

1.1.2. **The role of the IDEM quality manager**

Serving as the agency quality manager, the OCS AC shall:

- Ensure the approved quality system is appropriately documented and implemented.
- Coordinate with senior staff peers regarding any quality assurance-related services that may be needed by IDEM’s air, land, water, pollution prevention and technical assistance programs, and the OCS Northwest Regional Office.
- Advocate for agency QA staff with respect to their evaluation of program area office QA system components so that QA staff, who does report to the

agency quality manager, will remain fully independent of the authority of program area office management.

- Facilitate and oversee access and communications between agency QA staff and program area office management per U.S. EPA and ANSI/ASQ E4 requirements. Ensure that QA staff has access to program area office management, and that each may freely exchange input and feedback with the other.
- As appropriate per U.S. EPA and ANSI/ASQ E-4 requirements, preserve QA staff independence from program area office management interests and objectives so that quality system requirements are adequately addressed during the implementation of QA related policies, procedures, or project plans.

Roles of agency QA staff and the QA responsibilities of program area office staff are discussed in Section 2.2.

1.1.3. Importance of the agency quality system

The IDEM QMP serves as the organizing mechanism for the agency quality system. It also serves as an inventory of the various agency wide QA documents and individual QA-related responsibilities.

The development and ongoing use of the agency quality system has had and will continue to have a positive impact on agency efforts to meet its EnPPA and federal grant commitments with the U.S. EPA. IDEM's growing and continuously improving quality system also is helping the agency achieve its goals to be clear, consistent, speedy, and protective of public health and the environment while facilitating responsible economic activity.

Having a robust QA system in place also will help to create a culture of quality within IDEM that is anticipated to have a positive impact on all aspects of the work done by IDEM. It will help agency program office staff to view QA as part of their jobs, and to incorporate it into those jobs, rather than to simply view it as something they do in addition to their jobs.

1.1.4. QA goals and objectives

Although the evolution of the agency quality assurance (QA) system is considered an agency success, it is vital that IDEM continue to further develop and improve that system. Some specific agency quality system goals moving forward are to:

- 1) Simplify and redirect QA system – Repurpose our QA system toward simplification and an orientation towards improvement rather than simply instituting rigid standards, so that agency staff may more effectively meet U.S. EPA quality system requirements.
- 2) Accommodate U.S. EPA revisions to QA documentation – Make any adjustments and/or document revisions necessary to accommodate the pending release of U.S. EPA changes to its primary QA requirement documents, U.S. EPA QA/R-2 and QA/R-5, or to any associated U.S. EPA QA guidance.
- 3) Develop dispute resolution processes – IDEM QA staff will work with each of the separate program area offices to develop and document dispute resolution processes. Rather than a one-size-fits-all dispute resolution protocol to be used throughout IDEM, the process developed by each program area office will recognize the subtleties of that office's organizing laws and rules. Disputes not resolvable within the program area office will be elevated to the

Commissioner and agency quality manager for resolution, and then to U.S. EPA if necessary.

- 4) Enhance QAPP Development and Implementation – Coordinate with program area office staff developing Quality Assurance Project Plans (QAPPs) to ensure that QAPPs are properly developed using the graded approach, reviewed and approved by appropriate program area office and QA staff, tracked as part of the agency quality system, in place before work begins, followed by staff completing the work, and revised as needed to reflect changes to the plan. In addition, appropriate QA and program area office staff will stay current with data entry into all U.S. EPA QA-related databases and tracking tools (e.g., the Great Lakes Accountability System (GLAS)).
- 5) Encourage contractor use of QAPPs – Ensure program area office staff members that contract for data gathering or data analysis services are aware that contractors should:
 - Have an approved quality system in place that demonstrates they are qualified to perform data gathering and/or analysis.
 - Have an approved (by IDEM program area office or QA staff) project-specific plan (a QAPP or similar appropriate project plan) in place for data gathering and analysis.
 - Follow the specifics of the approved QAPP (to ensure the data gathering/analysis is scientifically sound and repeatable).
 - Verify and validate the data that is gathered or analyzed.
- 6) Continue to manage IDEM's QA-related documents – Continue to manage both agency wide and program area office quality system documents by:
 - Maintaining agency wide and program area office QMPs that accurately document the IDEM quality system and revise them when appropriate.
 - Maintaining electronic and hard copy QA libraries that house SOPs, QAPPs, training guidance documents, policies, and agency and office level QMPs and are accessible for use by all IDEM staff.
 - Reviewing existing and new program area office SOPs and other work process documentation with the goal of ensuring that each SOP brings benefits to the users.
- 7) Assess adherence to QA documentation – Further strengthen program area office and overall agency practices by assessing whether QAPPs and SOPs are implemented as written. This assessment will include an audit system and a process for addressing any deficiencies.
- 8) Promote QA training – Ensure that appropriate QA-related training requirements are identified by agency program area office management, who also shall determine the timeframe and priority for such training. QA-related training shall include QA-related webinars developed by U.S. EPA Region 5 or the U.S. EPA GLNPO. QA staff will ensure training is available and promoted to agency program area office staff as determined by their management. Such training topics may include:
 - Developing quality documentation, including QAPPs and SOPs.
 - Understanding and using U.S. EPA's Data Quality Objective (DQO) process as part of QAPP development.
 - Understanding and using each of the various QA components of a data gathering project, including developing the data quality objective, using data verification and validation, and comparing data to the data quality objective.
 - Reviewing and approving QAPPs.

- 9) Assume additional responsibility for QAPP review – Work with the U.S. EPA Region 5 QA manager to take more responsibility for reviewing QAPPs currently reviewed by them.
- 10) Improve review of existing data – Ensure that any program area offices using existing data (for secondary purposes) that do not already have an adequate process in place for assessing and using existing data for such uses receives the appropriate U.S. EPA GLNPO GLRI training, “Systematic Planning and Quality Documentation for Projects using Existing Data Training” available at epa.gov/greatlakes/qmp/qmtraining.html.

1.1.5. Commitment to staffing the agency QA initiative

Going forward, IDEM has reorganized the Office of Planning and Assessment (OPA), changing the leadership structure and assigning additional agency staff to participate in development of and improvements to the agency quality system. Although the QA staff always has been part of OPA, until the reorganization it was comprised of only four full-time equivalent (FTE) staff members – three full-time staff members plus a supervisor and administrative assistant, each of whom devoted half of their work time to QA issues.

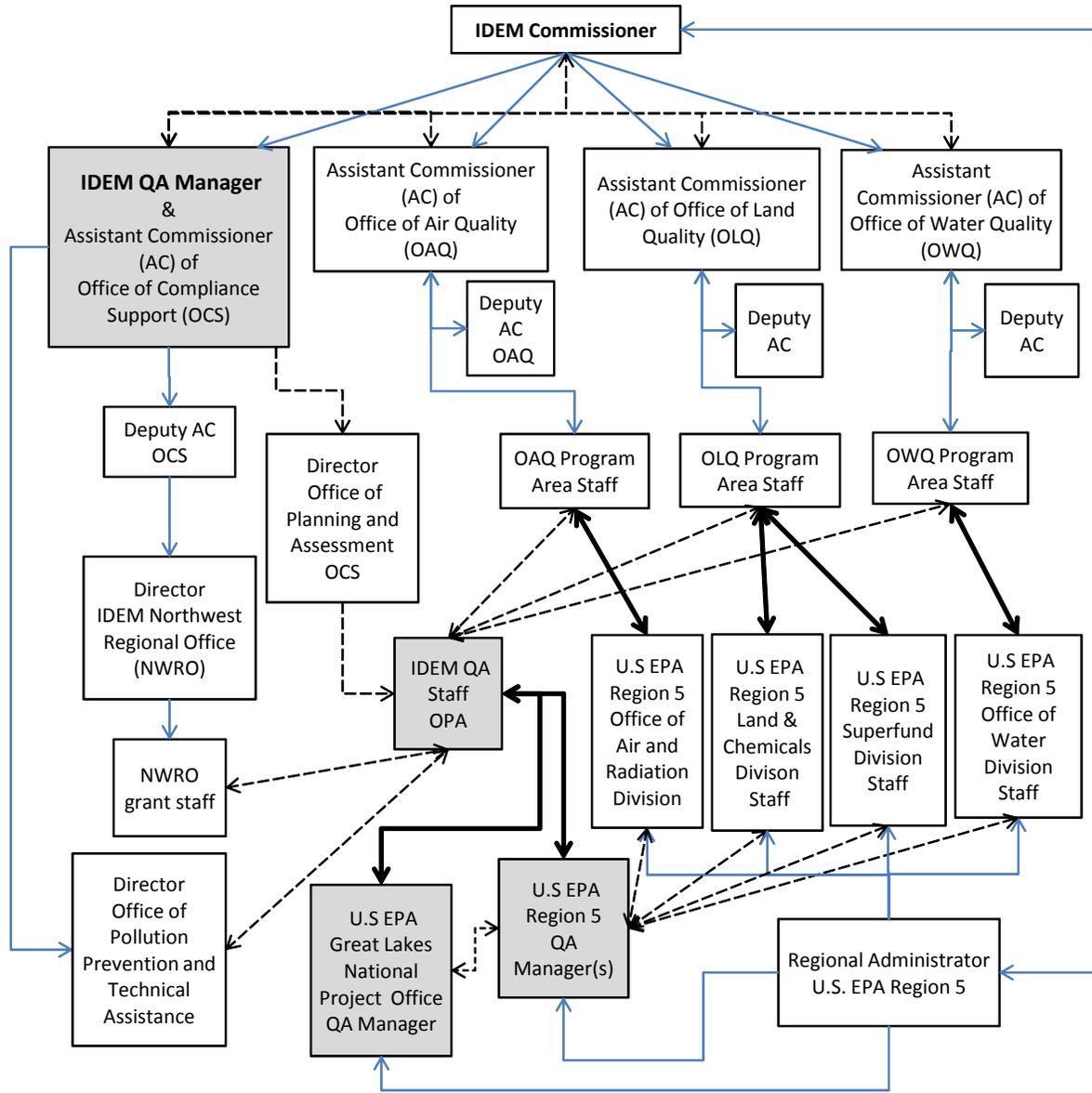
In March 2011, as part of an agency restructuring, OPA was moved from the now dissolved Office of External Affairs to the newly created Office of Compliance Support (OCS). The Quality Improvement Section was created within OPA, consisting of QA staff members and agency staff members who coordinate and implement the agency’s continuous improvement (CI) activities (improvement of work activities and processes to improve efficiency and reduce time, effort, and costs). As a result, IDEM now has approximately five FTE agency QA staff members.

IDEM has 85 FTEs working on QA-related issues. These staff members work on data gathering as well as the development of QAPPs, SOPs, and other QA-related documents. This figure also includes staff that performs QA reviews of data to ensure the accuracy of data uploaded into U.S. EPA databases (consistent with U.S. EPA Data Quality Guidelines and comparable IDEM quality requirements). At the office level, the Office of Air Quality reports approximately 32 FTEs working on QA, the Office of Land Quality reports 29 FTEs and the Office of Water Quality reports approximately 19 FTEs. Adding the five FTEs for QA staff to these reported numbers yields an agency wide total of 85 FTEs working on quality assurance issues. Details on the office level calculations of FTE staff working on quality issues are included in the office-level QMPs attached to this document.

IDEM’s work force was exactly 852 staff members on May 1, 2012, and has been hovering at approximately 855 (plus or minus three) staff members for much of the period mid-November 2011 through May 2012. An FTE employee at IDEM is expected to work 7.5 hours per day and generally is on state holiday 14 days per year. That is the equivalent of 49.2 weeks, or 1845 hours of work annually, minus any accrued leave each FTE employee may opt to use.

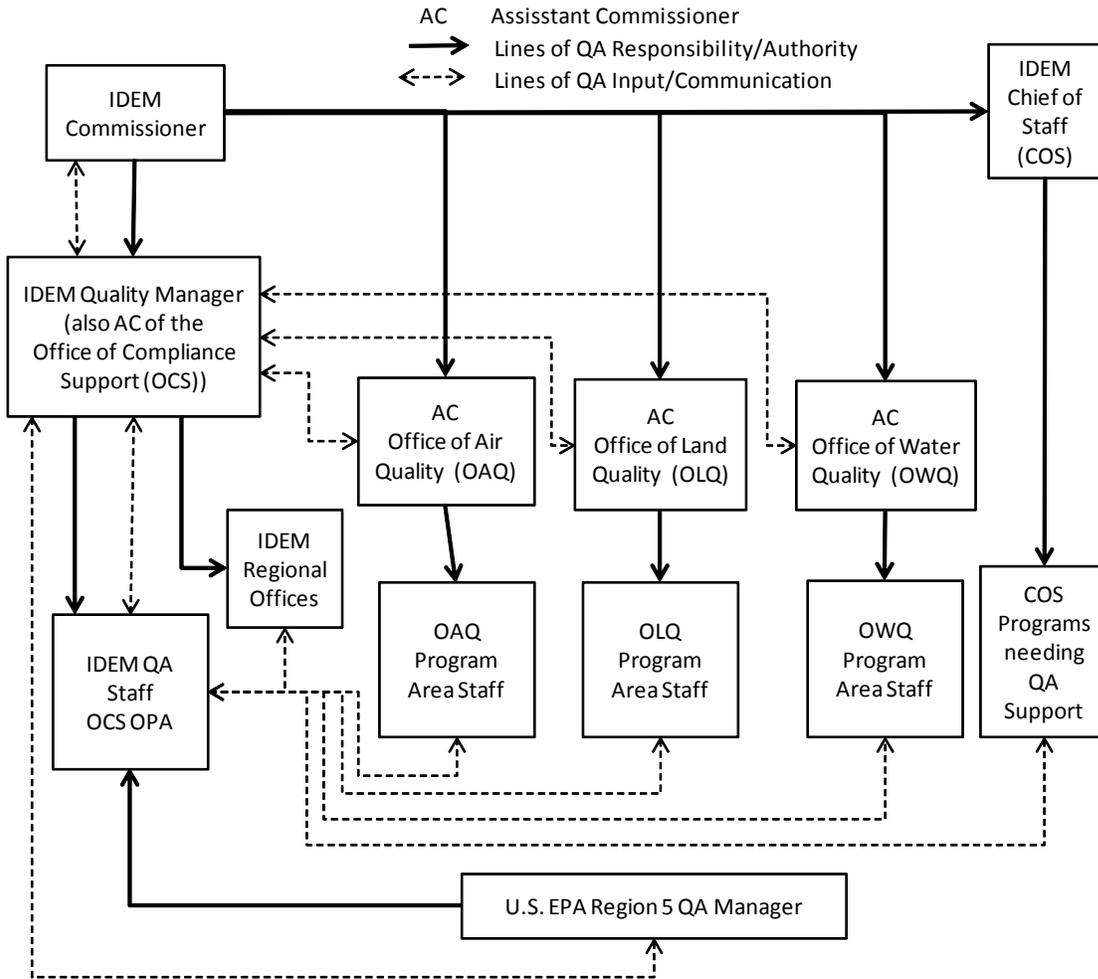
1.2. Quality System Organizational Chart

Organizational Relationships Within the IDEM Quality System



- Denotes the primary staff involved in implementing the quality system
- ↔ Denotes general lines of communication for multiple topics within the organization
- - - - -> Dashed lines denote communications, especially including quality system-related exchanges
- ↔ Heavy solid lines denotes principle lines of staff level quality system-related communications between IDEM and U.S. EPA staff

IDEM Lines of Quality Assurance Authority



IDEM Program Area and Support Office Organizational Charts

Appendix B is comprised of organizational charts for the various IDEM program area offices and for the IDEM Office of Compliance Support and the Office of the Chief of Staff.

Federal Environmental Statutes and Corresponding IDEM Program Area Activities

Appendix C features a crosswalk illustrating the link between the IDEM offices of air, land, and water quality and the various federal environmental statutes implemented by those IDEM offices.

1.3. **Programs Covered by QA System/Technical Programs Subject to QA/QC Processes**

1.3.1. **Technical activities or programs that require QA management**

QA management is required for all environmental operations, including:

Office of Air Quality:

- Field monitoring – site selection, site setup, ongoing operations *
- Laboratory analytical analysis of samples
- Data processing – collection, evaluation, corrections, submittal, etc.
- Standards laboratory – comparisons
- Photochemical modeling
- Prevention of significant deterioration (PSD) air quality modeling
- On-road mobile source inventory
- Emission statement review, correction, and coordination with reporting
- Tox-Watch screening (a review of air toxics data)
- The Asbestos Hazard Emergency Response Act (AHERA) component of the school air toxics monitoring initiative
- Regional Air Pollutant Inventory Development System (RAPIDS) inventory QAPP: Indiana Point Source Hazardous Air Pollutants Inventory quality assurance plan
- Lakeshore screening analysis for air toxics
- Southwest Indianapolis air toxics study QAPP: Southwest Indianapolis Neighborhood Air Toxics Study
- Inspections
- Stack test and CEMS/COMS observations
- Data input and tracking
- Sampling and monitoring
- NO_x (oxides of nitrogen)/Clean Air Interstate Rule (CAIR)/Cross State Air Pollution Rule (CSAPR) allowance calculations

** Note: OAQ Ambient Air Monitoring Branch field monitoring is conducted and assessed per the requirements of the IDEM OAQ Quality Assurance Manual (a multi-parameter QAPP) approved December 4, 2009 by Loretta Lehrman, Regional Quality Assurance Manager and Section Chief, U.S. EPA Region 5 Air Monitoring and Analysis Section, Air & Radiation Division.*

Office of Land Quality:

- Science Services Branch – sampling assistance
- Review and evaluate work plans and various work products
- Risk assessment
- Quality checks of data
- Database maintenance
- Site investigation and remediation
- IDEM-U.S. EPA Region 5 PCB Inspections, using the QAPP approved by U.S. EPA January 13, 2011
- Inspections
- Determinations for corrective action
- Evaluation of monitoring plans

Office of Water Quality:

- Implementation of the Water Quality Monitoring Strategy (WQMS), including targeted and probabilistic monitoring and the collection or analysis of quantitative data.

- Review of discharge monitoring reports (DMR), monthly reports of operation (MRO), and monthly monitoring reports (MMR)
- Data collection, entry, and maintenance
- Evaluation of operator certification applicants and trainers
- Calculation of waste load allocations
- Total Maximum Daily Load (TMDL) reviews

Details of these activities are provided in the office-level QMPs.

1.3.2. Oversight of delegated or extramural programs

The IDEM program area offices have an oversight role with their contract laboratories and subgrantees. Agency program area office staff members must ensure the laboratories they hire have quality systems in place that have been appropriately certified. A description of how the program area office staff handles these issues is addressed within the branch level QMPs.

1.3.3. Coordination between IDEM and other organizations to ensure consistent compliance with U.S. EPA quality system requirements

Coordination between IDEM and U.S. EPA regarding the review and uploading of IDEM data into U.S. EPA portals for posting on U.S. EPA websites has been in place for some time. Each of the program area office QMPs discuss in Section 6 of their office-level QMP how data is verified before it is uploaded to U.S. EPA.

1.3.4. Allocations for travel funds and personnel

Allocations for such funding will be at the discretion of IDEM's Commissioner. Travel and/or personnel costs associated with grant funding shall mirror the information provided with the funding request.

1.3.5. How management assures understanding and implementation of QA in all programs

IDEM's Commissioner has assigned the agency Assistant Commissioners to dedicate the resources to develop and implement program area office quality systems that meet U.S. EPA standards. The agency Quality Manager (OCS AC) and QA staff are committed to helping program area office management with that task. Details on how program area office managers assure understanding and implementation within their respective programs should be addressed in the program area office-level QMPs.

1.3.6. Resolving QA-related disputes

Currently, the IDEM quality system has not yet matured to a level at which enough program area office staff members are focused on QA-related issues to result in differences of opinion that would need dispute resolution. At this point, QA-related differences of opinion likely involve program area office staff and QA staff. In response, agency QA staff expresses its views and suggests to program area office staff how QA issues should be handled. Since program area office managers are responsible for implementing quality system practices within their programs, agency QA staff defers to program area office managers to make final decision on QA-related alternatives.

Although agency QA staff now defers to program area office managers with respect to QA-related decision making, that does not signal that QA staff no longer is in position to initiate movement toward a more robust QA system. To the contrary, QA staff still will be communicating with the program area offices, reminding them it is now their responsibility to meet established U.S. EPA quality system requirements. QA staff also will assist the program area offices to meet those requirements.

IDEM's previous system of dual lines of QA authority was awkward and ineffective. Now that the program area office managers are responsible for implementing QA, staff members are no longer trying to balance the direction they receive from their managers with the direction they receive from QA staff.

Under this restructured arrangement, the Assistant Commissioner (AC) of the IDEM Office of Compliance Support also serves as the IDEM Quality Manager. As an AC, he is a peer of the ACs of the Offices of Air, Land, and Water Quality. In this dual role as AC and agency Quality Manager, he also will be able to champion QA-related issues and the overall expansion of the quality system to his fellow ACs, and to pass along to them QA advice and insights provided to him from the QA staff that reports to him.

This new arrangement preserves the independence of QA staff, who answers only to a QA manager who can interact with the other ACs as an equal on behalf of quality system objectives. It also shelters QA staff from possible differences of opinion with ACs who not only have significantly more authority, but who also have more experience and expertise regarding the very programs for which the agency is trying to expand quality assurance practices.

The lack of identified specific dispute resolving practices in this document or in office-level QMPs should not be taken as an acknowledgment that no mechanisms for dispute resolutions exist within the agency or its specific program area offices. It is entirely possible that program area staff may be practicing such resolution protocol(s), but not realize that perhaps such practices merit documentation as policy within their office level or the agency wide quality system. At a minimum, current QA disputes are resolved by management, who generally has the most issue-related experience among staff in a given program.

Meanwhile, IDEM QA staff realizes the importance of having a resolution process in place before disputes arise so that resolution is systematically consistent, rather than situational and ad hoc. As outlined in Section 1.1.4. QA Goals and Objectives, IDEM QA staff commits to assisting each of the various program area offices with developing a dispute resolution process. However, they also realize that while the establishment of a dispute resolution process is essential to the development of a quality system, dispute resolution should be tailored to the specific program and the sort of data disputes that program may anticipate. Dispute resolution processes should be reflective of each program's:

- Unique statutory background.
- Existing experiential and institutional knowledge based decision-making hierarchy.

- Levels of risks to human health and the environment that may be associated with the final resolution of each dispute.
- Nature and quality of the data historically available for decision making within each particular program's jurisdiction

Because of these factors, of which existing program area office management and staff have a much greater understanding than agency QA staff does, existing management must be participants in the development of any QA dispute resolution policy. Agency QA staff can contribute the QA perspective essential to the development of such a resolution protocol, but no meaningful policy can be devised without also including the expert insight of the program area office staff who have a much fuller understanding of all the issues associated with the data.

Once programs have an internal dispute resolution process in place, any QA-related dispute that cannot be resolved by program area office management shall be presented to the Commissioner by the appropriate program area office AC and the agency quality manager. Issues still unresolved at that level may then be elevated to the IDEM/U.S. EPA dispute resolution process.

2. Quality System Components

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

2.1. *Description of the IDEM Quality System*

2.1.1. **History**

The first IDEM QMP to be approved by U.S. EPA was effective from July 2001, through December 31, 2004. A 'next generation' draft QMP submitted by IDEM in December 2004 was never approved. Prior to submittal of that 2004 draft, U.S. EPA Region 5 visited IDEM in August 2004 to conduct a Management System Review (MSR). The MSR team interviewed IDEM management and staff regarding their knowledge of the agency quality system as depicted in the IDEM QMP, and as it pertained to their work. They also reviewed documents and files related to the quality system. The report on the MSR that was sent to IDEM by U.S. EPA Region 5 in June 2005 is attached.

IDEM submitted a new draft QMP to Region 5 QA staff in October 2006. After the agency's written response to U.S. EPA Region 5 comments, the currently effective IDEM 2007 QMP was approved in mid-April 2007. IDEM subsequently has made significant additional progress toward both improving its overall quality system and addressing the issues raised by U.S. EPA Region 5 in the MSR. During that time, IDEM has worked to build on and mature its quality system following the model described in the *U.S. EPA QA/G-1 Guidance for Developing Quality Systems for Environmental Programs*.

Following that model, the IDEM QA staff was empowered to develop the agency QA system, to set the agenda for putting a quality system in place, and to drive QA down into the program area offices. Significant staff time and resources were invested in training staff members, expanding and improving the QA infrastructure throughout the agency, developing document templates and electronic libraries, and developing a large amount of QA-related documentation (including SOPs, TSOPs, and policies).

IDEM realized some benefits from this investment of staff time and resources. The agency now has a much better system in place for managing both its records and its QA documents. IDEM records are accessible through the Virtual File Cabinet. Hundreds of agency policies and procedures now are documented and signed, and those documents are managed in an electronic QA library protected by version control.

Unfortunately, there have been some adverse unintended consequences from the intensive focus on quality as well. IDEM's Quality Manager contends that there was significant resistance from program area office staff and management regarding the manner in which IDEM QA staff tried to implement the U.S. EPA-required quality management system. QA-related documents were produced to meet a requirement to produce them, not to improve the quality of the processes and work products they address. There has been significant push-back by agency staff that see QA as something extra it has to do, something in addition to its job rather than part of its job. Some agency program area office managers feel there has been very little return with respect to improved work products for staff time invested in QA activities, especially in this climate of tackling increased workloads with fewer staff members and reduced budgets.

During the effective period of the 2007 QMP, agency QA staffing increased threefold. However, IDEM QA staff members were tasked with additional responsibilities over time, including managing the development and approval of agency policies, nonrule

policy documents (NPDs), and fact sheets. This increased workload meant that IDEM QA staff members were unable to focus their full attention on the QA aspects of data projects.

The IDEM QA staff members struggled to develop program area office interest in QA under a system where they were the only ones accountable for QA-related progress. Because they were external to all of the program area offices involved with data gathering and use, QA staff members often were not in the loop between the IDEM program area office staff members using federal grant dollars and their U.S. EPA Region 5 project manager counterparts. When IDEM QA staff members inquired about whether projects were meeting U.S. EPA mandated QA standards, the answer was often that the quality aspects had been approved by U.S. EPA counterparts.

When the current Quality Manager assumed leadership of the IDEM QA program and staff, responsibility for nonrule policy document (NPD) development was returned to the program area offices, along with accountability for the quality of those documents. Program area offices are now given the option to develop one page work flow diagrams or simple work instructions in lieu of administrative SOPs. Program area offices may have every SOP reviewed by IDEM QA staff members, but this is no longer a requirement. Only technical SOPs must undergo QA staff review.

These changes have increased the ability of QA staff to assist program area office staff with developing QAPPs that are more consistent with U.S. EPA requirements and to review and comment on QAPPs and QAPP-related work plans. QA staff still tracks the status of and maintains version control over all QA-related documents except work flow diagrams and work instructions. The QA staff also retains responsibility for agency policies, but as most policies are now in place, the associated workload has been significantly reduced.

Through increased involvement with QAPP review, IDEM QA staff has discovered that the key driver of quality system development is at the project level. The focus of the quality system should be on development of QAPPs that are consistent with U.S. EPA requirements. The QA staff also should work to ensure program area staff properly implements QAPPs as they are written, and monitor how program area offices perform data verification, validation, and data quality assessment processes. When the QA emphasis is on QAPP-related processes, the need for a documented quality system becomes more important. When the emphasis is on the project quality documentation (the QAPP) and the proper use of it, then both the QAPP and the QMP become forceful, living documents that are referenced on a regular basis. When the QAPP is used and valued, the QMP serves an important function to ensure the consistent and systematic development of good quality, useful QAPPs to be followed and used to evaluate the data gathered.

Under IDEM's current Quality Manager, accountability for the development and use of QA-related documents will rest with the program area offices. The QA staff will assist the program area offices to properly develop and implement the PDCA – plan, do, check, act (assess) – cycle in developing quality program activities and documentation. When the program area office managers are accountable, they will budget the time and resources to get the work done and will expect a value added work product in return. They are more likely to ask the IDEM QA staff for review and input early in the process, rather than communicating exclusively with U.S. EPA project managers. Additionally, when the IDEM QA staff has the opportunity to provide input early in the development process, program area office staff is more likely to develop a QAPP that can be approved quickly and easily and that supports the collection and use of validated and verified data.

2.1.2. A change in approach

“... changing our focus to quality as how we do things around here, not as this extra thing we have to do.”

– IDEM Quality Manager Rick Bossingham, during opening remarks presented to the Second Annual Great Lakes Restoration Initiative (GLRI) quality conference at U.S. EPA Region 5 Headquarters in Chicago, December 6, 2011.

IDEM has made some strides under the current QMP, whether by degree or to completion. However, it is the consensus of IDEM management and QA staff that to further advance and mature our quality system, some change in approach is necessary.

Although following the approach outlined in the *U.S. EPA G-1 Guidance for Developing Quality Systems for Environmental Programs* did result in progress, it was received by IDEM program area office staff as a “top-down” approach. As stated above, QA is viewed as some additional thing that needs to be done rather than an integral part of the agency’s work. Attempts by QA staff to impose a QA system on the program area office staff clearly did not foster “buy-in” among them, perhaps in part because it denied them ownership of their own QA program. It seems apparent that no system of QA will be absorbed into and become the culture of a program area office unless they own it, feel they have a stake in it, and benefit from it.

Previous QA staff efforts to promote a culture of quality were not as successful as desired because the approach used to implement change did not adequately reflect the existing organizational structure and decision-making hierarchy that always has been in place at IDEM. That structure and hierarchy, as is specifically stated in the IDEM 2007 QMP previously approved by U.S. EPA Region 5, is quoted here:

“IDEM’s primary work product is documents that announce and record agency decisions. Notices of deficient information on an application (Notice of Deficiency, or NOD), draft permits, final permits, certifications, licenses, inspection reports, violation letters, and administrative orders all are examples of ‘decision-announcing-records.’ Most agency decisions are subjective, professional judgments. Decisions involving remediation plans, permit issuance, compliance determinations, or the pursuit of enforcement actions are based on the best professional judgment of agency program area office staff, using the most accurate and readily confirmable data available, to yield decisions that reflect environmentally-sound and widely accepted interpretations of statutes and rules.

“Because not all the data available to IDEM during decision making is verifiable by agency staff, and because not all the statutes and rules upon which decisions are based cover every possible scenario, interpretation of data, statutes, and/or rules is sometimes a necessary part of the agency decision-making process. That agency decisions may be appealed by those seeking a different interpretation of the data, statutes and/or rules further confirms that agency decisions are at least somewhat subjective in nature.

“A key component of ensuring that each agency decision is a product of ‘best professional judgment’ is the existing hierarchical chain of review and approval that comprises the agency decision-making process. Remediation, permit, compliance, and enforcement-related decisions are first proposed in draft form and then further reviewed, refined, and finalized by staff that is increasingly more knowledgeable and experienced. Some agency decisions are then further reviewed by U.S. EPA.

“This chain of review and approval is in place throughout the agency for each separate environmental activity. It is one of the principle means by which determinations are made, decisions finalized, requisitions approved, and training needs assessed. The agency uses a number of other quality system tools that are discussed in this quality management plan (QMP) to assure that all agency decisions and work products are protective of public health and the environment, based on effective use of the best available data and reflective of the best professional judgment of the agency.

“This internal chain of review also is used to review and approve some quality system documentation; particularly policies, standard operating procedures (SOPs), and quality assurance project plans (QAPPs).”

Because the IDEM program area offices already feature a decision-making hierarchy that ascends from section chief, up to branch chief, up to deputy assistant and assistant commissioners, IDEM’s commissioner has tasked the program area office assistant commissioners, rather than the IDEM QA staff, to drive development of the agency quality system and ensure that appropriate QA practices are in place. This new approach of incorporating quality through the existing work structure and decision making hierarchy, rather than having an external group trying to impose it on existing organization structures, should help to restart the effort to build a culture of quality at IDEM. It also should help program area office staff view QA practices as improvements to work they already have to do instead of additional work that now has to be done.

The IDEM QA staff will now assume a customer service role with respect to QA. Upon request, QA staff will assist the program area offices with implementing QA practices, but program area office staff must take ownership of their respective QA goals and practices. Their assistant commissioner will be responsible for ensuring their program area office quality system is developed in a value added manner. This reorientation is intended to ensure that quality assurance is an integral part of what each program area office staff member does while working to achieve the core mission (see Introduction) of the agency.

This extends to the development and implementation of QAPPs as well. Staff and managers working on projects requiring a QAPP will be responsible for the development and implementation of those QAPPs, with assistance from QA staff as requested. However, QA staff and IDEM’s Quality Manager will be actively working with the program area office staff, managers, and U.S. EPA program staff to improve communications regarding QAPP development and approval.

The agency Quality Manager (who also is the OCS AC) and the IDEM QA staff that report to him understand and acknowledge that this approach to promoting the implementation and expanded use of U.S. EPA-endorsed QA practices is unconventional and not altogether consistent with the approach put forward in the *U.S. EPA G-1 Guidance for Developing Quality Systems for Environmental Programs*. However, the IDEM Quality Manager and QA staff strongly maintain that taking this approach to further developing the IDEM QA culture from within the existing agency framework of authority and decision-making will ultimately result in a more robust and program-centric quality system than can be achieved by imposing QA practices on the programs from outside their area program offices.

Placing the accountability for implementing sound QA practices on program area office management should result in those managers and their designees more proactively seeking input from the agency QA staff to help accomplish that end. Implementing an effective quality system calls for teamwork and cooperation, and the IDEM Quality Manager and QA staff believe this approach will create an environment that fosters cooperation among program area office managers and staff and QA staff.

Holding program area office management more accountable for the development of QA practices does not diminish the level of accountability to which agency QA staff will also continue to be held. Indeed, this more program-centric approach to enhancing the IDEM quality system remains very dependent on the continued proactive diligence of QA staff to provide assistance, offer suggestions, and take advantage of each opportunity to help program area office managers and staff understand the benefits of the quality conscious approach to performing the agency's mission.

To acknowledge the accountability of agency QA staff while also addressing concerns about IDEM's new approach, IDEM QA staff also commits to track and regularly report the progress of agency program area office management and staff make toward developing the quality systems within their various program area offices to U.S. EPA Region 5 QA (R5 QA) staff. Progress will be reported to R5 QA staff each year in IDEM's QA Annual Report (QAAR), which will identify, office by office, specific program area improvements in:

- Staff participation in QA training.
- The quantity and quality of QA documents.
- The development and proper implementation of QAPPs and associated SOPs.
- The use of assessments to identify processes needing improvement.
- Overall program area innovation and quality system improvement.

IDEM QA staff will add a section to the standard U.S. EPA QAAR template to specifically address the progress of each program area office with respect to these issues in each annual report submitted during the effective period of this IDEM 2012-2017 QMP.

As previously stated, IDEM QA staff similarly will track the progress made toward achieving each of the QA goals established in this agency wide QMP and in each of the program area office-level QMPs.

2.2. Quality System Components

2.2.1. Quality system documentation

Quality system documentation that IDEM QA and program area office staff is required to follow in the course of their daily work to complete their portion of the agency mission includes:

- IDEM QMP (the IDEM 2007 QMP, which will be replaced by the IDEM 2012 QMP).
- Various IDEM program area office-level sub-QMPs that provide documentation of QA practices at the program area office level (developed in conjunction with this QMP), including the:
 - Office of Air Quality 2012 QMP and related OAQ Appendices
 - Office of Land Quality 2012 QMP and related OLQ Appendices
 - Office of Water Quality 2012 QMP and related OWQ Appendices
 - Office of Pollution Prevention and Technical Assistance 2012 QMP
 - IDEM Northwest Regional Office 2012 QMP
- *The U.S. EPA Requirements for Quality Management Plans EPA QA/R-2* (to be replaced by U.S. EPA's revised version of QA/R-2 when it is available).

- *The U.S. EPA Requirements for Quality Assurance Project Plans EPA QA/R-5*, March 2001 (to be replaced by U.S. EPA's revised version of QA/R-5 when it is available).
- All signed/approved agency QA documents in effect and available for use on the IDEM Extranet and/or SharePoint during the effective period of this QMP. A listing of document titles and/or copies of any of these documents are available to U.S. EPA upon request.
- IDEM Policy, SOP, Technical SOP (TSOP) and QAPP Documentation Policy of April 20, 2009 (slated for revision in 2012 to reflect changes to QA documentation requirements precipitated by the reorganization of the QA team into OCS).
- IDEM QA document templates (Policy, SOP, TSOP, and QAPP), the use of which is required.

Quality system documentation that IDEM QA and program area office staff may reference as additional QA-related guidance includes:

- IDEM Checklists to determine completion, and other tools for QA document development (such as a Glossary of Definitions and "How To" guidances on formatting and software use).
- The U.S. EPA Quality System: Agency-wide Quality System Documents posted online at www.epa.gov/quality/qa_docs.html (except for the *U.S. EPA Requirements for Quality Management Plans EPA QA/R-2* and the *U.S. EPA Requirements for Quality Assurance Project Plans EPA QA/R-5*, which establish U.S. EPA and IDEM QA system requirements).
- *American National Standards Institute/American Society for Quality (ANSI/ASQ) E4 2004* requirements.
- *"We Don't Make Widgets: Overcoming the Myths That Keep Government from Radically Improving,"* by Ken Miller, Governing Management Series, Governing Books, Washington, D.C.
- SOP and flowchart development training materials.

2.2.2. IDEM QA staff and its role in the quality system

The IDEM QMP and associated quality system are managed and implemented by the agency QA staff, and various program area office staff involved with the data gathering activities of the agency's program area offices (details provided in office-specific QMPs). Acting as QA support services throughout IDEM and across all program area offices, QA staff is responsible for the following:

- Assigning document control numbers to all agency quality system related documents.
- Tracking the status (under development, under revision, or in effect) of all agency quality system-related documents.
- Maintaining staff access to the current versions of all agency wide and program area office-specific quality system related documents on the agency Extranet (agency internal access web site).
- Maintaining and updating the agency QMP as needed.
- Serving as a liaison between IDEM program area office staff and U.S. EPA QA managers.

- Preparing U.S. EPA Quality Assurance Annual Reports and Work Plans using information provided by agency program area office staff.
- Developing and updating all quality system-related document development templates and maintaining them on the agency Extranet and/or SharePoint.
- Maintaining the agency Glossary of Definitions for Policies and SOPs.
- Providing training on the development of quality system-related documents and the software skills necessary to develop such documents.
- Assisting agency program area office staff with QA document formatting and otherwise helping to bring to approval all types of quality system-related documents the program area offices may have under development.
- Reviewing, commenting on, and approving agency quality assurance project plans (QAPPs) and/or QAPP-related work plans.
- Being available to serve program area office staff as QA consultants when requested and providing guidance and advice on the development, approval, and implementation of QA-related documents.
- Partnering with U.S. EPA Region 5 and Great Lakes National Program Office (GLNPO) staff to further improve agency QA-related documents and the agency quality system.
- Attending U.S. EPA trainings, conferences, or workshops as appropriate.
- Assessing IDEM program area office quality systems or quality system documents as requested or as directed by the IDEM Quality Manager.
- Planning and implementing continuous improvement events at which existing work processes are mapped out and restructured by a work group of experienced/affected staff to improve the process.

2.2.3. Program area office staff roles in the quality system

Program area office management shall be responsible for ensuring/determining:

- That program area office data gathering activities will conform to U.S. EPA QA requirements (consistent with *ANSI/ASQ E4* requirements).
- Which program area office staff shall be tasked with developing QA documentation or implementing QA-related activities, including QAPPs, SOPs, and TSOPs.
- The extent that agency QA staff will provide input to program area office management and staff.
- The extent of program area office staff participation in continuous improvement exercises, QA-related training, or other QA-related activities.
- When QA assessments will be performed within the program area office to ensure that work done follows the appropriate QAPP and/or SOP(s) and whether QA staff shall participate in those assessments.
- When agency QA staff will perform quality assessments of the overall program area office quality system in conjunction with the IDEM Quality Manager.

2.3. Tools for Implementing Each Component

IDEM will continue to grow its quality system using a new approach – assisting program area office staff to add or expand existing quality elements into their existing work practices. Program area office management will be responsible for ensuring work done in their respective offices incorporates U.S. EPA required QA elements. They will likely approach this responsibility with emphasis on investing more staff resources into those practices that add the most value to program area office work practices and work products.

QA staff is available to assist program area office management by providing QA-related expertise and insight. QA staff also provides the tools and training necessary for program area office staff to add or improve existing QA elements in a manner that instills staff ownership of QA-related activities and improvements.

IDEM QA staff can help with this implementation process by providing program area office staff by providing:

- Up-to-date QA-related templates to facilitate QA document development.
- Review of draft QA documents to ensure all required QA elements that could add value to the project or program the QA document is supporting (and the document itself) are adequately developed.
- Training on QA document development and other QA-related training.
- Management of program area office staff QA-related documents (web-accessible PDF files, archived Word files, paper copies, etc.) in the agency QA libraries.
- Associated document tracking tools to ensure program area office staff always has access to the correct version (version control) of any QA document they use.
- Ongoing counsel regarding the practical benefits to be derived using appropriate QA practices.
- The IDEM QA Annual Reports (and work plans) due to U.S. EPA Region 5 each year. The information will be gathered from program area offices to help them fulfill the reporting requirements and stay 'on task' developing the QA goals they adopted in their respective program area office-level QMPs.
- Assessments of overall program area office quality systems (or specific elements of those systems) when requested.
- Opportunities for continuous improvement events (when requested).

2.4. Incorporating QA Responsibilities into Performance Standards

IDEM participates in the State of Indiana's performance management program, which requires management and staff to establish annual work goals that are consistent with the agency's central mission. The goals are documented as Performance Expectations that staff must meet by the end of the evaluation year.

The current mission of the QA staff in the Office of Compliance Support, Office of Planning and Assessment (OPA) includes the following objectives:

- Create and implement approaches to marketing and communicating OPA services (including QA services).
- Re-vamp the agency quality management plan to better reflect the makeup and implementation of the agency quality system to create a stronger link to federal quality system requirements needed for states to receive federal funding.
- Provide improved templates and tools to assist staff in implementing a quality system.

- Identify the need for agency wide continuous improvement events and facilitate their implementation.
- Oversee the implementation of grant funding administrative requirements and commitments.

QA staff performance expectations are based on these and other objectives. It is expected that the QA-related work that remains to be done within each of the agency program area offices will similarly be included within the work performance expectations of those program area office staff.

3. Qualification and Training

Purpose – To document the procedures for assuring that all agency personnel have the necessary skills to effectively accomplish their work.

3.1. *Description of Training Policy*

Consistent with *Guidance for Developing Quality Systems for Environmental Programs U.S. EPA QA/G-1*, all IDEM staff received at least initial training about the importance of having a quality system, prior to and during the effective period of the 2007 IDEM quality management plan (QMP). During the effective period of this 2012 QMP, IDEM program area office management will define requirements for appropriate job training, including quality assurance training, for each position and establish a timeframe or otherwise prioritize when such training should be completed.

Nonetheless, IDEM management maintains that agency staff should only be required to participate in training for tasks it will be assigned to complete. As a result, just as with other types of training, the amount of QA training that each staff member is required to complete should be directly proportionate to the amount of QA-related tasks that staff member is expected to complete as part of their job. Staff members completing data gathering and other tasks that are the central focus of the agency QMP should receive appropriate QA training. Staff members not involved with data gathering activities need less QA-related training.

Program area office management is responsible for determining the training requirements for their staff. They similarly are responsible for ensuring that their program area office staff members have the necessary QA-related training, maintain their QA qualifications, and are retrained as necessary or when QA requirements change. In addition, it is the responsibility of program area office management to track the training needs and histories of their staff members as they deem appropriate and to document such histories as they deem necessary.

Since it is the role of IDEM QA staff to provide support and assistance to program area office management, IDEM QA staff provides QA-related training when requested. This can include conducting QA-related training developed by agency QA staff, such as the trainings on developing flowcharts and writing SOPs, or promoting U.S. EPA-generated training webinars available on the Internet.

Although IDEM agency QA staff now assists rather than directs program area office management and staff with respect to developing and improving the agency quality system, they are proactive in evaluating program area office staff members' understanding of QA-related practices. During the course of QA-related document reviews, QA staff members are able to identify any program area office staff members that may not adequately understand quality assurance issues or techniques and offer training or other assistance. IDEM QA staff already has demonstrated success at taking advantage of this type of QA-related surveillance to target particular staff members for additional QA-related training. Staff members identified in this manner are frequently eager to participate in training. When staff members do not respond to opportunities to attend training, program area supervisors have been contacted with the suggestion that particular staff members may benefit from such training. This selective targeting for QA-related training has been the practice of agency QA staff during the past few years, rather than to require broad based attendance in mandatory trainings. This approach also has helped agency QA staff to identify and train 'new' staff that has begun working at IDEM subsequent to the initial roll-out of QA training that pre-dates the 2007 QMP. QA staff also has sponsored several "open house" training sessions in which program staff could voluntarily participate.

As IDEM QA staff has become more engaged in the development and review of QAPPs associated with the U.S. EPA GLNPO grants, they have also been working to become more involved in improving the manner in which all IDEM program area staff members develop, review, and/or use QAPPs. IDEM QA staff is currently working with each of the IDEM program area

offices to determine which staff members may need additional training for development and or review of QAPPs. Most of IDEM QAPPs review has been completed by either a trained IDEM QA staff member or by U.S. EPA program office staff (e.g., for older ongoing program QAPPs).

3.2. Future Training

As also is stated in Section 1.1.4. "QA Goals and objectives," during the effective period of the 2012 QMP, IDEM QA staff will actively promote participation in the QA-related webinars developed by U.S. EPA Region 5 or the U.S. EPA GLNPO. Promoting the use of these training webinars is a job performance goal for appropriate IDEM QA staff members as well as an agency QA goal (per Section 1.1.4. *Quality System Goals and Objectives*, of the 2012 IDEM QMP).

IDEM's long-term training goal is to assist the various program area offices with the development of a QA-related training menu, with assistance from U.S. EPA Region 5 QA managers and program offices as available. IDEM QA staff will keep IDEM program area office management apprised of training session content and availability and of any suggestions regarding program area office staff members that should attend. IDEM program area office management will make all decisions regarding requirements for QA-related training for program area office staff and what staff members should attend which trainings.

IDEM QA staff will ensure that interested IDEM program area staff members responsible for QA activities within their areas have the opportunity to receive QAPP development and QAPP assessment training from IDEM or U.S. EPA QA staff. IDEM QA staff will provide follow-up mentoring. The QAPP training will also be beneficial to the IDEM program areas and to the overall IDEM QA system, by increasing the number of staff members within the agency that have the training and skill to develop, review, and approve QAPPs. Given that the U.S. EPA Region 5 QA manager has suggested that IDEM take a greater role in reviewing QAPPs previously/currently reviewed by U.S. EPA staff, expanding the number of agency staff trained to do QAPP review may enable the agency to assist U.S. EPA R5 QA staff with QAPP reviews.

4. Procurement of Items and Services

Purpose – To document the agency’s purchasing procedures.

4.1. *Regarding IDEM Grant Activities*

Each grant effort begins as a response to solicitations from federal funding sources offering financial assistance to state agencies to complete environmental endeavors. The IDEM grant director sends notification of grant opportunities to the appropriate program area office grant coordinators.

Once the program area office has determined that it will pursue a particular grant solicitation, the program area office grant coordinator works with program area office technical experts and the IDEM grant director to develop a work plan and application package that describes and details the work necessary to fulfill the goals of the grant funding. The application package is measured against the Request for Proposal (RFP) of the grant opportunity to ensure it follows the parameters necessary for funding.

The level of QA documentation needed for each grant generally is determined by the terms and conditions set by the grant. If there is data gathering or analysis involved, a QAPP is required by IDEM because it is required by federal grant policy. The graded approach also is considered with respect to the level of detail or the degree of confidence that might be required in the final results.

When the activity to be funded is very much like other data gathering projects that have been performed in the past under similar conditions (drought, high water, similar industrial activities nearby), and the activity differs only in timing or location (a year or two years later, at a site very similar to those where past QAPPs have been implemented), a program QAPP, or even a work plan that is a subset of a program QAPP may suffice.

Grant-related documents such as applications, amendment requests, awards, and closeout forms are formal, binding documents recorded on the appropriate standard federal grant-related form or template. Completed grant forms go through an internal IDEM review process that begins with the author and finishes with agency senior staff sign off. This process is explained in detail in the IDEM Grant Management Policy A-018-OEA-07-P-R1, and three associated SOPs:

- Grant Application Process SOP A-024-OEA-05-S-R0
- Grant Post Award Process SOP A-025-OEA-05-S-R0
- Grant Closeout Process SOP A-055-OEA-P-GM-07-S-R0

If the work funded by a grant or cooperative agreement (CA) requires the submission of a QAPP (for direct measurement or data generation, environmental modeling, or compilation of data from literature or electronic media) it is usually referenced as a term and condition of acceptance of the grant. QAPPs are due to the awarding agency within 90 days of the grant award. In grants and CAs requiring a QAPP, the agency technical program area office is responsible for its development. Those receiving funding generally must also have quality system documentation in place, generally in the form of a quality management plan (QMP).

4.2. *Regarding the Ability of IDEM to Make Timely Draws Against a Grant Award Account*

Indiana Code IC 4-13-2-20 “... payment for any services, supplies, materials, or equipment shall not be paid from any fund or state money in advance of receipt of such services, supplies, materials, or equipment by the state,” prohibits IDEM (or any agency or office of the state of Indiana) from making a draw against a fund balance (such as a federal funding award, in the form of a grant) until the work product or service to be purchased with such funding is completed entirely and is immediately available for use by IDEM. This requirement may from time to time jeopardize IDEM’s chances of being awarded additional, needed funding because of the perception that the agency is not spending down existing grant awards at a pace deemed

adequate by the entity that provided that funding. Nonetheless, IDEM may not deviate from that statutory requirement.

4.3. Contractual Grant or CA Sub Agreements

All agency contractual and sub-grant agreements require justification that the service is grant-eligible and the purchase is required in order to accomplish the goals of the primary grant agreement. Each contract contains the same terms and conditions as the primary grant agreement and all subsequent contracts or sub-grants must follow the same terms.

IDEM QA staff advises agency program area office staff of U.S. EPA requirements that when federal funds are expended for services associated with data gathering projects (including sampling and/or laboratory analysis of those same, or other samples), the same federal requirements that must be met by IDEM also must be met by any contractors (including laboratories) gathering or analyzing data on the agency's behalf. This includes requirements to have an approved quality management plan in place, and to conduct data gathering and/or analysis using an approved QAPP(s). IDEM QA staff will continue to emphasize this to program area office staff responsible for meeting this requirement.

IDEM QA staff will further advise that while IDEM program area office staff may not be required to actually perform an audit of, or review the quality systems or quality system documentation of laboratories contracted to gather data (through sampling and/or data analysis), they must make certain that contracted laboratories have in place a quality system that has been certified by a third-party organization. Such organizations include the National Environmental Laboratory Accreditation Conference (NELAC), the Indiana State Department of Health, or other organization widely acknowledged as qualified to make such a certification. IDEM program area office staff are similarly responsible for ensuring that any data gathering by a contracted laboratory or other entity on behalf of IDEM is performed using a QAPP or other credible plan (and associated SOPs) that is consistent with *U.S. EPA Requirements for QA Project Plans QA/R-5*. They are also responsible for ensuring that the QAPP has been approved (by IDEM QA staff, U.S. EPA staff, or appropriately trained IDEM program area office staff) and the approving entity signs it to signify such approval.

IDEM QA staff bases this advice to program area office staff on the principle that when an IDEM program area office accepts a federal grant, they are legally bound to meet the terms and conditions of the grant. When work done under the grant is contracted to another, each such contract contains the same terms and conditions as the primary grant agreement and all subsequent contracts or sub-grants must follow the same terms. If the grant is later audited, and it is found the terms and conditions (such as the contractor has a certified quality system in place, and the data is gathered following an approved QAPP) are not met, reimbursement could be required or penalties could be imposed.

4.4. The Grant Review Process

Each contract and grant agreement goes through an internal review process during which the funding source of the agreement is checked to ensure funds are available and eligible for the expenditure. Also reviewed and checked is the justification of the service to be provided. It is the responsibility of the program area office staff to ensure the goods and/or services being offered by the vendor meet the technical specifications of the project. The justification is reviewed to make sure the purchase meets the goals of the primary grant funding the contract or sub-agreement. The review process for contracts and grant sub-agreements begins with the program area office technical staff of the program area office that is the primary grant recipient or cooperative agreement (CA) partner.

These program area office technical staff members draft the terms of the contract or sub-agreement based on the requirements of the grant and forwards the draft contract to IDEM's Office of Legal Counsel for review. After legal review the contract is forwarded to IDEM's

accounting office to review for funding certification (making sure funds are available to pay for the contract or sub-agreement). Once approved in Accounting, the contract or sub-agreement is forwarded to the Indiana Department of Administration (IDOA) for final review. After final approval at IDOA, the contract is executed and work on the project can begin. Further review occurs as work on the project proceeds as scheduled. Each invoice received for reimbursement by the sub-recipient is reviewed as described in the following paragraphs.

In order for a project to qualify for grant or CA funding, each sub-recipient (vendor) proposal must meet the priorities and goals of the primary grant funding source. Each sub-recipient proposal is reviewed and scored on how it meets the grant requirements. Those contracts meeting the priorities are selected for funding.

Program area office technical staff members review the project deliverables and either approve or deny a request for payment from the sub-recipient. If the project deliverables are consistent with the requirements and objectives of the sub-recipient agreement, the invoice is approved for payment and a reimbursement warrant is generated through the agency accounting office and state auditor's office. If the request for payment is not approved, the appropriate program area office technical staff members will request corrective action to the project. Only after the program area office technical staff is satisfied that the project meets the requirements is an invoice approved for payment.

The agency has in place a rigorous procurement review process to ensure that goods and services purchased by the agency are necessary and meet all the technical specifications and requirements of the tasks for which they are being procured. Much of the scrutiny associated with purchase-related quality assurance is done at the program area office level, or lower, where environmental activities are conducted. The procurement process begins with a request from program area office staff "requesters," who establish the desired characteristics of the goods or services to be purchased and determine the specifications that must be met to ensure the quality of those goods or services. Each program area office has designated requesters that have been formally trained (See www.IN.gov/idoa/services/proctraining/) in the acquisition request process, as detailed in the IDOA Procurement Manual.

4.5. Delegation of QAPP Review

IDEM QA staff, IDEM program area office staff, and/or U.S. EPA QA managers currently review IDEM's QAPPs. Moving forward, program area office managers will review QAPPs in conjunction with input from agency QA staff and U.S. EPA staff. Any encountered disputes will be elevated to program area ACs, IDEM's Quality Manager, and the Commissioner, if necessary, for resolution.

5. Documents and Records

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

5.1. *IDEM's Commitment to Information Quality*

IDEM's documents and records carry information that must be accurate and reliable to both assist agency decision making processes, and to be shared with stakeholders and the public as a work product that:

- Protects public health and the environment.
- Provides the regulatory foundations for the promotion of the sustainable commercial, industrial, and agricultural activity that benefits all Indiana residents.
- Justifies the funding expended by Hoosier taxpayers, the regulated community, and the U.S. EPA (in the form of federal grants and partnership agreements) to support IDEM operations.

Because of this need for the most reliable information possible, IDEM strives to parallel U.S. EPA's own efforts to maximize the quality, objectivity, utility, and integrity of the information it uses and disseminates in compliance with U.S. Office of Management and Budget's Information Quality Guidelines.

IDEM's commitment to information quality is manifested through agency efforts to:

- Build and accurately document its quality system in its QMP, QAPPs, SOPs, and related quality documents.
- Continually improve QA-related tools and templates.
- Effectively manage its QA documents (approximately 1,053 documents as of May 31, 2012).
- Strengthen its oversight of data gathering and analysis by contractors.
- Continually review the accuracy of information submitted by the program area offices to U.S. EPA, which the agency subsequently posts to its websites (such as Enforcement Compliance History Online (ECHO), etc.), and to follow up with U.S. EPA to correct any errors that are posted.
- Improve the ease with which agency records can be retrieved from the Virtual File Cabinet (VFC).
- Provide risk characterization as documented in the Remediation Closure Guide and associated Remediation Program Guide, both of which were finalized by IDEM's Office of Land Quality on March 22, 2012.
- Schedule, complete, and report on continuous improvement events that evaluate, streamline, and improve the effectiveness of processes associated with the quality system and/or the agency's core mission.
- Upon request, expand the assessment and review of the program area office quality systems and practices.

5.2. *Identifying Records and QA-related Documents Important to the Agency Mission*

As stated above, the purpose of this "Documents and Records" section is: "To document appropriate controls for quality-related *documents and records* determined to be important to the mission of the organization." It is IDEM's view that "QA-related documents" (which IDEM considers as QMPs, QAPPs, and SOPs as well as the related forms, checklists, templates and

other QA-related tools) are living documents that should be *revised* whenever such revisions are needed. Even a QA-related document that previously was approved by signature(s) can be reapproved after revision and re-signed. A QA document that is no longer of use – because it is an older version of the document or because it documents a QA practice, process, or policy no longer needed – is considered by IDEM QA staff as expired, and is archived and managed as an expired QA document.

By comparison, IDEM considers a “record” as “a completed document that provides objective evidence of the execution of the agency core mission,” such as a report, completed application, issued permit, order, and any other final work product. It may not be *revised*. A document is written information that is dynamic, and subject to change, while a record is written information that is final, and not subject to change. A revised record is either an altered record or new record that is separate from the original record.

5.3. IDEM Quality System Documents

5.3.1. Managing QA documents

IDEM quality system documents are managed by QA staff. All QA documents are posted on the agency Extranet or SharePoint, where they are available to all IDEM staff.

It is the responsibility of the program area office staff to periodically review and revise their respective QA documents, if they are not up-to-date. IDEM requires that SOPs be revised any time there is a change to the process or the process requirements of the SOP. An SOP also should be revised any time that it does not match the actual steps taken to complete the task. Otherwise, each SOP should be reviewed once every four years. The SOPs reviewed in that time frame that still accurately document the actual steps taken to implement the process they describe do not need any revision, and may simply be re-signed and a new effective date affixed to them.

QAPPs need review and/or revision either each year (for project QAPPs) or sooner if the project parameters or goals change. However, program QAPPs used for “like studies” (iterative data gathering processes) done annually, or that are conducted in the very same manner several times and/or at differing locations annually, need only be reviewed and/or revised once every five years so long as there are not changes to the study goals or parameters. Program QAPPs that rely on individually-prepared work plans at each new instance or location when or where they are to be implemented need only have the work plan itself updated and/or revised for each separate data gathering event.

Although the majority of IDEM’s quality system documents are managed by agency QA staff, some are maintained by program area office staff. The management of any QA-related documents not maintained by agency QA staff and accessible by way of the agency Extranet or SharePoint should be discussed in the accompanying office-level QMPs.

5.3.2. Summary of responsibilities for developing and maintaining QA-related documents

Agency QA staff shall:

- Develop and maintain the agency QMP.
- Assist program area offices with reviewing and formatting their office-level QMPs.
- Advise program area offices to ensure QA documents they develop are consistent with IDEM and U.S. EPA content requirements.

- Develop and maintain the templates for QA-related documents.
- Maintain the agency QA glossary of terms.
- Review, at the request of the program area offices, any QAPPs under development or in use in conjunction with any significant federal grant involving data gathering.
- Review, at the request of any program area office, any SOP being developed by that office.
- Catalog and track the status of all QA-related documents including, but not limited to:
 - Maintaining them on the agency Extranet (Internal agency website) so that they are readily accessible to all staff.
 - Monitoring their effective dates and advising program area office staff when an increment of time has passed so that the document(s) should be reviewed to determine if it still is up-to-date.
 - Reviewing QA-related documents under development to advise program area office staff of whether the document(s) meets agency standards.
 - Retiring QA documents that are no longer in effect.
 - Maintaining an archive of expired QA documents. (The value of the archive is that it preserves QA documents that no longer are in effect, but which may need to be referenced if past data gathering or work practices should be in question, and also to facilitate further revisions by preserving electronic files so that no document or portion of a document needs to be retyped into a newer, revised version.)
- Assess, at the request of a program area office management and/or direction of the IDEM Quality Manager, the effectiveness of the QA-related documents of that office.
- Maintain and implement a schedule for suggested document review and revision.
- Prepare and submit the Quality Assurance Annual Report and Work Plan (QAARWP) to U.S. EPA Region 5 each year.

Agency program area office staff should:

- Develop and revise their office-level QMPs.
- Develop the required QAPP for the gathering or use of environmental data for which funding has been provided by the U.S. EPA or other federal source.
- Develop any SOP(s) that may be needed in conjunction with a data gathering activity as well as for any process the program area office staff determines should be documented in an SOP.
- Use the program area office QA documents (SOPs, QAPPs, etc.) posted in the QA library on the agency Extranet or SharePoint, in order to prevent the use of multiple versions of the same agency QA document.
- Update program area office QA-related documents in accordance with the time frames for QA-related documentation established in this document.

5.4. Agency Records

5.4.1. Managing IDEM records

Record management practices at IDEM are driven by the Indiana Access to Public Records Act (APRA) (IC 5-14-3). APRA defines a public record as "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."

IDEM manages its records consistent with the requirements of the Indiana Commission on Public Records (ICPR) and with related agency policies (copies of which are available on IDEM's Extranet and upon request), including:

- The Records Management Policy A-49-OEAA-09-P-R0 (November 9, 2009), which provides a framework for the management, storage, and disposition of agency records.
- The E-mail Management Policy A-002-OEA-090P-R2 (June 6, 2005), which sets forth agency staff requirements for:
 - E-mail use and management, including sorting, saving, retrieving and deleting e-mail.
 - Ensuring that e-mail is managed correctly if needed for evidentiary purposes.
 - Labeling and handling requirements for confidential e-mails.
 - Appropriate content and distribution of e-mail.
- The Public Records Request Policy A-017-OEA-10-P-R3 (April 1, 2006), which ensures a timely and complete response to public record requests related to the conduct or administration of the agency's business.
- The Litigation Hold Policy P-001-OLC-X-XX-10-S-R1 (Federal Rule of Civil Procedure 34, Indiana Trial Rule 34) October 18, 2005, which ensures all documents relevant to pending or reasonably anticipated litigation are preserved in accordance with applicable State and Federal Trial Rules even when there may be a record retention schedule that would otherwise allow the record to be destroyed.
- The Posting Public and/or Legal Notices on the Agency Websites Policy A-067-OEA-09-P-R0 (April 20, 2009), which establishes the approval process for posting documents on the IDEM (internal and public) websites.
- The Personal Identifying Information Disclosure, Prevention, and Response Policy A-071-OEA-10-P-R0 (May 12, 2010) and the Social Security Numbers Confidentiality Policy A-019-OEA-09-P-R2 (July 1, 2006), which together protect the legitimately private personal information of IDEM staff members and persons interacting with the agency.
- The Forms Management Policy A-053-OEA-08-P-R2 (11/1/2005), which sets forth requirements to:
 - Ensure compliance with all applicable state regulations.
 - Ensure the efficient development, standardization, accuracy, and need of new and existing forms.
 - Address legal, financial and other issues that agency forms may involve.
 - Control the costs associated with recording, storing and retrieving forms.

- Ensure all agency forms are approved by the ICPR.

5.4.2. Responsibility for managing IDEM records

IDEM records that document the execution of the agency core mission generally are managed in the agency Virtual File Cabinet (VFC) or in the various agency (or federally managed) databases. The VFC is 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 area offices within the agency. Management of the electronic side of the VFC is handled by IDEM's Office of Information Services (IDEM IS) and shall be discussed in Section 6 of this QMP.

The content side of the VFC is also managed by the IDEM IS staff. Previously existing paper records are scanned into the VFC by IS staff, program area office staff, or IDEM Public Records Office staff. Newly arriving (via U.S. mail or deliver) hard copy records are scanned into the VFC by program area office staff or PRO staff. New records that are submitted electronically now are uploaded directly into the VFC.

Program area office staff then indexes the records that have been scanned into the VFC, to facilitate their retrieval. Staff from the IDEM PRO also retrieves records from the VFC in response to public records requests. In addition to retrieving records from the VFC, PRO staff also may retrieve e-mails and other work documents stored electronically by agency staff members on their individually-assigned personal computers, home network drives, and shared network drives.

5.4.3. Record retention schedules

All state and agency records are subject to record retention schedules approved and maintained by the ICPR. The purpose of record retention schedules is to ensure records are retained for as long as legally required, but also to provide time tables for determining when certain records may be obsolete, and therefore no longer need to be kept. Agency records are retained in the VFC, based on ICPR retention schedules. The General Retention Schedule for state of Indiana records is available upon request. Similarly, the record retention schedules for records generated by the agency program area offices may be found in the appendices associated with the respective office QMPs.

5.5. Document and Record Handling Processes

In accordance with U.S. EPA's quality system requirements, this QMP describes the process for preparing, reviewing, approving, issuing, using, authenticating, and revising documents and records. The following text describes how IDEM approaches each of these processes regarding both our QA-related documents and agency records.

5.5.1. Handling agency QA documents

As discussed above, handling agency quality assurance (QA)-related documents is the responsibility of the program area offices and the agency QA staff. SOPs, QAPPs, and QAPP-related Work Plans are prepared (developed) by agency program office staff. Upon request from program area office staff, these draft QA documents will be reviewed by agency QA staff members who (consistent with their mission to provide QA support to program area office staff) shall provide corrections and/or comments. These documents are then approved by signature, and posted by agency QA staff on the agency Extranet, where they may be used by appropriate staff. Revision requirements for these documents were discussed previously.

Lists of program area office-specific QA documents can be found in the various office-level QMPs or associated appendices.

5.5.2. Handling agency records

The handling of agency records is the responsibility of the program area offices, the IS staff, and the agency PRO staff. The various sections of the program area offices develop records during the course of conducting agency business. The resultant reports, permits, orders, and other work products are prepared by those program area office staff. At the end of each particular work process, program area office managers review and approve these draft documents. After management approves them through signature, these documents are issued by the program area office. They are used by the stakeholder and may be referred to by agency staff making onsite inspections. However, once these work products are signed, they become agency records and may not be further revised.

5.6. Ensuring Documents and Records Accurately Reflect Completed Work

Records (per discussion above) are the actual work products generated by the agency during the course of conducting agency business. These work products are stored in the VFC. Most are available for review by IDEM staff members, while some portion of agency records are available to the public online. Similarly, data gathered by the agency is a work product of the agency and is stored either on agency databases or on U.S. EPA-sponsored databases. Agency data uploaded to U.S. EPA databases is generally available via the Internet. To ensure accuracy, agency program area office staff review data both prior to upload and on U.S. EPA websites where the data appears. Corrections are submitted to U.S. EPA as appropriate.

5.7. Document and Record Maintenance Processes

In accordance with U.S. EPA's quality system requirements, this QMP "describes the process for maintaining documents and records including transmittal, distribution, retention, access, preservation, traceability, retrieval, removal of obsolete documentation, and disposition." The following text describes IDEM's approach to each of these processes for both QA-related documents and agency records.

5.7.1. Maintenance of agency QA documents

Agency QA documents, including those generated by the program area offices, are distributed to agency staff via the QA library maintained on the agency Extranet or SharePoint. Program area offices are discouraged from also housing these documents on internal program area office computer system shared drives, even if the QA documents originally were developed by the program area office. Limiting the accessibility of QA documents to the agency QA library helps to maintain version control and prevent multiple or differing versions of the same QA document from being available for use by program area office staff.

Agency program area office staff is responsible for notifying agency QA staff of QA documents that are obsolete. Agency QA staff is responsible for the removal of obsolete QA documents from the Extranet so that the versions accessible to program area office staff are always the most current versions. They also maintain limited-access storage of QA-related documents in SharePoint document libraries that are not accessible to program area office staff. This off-line repository of agency and program area office QA documents preserves the integrity of current and past document versions and allows QA staff to trace revisions to previous versions and to archive QA documents no longer in use.

5.7.2. Maintenance of agency records

Most agency records are maintained electronically in the VFC. As a result, all transmittal and/or distribution are done by way of the Internet and/or the agency Extranet. The VFC has three levels of security/access:

- Available to the public (records that may be viewed by anyone requesting access).
- Available only to IDEM staff (records that can be viewed by any IDEM staff, but are not accessible to the public).
- Available only to specific IDEM staff members (records that may contain confidential information and so may only be viewed by specific agency staff members).

The IDEM PRO is responsible for assisting agency staff members and the public with the retrieval of agency records. Public records staff:

- Track records requests and the agency response to records requests.
- Assist with records researches in the VFC.
- Coordinate responses to records requests that may involve records not accessible via the VFC, such as e-mail or other materials held by staff members.
- Prepare explanations for why specific records may be exempt from public disclosure.
- Ensure program area office records retention schedules are kept up-to-date.
- Implement disposition of obsolete records.

5.8. Compliance with Statutory/EPA Recordkeeping Requirements

The ICPR requires state agencies to develop records retention schedules for records that are subject to Indiana Code (IC) 5-15-5.1 and thus qualify as "retainable records." The agency also takes into consideration all other applicable state and federal legislation when developing record retention schedules. The IDEM Office of Legal Counsel reviews draft records retention schedules before they are sent to the ICPR for approval to verify that all applicable state and federal record keeping requirements are met.

5.9. Procedures for Implementing Chain-of-Custody for Evidentiary Records

IDEM recognizes that good chain-of-custody practices are essential to protecting the integrity of any sampling done as part of a data gathering exercise. Quality-based sampling practices and sample transport practices are the first steps in obtaining quality results. Without ensuring quality at this level, even associated quality control practices, such as submitting duplicates, spikes, or blanks to measure precision or identify potential bias, are pointless. Maintaining good chain-of-custody practices helps to ensure the data gathered will be scientifically and legally credible.

IDEM does not currently have a formalized, agency wide chain-of-custody procedure. Chain-of-custody practices are used primarily by those program area offices involved with data sampling; the specific use of such practices, and any associated documentation, are discussed in the respective office-level QMPs.

For example, in OAQ the Ambient Monitoring Branch chain-of-custody requirements are documented in Chapter 10 of its AMB Quality Assurance Manual, which must periodically be re-approved by the chief of the U.S. EPA Region 5 Air Division Air Monitoring and Analysis Section. The Air Compliance and Enforcement Branch follows its Air Compliance Particulate and Asbestos Sampling Guidelines and Procedures SOP for asbestos sampling, which is the only field sampling conducted by that branch.

Similarly, project managers in the OLQ Remediation Service Branch follow the chain-of-custody protocols in the Science Services Branch (SSB) Chemistry Support Field Documentation SOP for samples sent to contracted laboratories, while staff in the federal remediation programs follows U.S. EPA chain of custody requirements and Site Investigations staff follows their Site Investigation Program – Documentation of Site Activities SOP. OLQ Inspection and emergency response staffs also follow the chain-of-custody protocols in the aforementioned OLQ SSB SOP, and as per SW-846 Sample Protocol.

OWQ's Watershed Assessment and Planning Branch relies on the chain-of-custody practices documented in their "Biological Studies Section Standard Operating Procedures Manual" and "Surveillance Group Standard Operating Procedures Manual." The OWQ Compliance Branch also has a Wastewater Inspections SOP that includes chain-of-custody processes. The drinking water program relies on public water systems to perform sampling activities.

In addition, IDEM QA staff commits to ensuring that any program area office chain-of-custody protocol not currently in compliance with with EPA Order 2160 and EPA Directives 2100, chapter 107 will be brought into compliance with those requirements over the effective period of this 2012 QMP.

6. Computer Hardware and Software

Purpose – To document how IDEM addresses all computer-use related issues common to the entire agency and ensures that computer hardware and software satisfies the agency's requirements.

Shared Service Roles – Planning, development, deployment, control, use, and maintenance of the computer infrastructure (e.g., servers, network, desktops) within the agency is shared between IDEM's Office of Information Services Office (IS) and the Indiana Office of Technology (IOT). Section 6.1. (below) identifies which of the respective offices (IS or IOT) is responsible for each of the various hardware and/or software issues.

Shared Service Background - IOT has consolidated the infrastructure hardware and services of all state of Indiana executive branch offices under their control. The consolidation extends across the nearly ninety state and quasi-state agencies. IOT has established a set of Service Level Objectives that describe the nature of those services and the level of service to be provided.

Business Systems Consultants' (BSC) Roles and Responsibilities

Each BSC is assigned to one or more program area offices. In that capacity they:

- Serve as the initial and primary point of contact with the program area offices.
- Assemble basic needs and problem definitions prior to application development consideration.
- Develop application requirements for all application development projects.
- Develop user documentation for all agency developed applications and provide training to users.
- Perform appropriate duties as part of a Project Team.

Project Managers' (PM) Roles and Responsibilities

The PMs play a central role in developing medium to large, complex, multi-program area enterprise application projects. In that capacity they:

- Work with the appropriate BSC throughout the process.
- Assure that all resources are managed.
- Serve on the Application Development Team with the BSC and Application Developers.
- Provide background on the software application to the Application Developers.

Application Development (AD) Team's Roles and Responsibilities

The members of the AD Team create and manage IDEM-specific application software. In that capacity they:

- Serve as part of the AD Team with the BSC and PM.
- Manage and interact with any contracted third party software application developer.
- Create/develop, test, and manage IDEM-specific application software.
- Perform database administration, security, installation/configuration, back-up, and recovery.

Office of Information Services Administrative Assistant's Roles and Responsibilities

The IS Office Administrative Assistant plays a pivotal role in meeting agency hardware and software needs by:

- Preparing and expediting requisitions for hardware and third-party application developers.
- Interacting with agency and state procurement staff and policies.

6.1. Interacting with Agency and State Procurement Staff and Policies

Topics in this section, listed below in Sections 6.1.1 through 6.1.5, are derived from U.S. EPA Requirements for Quality Assurance and through an Information Resources Use Agreement (IRUA) between IDEM and IOT. The term "Information Resources" includes all state hardware, software, data, information, network, personal computing devices, phones, and other information technology. To use Information Resources, IDEM has agreed to adhere to the provisions of this agreement, which are established to ensure security and inform users of the conditions of use.

6.1.1. Processes associated with software/hardware testing

Commercial off-the-shelf software (e.g., ESRI-ArcGIS) testing is done through the Indiana Department of Administration (IDOA) contracting/procurement policies. Procedures and enterprise software such as Microsoft Office or McAfee Virus procurements fall under IOT control.

In-house software development (e.g., NEIEN Node 2.0 and Data Flows for moving data from IDEM to U.S. EPA) testing is done according to the following:

- Software Development Document (SDD).
- Data Management Guide (DMG).
- Data Standards (DS) (EDSC/Security, etc.).
- IDEM Testing Procedures (ITS) -First unit testing by developers to make sure requirements or scope or deliverables are met and 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 as well as the above-listed SDD, DMG, DS, and ITS procedures.

Desktop hardware testing is done through IDOA and adheres to State Quantity Purchase Agreements and the Exception Process.

Server hardware and network environment hardware testing processes and related activities are controlled by IOT (see IOT service descriptions at www.IN.gov/iot/2416.htm).

6.1.2. Processes associated with software/hardware use

Commercial off-the-shelf software, in-house software development and third-party created software use is controlled through user manuals and the state Information Resource Use Agreement (IRUA). A copy is available online from www.IN.gov/iot/IRUA.htm. Desktop hardware, server hardware, and network environment hardware use is also controlled through the IRUA.

6.1.3. Processes associated with software/hardware maintenance and any relevant maintenance, upgrade, and backup processes

Commercial off-the-shelf software, in-house software development, and third-party created software are maintained according to the DMG. Desktop hardware, server hardware, and network environment hardware maintenance activities are controlled by IOT.

6.1.4. Processes associated with software/hardware control (e.g., access control, security) relevant to software, programs, or drives with limited access

Commercial off-the-shelf software is controlled by the following:

- IDEM IS Director or the agency Security Coordinator submit access requests to IOT.
- IDEM IS Director controls the licenses and media.
- Indiana Resources User Agreement (IRUA).
- IOT Information Security Framework (ISF) at: www.IN.gov/iot/2339.htm.
- IDEM Information Services Strategic Plan and Road Map (draft available upon request).

In-house software development and third-party created software are controlled by the following:

- IDEM IS Director or the agency Security Coordinator submit access requests to IOT.
- IRUA.
- Security and/or administration manuals.
- IOT ISF.

Desktop hardware control is through IRUA and activities controlled by IOT.

Server hardware and network environment hardware control is through ISF and activities controlled by IOT.

6.1.5. Documentation associated with hardware/software

Commercial off-the-shelf software documentation is provided to requestor of software through ISF and IRUA.

In-house software development documentation is maintained in document systems and compiled in Software Developer Documents and user manuals.

Third-party created software documentation is provided by contractor as a deliverable.

Desktop hardware manuals are left with the desktop hardware.

Server hardware and network environment hardware documentation are activities controlled by IOT.

6.2. *Hardware/Software Usage Assessment and Documentation*

Agency hardware and software is selected specific to user requirements. If there is a change in user requirements, there is a change in hardware or software. With IS Director approval, the various agency program area office staff work with BSC, PM, and the AD Team to institute these changes.

6.3. *Hardware/Software Evaluation*

Evaluating hardware and software to ensure it meets program area office needs is done by program area office managers and staff working in conjunction with IDEM IS. Individual IDEM program area offices may further discuss how they evaluate hardware and software and determine appropriate purchases in their respective office-level QMPs.

6.4. Data QA/QC Standards

IDEM's Data Management Guide (DMG) lists the agency's enterprise data standards. The DMG was developed with input from all parts of the agency. State, national, and international standards were reviewed and incorporated as appropriate. The DMG lists all aspects of database administration, security, and data object naming conventions. All agency staff are required to follow the DMG. The members of the AD Team, IS Project Managers, and the BSCs ensure that applications and data produced internally, produced by contractors, or collected by computers adhere to the standards contained in the DMG.

Compliance with data standards is ensured by reference to the DMG by all members of the Data Management Team before and during the development process. Compliance is further assured since all development requests must be reviewed and approved by the IS Director prior to the start of any development work.

7. Planning

Purpose – To document the agency’s planning process to ensure data or information collected is of the needed and expected quality for its desired use.

The U.S. EPA’s Data Quality Objective (DQO) and Quality Assurance Project Plans (QAPPs) are essential in the gathering of data and other information intended for use in environmental and regulatory decision making. While the DQO and QAPPs will be the focus of this section of the agency’s QMP, IDEM also utilizes a number of QA-related documents as planning tools which contribute heavily to both planning and implementation of programs and projects.

In particular, IDEM uses SOPs as planning tools. While QAPPs document how issues associated with gathering quality data are to be addressed, SOPs document the steps to be completed in a sequential fashion to complete a process that yields a result. The result could be data, but it also could be a work product such as a permit, an inspection report, or an order.

In addition to the DQO, QAPPs, and SOPs, the types of other QA-related planning tools that IDEM relies on to complete its agency mission are:

- IDEM 2012 QMP, which documents how the agency intends to continue incorporating QA practices into the way it conducts its business.
- Standard work instructions, which provide a means for a program area office to capture a procedure that doesn’t require the same level of documentation as an SOP in a format of the office’s choosing.
- The IDEM-U.S. EPA Environmental Performance Partnership Agreement (EnPPA), which establishes work goals to be completed in addition to/in conjunction with the ongoing mission of the agency.

7.1. Systematic Planning Process Description

IDEM recognizes the importance of using an appropriate means of systematic planning associated with data gathering. The key elements of systematic planning (as described in *Guidance on Systematic Planning Using the Data Quality Objectives Process, U.S. EPA QA/G-4*, February 2006, page 4) are:

- **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 field and laboratory, audits, technical assessments, performance evaluations, etc.).

- **Analysis:** Description of how the sample will be analyzed (either in the field or the laboratory) and how the resulting data or the acquired data will be evaluated, analyzed, and assessed against its intended use and the quality performance criteria (QA review/verification/validation and use).

The DQO process provided by U.S. EPA is simply a more refined enumeration of the issues that must be considered when establishing performance or acceptance criteria. These criteria serve as the basis for designing a plan for collecting data of sufficient quality and quantity to support the goals of a study. The DQO process consists of seven steps which, while they are listed here in a sequential fashion, may be implemented so that one or more steps of the process may be revisited as more information on the problem is obtained.

Each step of the DQO process defines criteria that will be used to establish the final data collection design:

- **Step 1. State the Problem.** Define the problem that necessitates the study; identify the planning team, examine the budget, set a schedule.
- **Step 2. Identify the Goal of the Study.** State how environmental data will be used in meeting objectives and solving the problem, identify study questions, and define alternative outcomes.
- **Step 3. Identify Information Inputs.** Identify data and information needed to answer study questions.
- **Step 4. Define the Boundaries of the Study.** Specify the target population and characteristics of interest; define spatial and temporal limits, and the scale of inference.
- **Step 5. Develop the Analytic Approach.** Define the parameter of interest, specify the type of inference, and develop the logic for drawing conclusions from findings.
- **Step 6. Specify Performance or Acceptance Criteria.**
 - Specify probability limits for false rejection and false acceptance decision errors.
 - Develop performance criteria for new data being collected or acceptable criteria for existing data being considered for use.
- **Step 7. Develop the Plan for Obtaining Data.** Select the resource-effective sampling and analysis plan that meets the performance criteria.

IDEM QA staff has studied the *U.S. EPA Guidance on Systematic Planning Using the Data Quality Objectives (DQO) Process EPA QA/G-4*, in order to better understand the use of these methods. In addition, various agency program area offices developing QAPPs have incorporated or striven to incorporate this U.S. EPA-preferred systematic planning process into their QAPP development process with varying degrees of success.

During the effective cycle of the 2012 IDEM QMP, IDEM QA managers will continue to work towards a greater understanding of how best to employ the DQO process. QA staff will also assist program area offices' staffs to more fully understand and adopt the use of this planning method. To achieve this end, they will continue to maximize their use of available U.S. EPA training (including both Webinar-style trainings and available in-person training) on this topic.

7.2. IDEM QAPPs

A QAPP is a document describing the activities of an environmental data operations project involved with the acquisition of environmental information, whether generated from direct measurement activities, collected from other sources, or compiled from computerized databases and informational systems. In addition to the project plan, a QAPP also includes adequate QA measures and may reference one or more standard operating procedure or other guidance. A QAPP does the following:

- Documents the results of a project's technical planning process.

- Provides in one document a clear, concise, and complete plan for the project's environmental data operation.
- Describes the quality objectives of the project.
- Identifies key project personnel.

Note: This agency wide QMP details IDEM's overall approach to developing and using QAPPs. Details about how the various IDEM program area office staff plan data gathering and other projects is included in the attached office-level QMPs.

Data gathered by IDEM staff, or by any contractor on behalf of IDEM, must be accurate and reliable for decision making purposes. In pursuit of those ends, all IDEM data gathering activities will be documented in a QAPP.

Within IDEM, a QAPP will be approved by different staff members than those who write the QAPP. The QAPP will be reviewed and approved by IDEM QA staff members and/or by U.S. EPA QA managers, or at minimum, by IDEM program area office staff members familiar with *U.S. EPA Requirements for Quality Assurance Project Plans (QA/R-5)*. Work will not begin before the QAPP is completed and approved. However, a QAPP may be conditionally approved (temporarily approved for a brief time; e.g., a week or two) in instances when:

- A QAPP that is nearly completed has been provided to a reviewer to confirm that it is near completion.
- A brief window of seasonal or limited conditional opportunity is approaching during which specific tasks related to the data study must be completed, and if they are not completed during that time period, the timetable of the entire study could be delayed for a much longer period (e.g., student or volunteer help is temporarily available, difficult to access equipment briefly is available, or the study must be conducted during specific weather conditions or while access is available to a site that is otherwise difficult to access).
- The work to be done during the temporary approval period is limited to sections of the QAPP that have been completed.

Work to be done during such a conditional approval should be specified by the project manager in advance, and only work specifically approved as part of the conditional approval may be done at that time.

7.2.1. QAPP format

IDEM QAPPs will be in a format that meets at least one of the following criteria:

- Is consistent with the QA requirements detailed in *U.S. EPA Requirements for Quality Assurance Project Plans QA/R-5* or other U.S. EPA approved format (such as a future revision of QA/R-5, or the Uniform Federal Policy format for QAPPs).
- Is in a format verified as being provided to IDEM program area office staff by U.S. EPA or U.S. EPA Region 5 program or QA staff.
- Uses an alternate Data Quality Objective (DQO) process that is identified and explained in the program area office QMP.

7.2.2. QAPP development

QAPPs will be developed by IDEM program area office staff designated by their supervisors for the following:

- Repeatedly gathering a specific type of environmental data (at a specific location or at multiple locations on an ongoing basis) for ambient monitoring or assessment (i.e., program QAPPs).

- Gathering environmental data (at a specific site on a short term or one time basis) to characterize some environmental parameter at that location (i.e., project QAPPs).
- Gathering environmental data using federal grant funding for any reason not already addressed above (can be either a program or project QAPP).

The development of a QAPP by agency program area office staff members will be a collaborative effort that includes the QAPP author(s) and/or the project manager, program area office supervisory staff, the appropriate agency science support staff, and staff from any agency or contract laboratory involved in related sample analysis. Program area office staff also may want to include agency QA staff in any initial planning meetings to benefit from their insight regarding U.S. EPA QAPP requirements and how those requirements may be interpreted when considering the graded approach.

7.2.3. QAPP review and approval

IDEM QA staff has a QA goal (See Section 1.1.4.) to offer QAPP review and approval training to all designated program staff, and to work with program area office managers to promote such training to all program staff who will review and approve QAPPs. QAPPs prepared by IDEM program area office staff will be reviewed and approved by at least one of the following:

- IDEM QA staff.
- IDEM program area office management (based on the recommendation of IDEM QA staff or staff they designate).
- U.S. EPA Region 5 QA managers.
- U.S. EPA Region 5 program staff (approved by the U.S. EPA Region 5 QA manager and identified by name to IDEM QA staff as qualified to review and approve QAPPs).

Since QAPPs are required by U.S. EPA, usually in association with a grant award (a binding legal agreement), IDEM requests that any U.S. EPA QA, program, or project manager declaring that a QAPP meets U.S. EPA requirements be asked to sign the QAPP to acknowledge accountability for that declaration. This will assist IDEM in meeting U.S. EPA's quality system requirements associated with data gathering projects, by documenting U.S. EPA's approval of the QAPP for a particular project.

QAPPs will be implemented as written, consistent with all quality considerations, and following all instructions documented in the QAPP or attached to the QAPP as SOPs. Additional discussion on implementing a QAPP is contained in Section 8, Implementation of Work Processes. As previously stated, all work to implement a QAPP must cease if changes to the data gathering plan merit revision, and may not restart until the revised QAPP is reapproved.

The U.S. EPA Region 5 QA manager has requested that IDEM assist with QAPP reviews and approvals. IDEM QA staff agrees to work with the U.S. EPA Region 5 QA manager regarding reviewing and approving QAPPs currently approved by that office. In return, IDEM QA staff requests that the U.S. EPA Region 5 QA manager prohibit U.S. EPA Region 5 program staff from directly approving QAPPs developed by IDEM program area office staff unless they:

- Sign the approval page of the QAPP and
- Notify IDEM QA staff and the U.S. EPA Region 5 QA manager that they have approved the QAPP with their signature, and provide a copy of that signature page to all parties.

7.2.4. QAPP responsibilities

It is U.S. EPA policy, as stated in *U.S. EPA Requirements for Quality Assurance Project Plans QA/R-5*, page 7, that; “All work funded by U.S. EPA that involves the acquisition of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized databases and information systems, shall be implemented in accordance with an approved QA Project Plan.” It is the responsibility of the IDEM program area offices to ensure this policy is followed.

An Assistant Commissioner (AC) or their designee(s) will determine which staff shall draft the QAPP. They similarly reserve the right to request IDEM QA staff assistance with planning and/or review and approval of the QAPP. An AC or their designee also will determine who should appear on the QAPP distribution list and signature page, noting that IDEM requests that any U.S. EPA staff that approves the QAPP also signs the QAPP. An AC also may designate staff to review and approve QAPPs. As stated in Section 1.1.4. QA Goals and objectives, it is the goal of IDEM QA staff to work with program area office management to establish appropriate training for any program staff designated to approve a QAPP(s).

Program area office staff designated to work on QAPPs also are responsible to ensure:

- They participate in available QAPP-related trainings.
- A QAPP shall include all the elements required by the U.S. EPA in *U.S. EPA Requirements for Quality Assurance Project Plans QA/R-5* (or any subsequent U.S. EPA requirements). Program area office staff developing a QAPP may use U.S. EPA’s graded approach, which allows exemptions from those U.S. EPA-recommended QAPP elements not applicable to the process being documented.
- A QAPP is not developed and approved by the same staff.
- The QAPP is approved (signed) before work begins, and if work is halted, the QAPP is reapproved (re-signed) before work begins anew.
- Parties on the QAPP distribution list receive updates of all significant events related to the development and implementation of the QAPP as necessary.
- When the work described by the QAPP is funded in part or in full by a federal grant, the program area office grant coordinator and the agency grant director will be included on the distribution list.
- Once work begins, the QAPP is properly implemented, ensuring that all project activities are performed as planned.
- Requirements for the development and use of QAPPs also are included in any contracts and/or subcontracts, as appropriate.
- Any contractor and/or grant sub-recipient that IDEM staff oversees that is performing data gathering meets the same U.S. EPA QA requirements that IDEM staff must meet.

7.2.5. Using an approved QAPP

Staff conducting the data gathering activities will regularly consult the plan (and any associated SOPs) as the QAPP is implemented. If circumstances arise that require changes to the plan, work will be halted until the plan is revised and reapproved. Program area office staff will check periodically during the implementation of the

QAPP to ensure that it is being followed. When the data gathering activities have been completed, staff implementing the QAPP will perform data validation and verification of the results.

All parties on the QAPP distribution list will be notified by staff implementing the QAPP when:

- The QAPP is approved.
- Work begins on the QAPP.
- QAPP implementation is halted due to changes.
- QAPP implementation that was halted is restarted.
- Checks have been done to ensure the QAPP is being followed.
- Work to implement the QAPP has been completed.
- Data validation and verification have been completed.
- A final project report or finding has been issued. For work funded by a grant, this reporting also may be included as part of the grant close out.

These actions will be taken by any IDEM staff or IDEM contractor preparing or implementing a QAPP to gather data for the agency. Only by developing a plan and ensuring that plan is followed can IDEM be sure that other entities using the same plan, at the same location, are likely to achieve the same results. Such repeatability ensures the data is scientifically and legally defensible.

When using a contractor to gather data, IDEM also will ensure that contractor is operating under a quality system certified by a qualified third party, such as the U.S. EPA, the National Environmental Laboratory Accreditation Conference (NELAC), the Indiana State Department of Health, or some similar certifying body. Such a certified, contracted entity still will only engage in data gathering activities following an approved QAPP.

7.3. Existing Data

Until recently, U.S. EPA QA documentation referred to data that was gathered previously as “secondary data,” meaning data originally gathered for a particular use but later considered for a different “secondary” use. U.S. EPA has dropped the use of that term; data that was gathered previously is now simply referred to as “existing data.” Being able to use such data can be very useful, in part because the cost of data collection has already been paid.

Before existing data can be reused for a secondary purpose, it needs to be evaluated to determine its suitability for the new purpose. For previously gathered data to be useful, it must originally have been gathered according to a plan that clearly documented what data was to be gathered, and how. When data is gathered following a detailed data gathering plan (QAPP or other quality documentation), that was reviewed to ensure the plan was properly implemented (the data verification and data validation reports), and subjected to analysis confirming the final data was suitable for the purposes for which it was gathered (data quality analysis findings), it is much more likely that all the information (metadata) needed to evaluate such existing data for additional, secondary use will be available.

The responsibility for the assessment of existing data for secondary purposes and the extent to which existing data is used by IDEM program area offices should be addressed in the respective program area office-level QMPs. How that existing data is assessed for such secondary uses also should be documented in those same office-level QMPs. When applicable, those using existing data also should develop a QAPP consistent with the U.S. EPA GLNPO training: “Systematic Planning and Quality Documentation for Projects using Existing Data Training” available at: www.epa.gov/greatlakes/qmp/qmtraining.html.

7.4. QAPPs – A New Direction

As with any issue in any large organization, communication between IDEM program area office staff and IDEM QA staff in the development and approval of QAPPs can be challenging. When communication and cooperation between two large organizations – such as IDEM and U.S. EPA – is necessary, the task is even more complex. IDEM is seeking a better way for QA staff and program area office staff to communicate and cooperate both within and between their respective agencies.

To this end, IDEM QA staff has launched a fresh initiative with two key messages: that agency QA staff is a valuable resource in developing QA-related documents, and that meeting U.S. EPA QA requirements will improve the quality of the final work product. The goal is for agency program area office staff and managers to understand that rather than being an obstacle that adds more work to the process, quality assurance practices can ensure the final work product is reliable, and that early interaction with IDEM QA staff can facilitate putting those practices in place.

Agency QA staff is working to communicate the following types of assistance they can provide, when invited to participate in the development and review of QAPPs:

- Identifying the right parties for inclusion on the signature page or distribution list.
- Establishing who will have the final sign-off on decisions made once the project is underway.
- Anticipating required QAPP elements that could be overlooked.
- Clarifying project objectives and issues to be addressed.
- Making judgments about the degree of detail that may be required in the QAPP, based on interpretations using the ‘graded approach.’
- Ensuring all locational issues associated with the study have been adequately addressed.
- Setting a work schedule, and identifying milestones.
- Specifying what SOPs or other process instructions might be needed to implement the QAPP.
- Identifying parties associated with the project that may need to be consulted for input (e.g., if samples are gathered, it is best to consult with the laboratory that will analyze the samples to ensure the samples that arrive at that lab will meet any criteria the lab may have with respect to retention time, temperature, sample size, container type, time of day, accompanying documentation, or other characteristics).
- Helping program area office staff to ensure that no important details are omitted from the QAPP.
- Developing a plan to promote follow up on project implementation so that once approved, the QAPP is followed as written during the data gathering process, rather than simply placed aside once it is approved.

7.5. Quality Assurance as a Team Effort

Development of a useful QA system and associated QA documents is best approached as a team effort. The more communication program area office staff has with IDEM QA staff, other IDEM and U.S. EPA program staff, and any other parties that have a role in the implementation of the QAPP, the more complete, accurate, and useful the QAPP will be.

IDEM QA staff will provide the following assistance as part of that team effort:

- Provide a reminder of details that need to be in the QAPP, as well as feedback on the degree of detail that may be required based on the graded approach.
- Review the final draft QAPP.
- Participate in approving a QAPP for use in data gathering. IDEM QA staff reserves the right to not sign (approve) a QAPP it has not had the opportunity to review or provide comment on prior to the approval process.

8. Implementation of Work Processes

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

Currently, IDEM program area office staff have several tools available (described in Section 7) to help ensure that adequate planning is in place so that work will be properly completed. However, plans are only useful if they are followed.

IDEM uses Standard Operating Procedures (SOPs) to document the sequential steps in work processes. SOPs are the mechanism by which QAPPs are implemented, and are the documents used by staff to make sure they know how to correctly perform their work.

IDEM currently does not have an agency wide procedure in place to ensure that QAPPs, SOPs, or other work plans are followed as written. However, the IDEM program area offices do employ varying standard QA-related practices, as documented in their respective office-level QMPs, to confirm that data gathering procedures follow written QA plans (QAPPs, QAPP related work plans, or SOPs). For example:

- OAQ Ambient Monitoring Branch (AMB) performs QA audits to ensure planning document or standards requirements were followed at sample sites, for evaluating data, or for certifying equipment in the AMB QA standards laboratory;
- OLQ Science Services Branch (SSB) Chemistry Services Section performs data verification and validation on samples taken by the OLQ Remediation Branch;
- OWQ Watershed Assessment and Planning Branch (WAPB) reviews the results from contract laboratories for compliance to QA/QC procedures, including review of field sample QC performance (field blanks, equipment blanks, field duplicates) and the verification of field calibration (evaluating the relative percent difference (RPD) of data sonde (electronic sensor to measure or monitor conditions, i.e., a water sonde) vs. independent test method). Deviations noted in this process are investigated.

IDEM QA staff assists program area office management and staff with the development of SOPs to ensure that staff has accurate work plans in place. QA staff realizes following work plans (QAPPs, SOPs, or other plans) as written is essential to preserving the integrity of the work completed. A goal for IDEM's QA staff during the 2012 QMP effective period is to develop a mechanism to assist program area office managers and staff in regularly checking the QAPP or SOP in use to ensure the project or process being conducted is implemented as written or is revised accordingly.

8.1. *Implementing QAPPs*

When data is gathered by following an approved QAPP, another person(s) wishing to confirm those data can be reasonably certain that if they follow the same QAPP at the same location, under the same conditions, they can expect to get consistent results. They may also be able to determine that the QAPP could be effective at other, similar sites, or that data gathered using that QAPP could be comparable to data gathered under the same circumstances, at a similar location, or at a different point in time. When such data also is successfully evaluated using the data verification and validation processes, one also can be more confident the data will be scientifically and legally valid data. However, if the manner in which the data is initially gathered is not accurately documented, or if a QAPP is developed but not followed, it is less likely others will be able to achieve consistent results when they attempt to gather the same type of data at the same location. Such data will be less likely to be scientifically and legally valid.

For this reason, it is IDEM's policy to develop QAPPs that accurately reflect sound data gathering practices, and to follow those QAPPs during project implementation. While experienced staff may not see the need for planning and documenting the process they use for gathering data, such planning and documentation will be essential for those using the data at a later time. In addition, if the data gathered was to measure a change in conditions (such as before and after

implementation of a remedial action), following the same process during all data gathering events ensures valid data that can be used in such an assessment.

8.2. Developing and Implementing SOPs

When work is done following an SOP, the program area office management and staff should be assured that work is completed according to the best and most effective practices currently identified for completing that work. SOPs should be developed by the staff that actually performs the work described by the SOP. When this is the case, those staff members have the opportunity to discuss with their counterparts how that work is done and to identify, as a group, what the best methods are for completing that work. The agreed-upon best method is documented in an SOP that represents the standard method they each will follow; the SOP is then used as a tool to train other staff on the best process for completing the work.

SOPs are most useful for documenting processes that must be completed many times over, and completed the same way each time they are done. When that work is done accurately, following the SOP created to document how that work should be done, management can be assured that the work is done in the most effective manner possible, and will be completed the same way, each time it is completed.

8.2.1. When an SOP is needed

The 2007 IDEM QMP set a requirement for each section in the agency to develop 10 SOPs by July 2007. This requirement and the associated agency wide push to complete them resulted in significant staff resistance to what they saw as arbitrary “beans to count” by an impossible deadline, and a number of meaningless SOPs were developed just to meet the requirement. As a result of lessons learned from this series of events, IDEM QA staff and program area office staff representatives undertook a continuous improvement event in September of 2011 to reevaluate what processes need to follow a formal SOP and what elements need to be documented in an IDEM SOP. It was determined that SOPs were most appropriate for: 1) complex work processes that contain numerous steps and/or several junctures requiring decisions to be made, or 2) work processes that required the participation of multiple persons or program area offices. It previously was determined by the IDEM Quality Manager that processes associated with data gathering activities should be documented in Technical SOPs.

It also was determined that work processes for tasks that could be performed by one person, or that were not sufficiently complex for staff performing them to need to regularly refer to written instruction, probably did not merit documentation as an SOP. Those simpler work processes that program area office management still feel should be documented can instead be documented in standard work instructions, a simpler SOP-type document based on a format of the program area office’s choosing.

Development and proper implementation of QAPPs, SOPs, and other work plans is the responsibility of the individual program area offices. Agency QA staff are available to assist upon request. Ensuring that the work done by the various IDEM program area office staff is done in accordance with any associated QAPP, SOP, or other QA-related work plan also is the responsibility of the program area office management. As explained above, agency QA staff is available to help explain why QAPPs, SOPs, and other work plans should be followed as written, and to provide the appropriate templates as needed.

8.2.2. IDEM requirements for SOPs

As stated in Section 7, Planning, IDEM considers SOPs to be planning tools as well as implementation tools. A well written SOP provides detailed plans about the sequence of actions to be taken to complete a task. They document, in a step-by-step

fashion, the best work practices associated with the iterative work processes that generate the agency's primary work product: decision-announcing records such as permits, inspection reports, enforcement referrals, orders, cleanup plans, etc. As mentioned above, as a result of the September 2011 continuous improvement event focusing on SOPs, IDEM now has narrower criteria for the types of processes that should be documented in an SOP. The agency SOP templates also were revised in conjunction with that event, to make sure they met the needs of the customers – in this case, program area office management and staff.

IDEM now encourages use of two separate types of SOPs:

- Technical SOPs (TSOPs) remain more formal, and more reflective of the “*Guidance for Preparing Standard Operating Procedures U.S. EPA QA/G-6.*” TSOPs require flowcharts, written procedural steps, information on health and safety, cautions, interferences, calibrations, and trouble shooting. They also must include descriptions of staff roles, responsibilities, training, forms and equipment, resources, definitions, quality assurance and quality control requirements, records management details (again, management of the documents generated by using the TSOP), and appendices as appropriate. TSOPs are required for data gathering procedures.
- Administrative SOPs have been streamlined, and require only documentation of the procedural steps, any training requirements, records management (of the records generated using the SOP), references, and appropriate definitions. Administrative SOPs may include any visual tools (flowcharts, diagrams, screenshots, photos, tables, illustrations, etc.) that help the user, or they may be comprised entirely of text if that is all that is needed to convey the information needed to properly complete the task.

Program area office staff also may decide that less complex work process they still wish to document may be documented as standard work instructions, as mentioned above.

Program area office staff responsible for documenting a work process also is responsible for determining which work process document format to use.

8.2.3. SOP development and review process

Whenever program area office staff determines an SOP is needed, they select the appropriate SOP or TSOP template (as developed by the agency QA staff). The templates are available on the agency SharePoint site. They are encouraged to contact the IDEM QA staff early in the SOP development process and a QA system document number will be assigned at that time.

Each process involving data gathering, or otherwise associated with implementing a QAPP, must be documented as a technical SOP (TSOP). TSOPs each must be submitted to the agency QA staff, who will review the draft TSOP to ensure consistency with the agency standards (and U.S. EPA SOP requirements), as reflected in the TSOP template format. The format may not be altered, and must be followed except that elements of the template may, consistent with the graded approach, be left uncompleted if they are not relevant.

Any revisions to a TSOP suggested by the QA staff will be offered using the MS Word Track Changes feature. After review, the draft TSOP is returned to the program area office staff for completion. Consistent with the approach that QA staff is providing a service to the program area office staff, the program area office staff will determine the extent to which it will adapt suggestions made by QA staff. This is consistent with:

- The principle that program area office staff, who best know their own processes, should have ownership of and be responsible for their QA documents.

- The expectation that program area office staff will follow the TSOP once it is finalized (approved), and will further revise the TSOP if the version approved does not deliver the desired results. This is the ideal result, and will be the approach used by those program area office staff that want their TSOPs (and other QA-related documents) to add value to the work processes they document.

8.2.4. Responsibility for managing SOPs

IDEM QA staff shall continue to track the status of all program area office QA-related documents with respect to whether they are under development, approved, or expired. All approved and effective QA documents shall be available to all program area office staff, in the QA document library maintained by QA staff on the agency Extranet or SharePoint. QA documents posted on the agency Extranet or SharePoint can be withdrawn upon request by their respective program area office, or may be withdrawn by agency QA staff if it is determined a QA document is expired, and/or no longer utilized.

As detailed in Section 5, agency QA staff is responsible for the archiving of all expired QA documents, and for the version control of all effective QA documents submitted to QA staff by program area office staff, for document management purposes. Program area office staff QA documents not submitted for management by agency QA staff are the responsibility of the program area offices. Each program area office's document management practices should be addressed in their respective office QMPs.

As previously stated, IDEM QA staff also has made a less-complex SOP template available on the agency Extranet for use by all agency staff. However, while QA staff review is required for TSOPs, it is optional for SOPs and will be completed at the discretion of program area office staff.

Consistent with the principle that each program area office staff should take responsible ownership of its own QA documents, they may request that IDEM QA staff assist in reviewing a draft SOP, or they may decide such external input is unnecessary. Program area office staff may similarly decide that IDEM QA staff will continue to manage all their SOPs in the QA tracking spreadsheet and on the agency Extranet, or that program area office staff will instead manage their SOPs internally, within the office. Program area offices that opt to manage their SOPs internally are responsible for documenting in their respective office-level QMP, how they manage and establish version control over those SOPs.

Program area office standard work instructions also will be developed, managed, used, or removed from use solely at discretion of program area office staff.

9. Assessment and response

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

9.1. *Assessing the Adequacy of the IDEM Quality System*

While the IDEM quality system has expanded and matured significantly since the 2007 QMP was developed and approved, some aspects of the system still are under development. One significant aspect still under development is the agency's ability to assess its quality system. This does not mean that IDEM's quality system has not undergone significant assessment; however, it is not yet advanced enough to claim success using some of the more sophisticated quality assessment tools recommended in the various U.S. EPA quality assurance requirement and guidance documents (available online at www.epa.gov/quality/qa_docs.html).

There are currently two primary drivers for assessment of the agency's quality system. The first is the Quality Assurance Annual Reports that IDEM has submitted to U.S. EPA Region 5 QA managers each June since 2008. The annual review of agency QA-related practices, and the progress each of the various program area offices made each year with respect to those practices, provides IDEM QA staff and managers a comprehensive and useful assessment of QA-related progress during each year.

The second driver for assessment is the ongoing work by IDEM QA staff to develop quality related documents and practices. When QA documents and practices are put into place, new potential gaps in quality management may become apparent even if no formal assessment was conducted to look for such gaps; this shows quality planning and implementation builds upon itself, just as the lack of quality planning and implementation can further obscure the root cause of problems.

9.1.1. **Assessment tools**

Formal assessment tools recommended by U.S. EPA are in use at IDEM, although not yet widespread. The U.S. EPA description (from Terms and Definitions, *U.S. EPA Requirements for Quality Management Plans, EPA QA/R-2*, March 2001) of each such tool is provided in the list below, and each description is followed by a brief explanation of how that assessment tool has been incorporated into the IDEM QA system, to date:

- **Surveillance (quality)** is a continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

Surveillance is a primary quality control component of the IDEM quality system and is used extensively throughout the agency. IDEM traditionally has relied on a chain-of-review and approval by more experienced staff, most of whom also are managers. The agency's managerial surveillance is the principle method of review to ensure the quality of the work product, which at IDEM is either a decision-announcing-record or a document supporting a decision. Surveillance also is the principle quality assessment tool to ensure work is being done by staff with the proper training and experience, using the right equipment, the right methods, and/or the most appropriate data available.

- **Peer review** is a documented critical review of work by qualified individuals (or organizations) that are independent of those who performed the work, but are collectively equivalent in technical expertise. A peer review is conducted to ensure that activities are technically adequate, competently

performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them.

Peer review is officially encouraged and is in use throughout IDEM. Although there may be some overlap of responsibility for work products within each of the various agency program area office science support staff, due to the small size of the staff and the reliance on team work, IDEM staff doing peer review have an adequate degree of distance from the work product to be considered organizationally independent. The use of peer reviews may be further discussed in the associated program area office-level QMPs.

- **Performance Evaluation** is a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

This assessment activity is used by IDEM program area offices that rely on contracted services, especially contracted laboratory services.

- **Management Systems Review (MSR)** is a qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.

U.S. EPA QA managers sometimes perform MSR onsite reviews, which are conducted in a manner similar to a quality system audit, with a final report that may identify findings which require corrective actions. U.S. EPA Region 5 conducted an MSR at IDEM in August 2005.

- **Technical Review** is a documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

Like peer review, technical review is conducted by agency staff with technical expertise equivalent to or greater than those who produced the initial work product. As is the case with peer review, staff that conduct technical reviews generally have an adequate degree of independence from responsibility for the final work product.

- **Data Quality Assessment** is a statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test, and to determine the adequacy of the data set for its intended use.

Information is not available regarding the degree to which program area office staff conduct data quality assessment to determine the validity of data they collect. One of IDEM's QA goals under the 2012 QMP is to promote the use of any additional training available from U.S. EPA on the use of this QA tool.

- **Quality System Audit** is a documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the quality system are suitable and have been developed, documented, and effectively implemented in accordance with specified requirements.

To date, IDEM QA staff has not performed a formal quality system audit like those described in *U.S. EPA Guidance on Assessing Quality Systems QA/G-3*. IDEM's assistant commissioners and deputy assistant commissioners are responsible for driving the development and use of QA-related practices. When agency senior management or program area office management requests such an audit, QA staff will perform that audit. An executive-level staff member has been tasked with developing internal auditing skills and spending a portion of time conducting quality system audits.

- **Readiness Review** is a systematic, documented review of the readiness for the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

Information is not available regarding the degree to which program area office staffs rely on readiness reviews prior to the implementation of QAPPs and activities for which a planned QA-related process exists.

- **Technical Systems Audit** is a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system.

Information is not available to determine whether any program area office staff relies on technical system audits as an assessment tool for evaluating any agency quality system(s) or quality system(s) of any contracted entity, such as a laboratory. Program area office staff that conduct technical system audits discuss their processes in their respective office-level QMPs.

The degree to which program area offices use these assessment tools, or practices similar to them is addressed in the IDEM office-level QMPs that supplement this IDEM agency wide QMP. Under IDEM's program area office-centered approach to building a quality system, each program area office (air, land, water, and pollution prevention and technical assistance) is responsible to report on which assessment tools are employed, and how. Similarly, each office is responsible for its own QA assessments, QMP and annual reports, and for developing its own project (QAPPs) and process level (SOPs, work flows, etc.) quality documentation. IDEM agency wide QA staff provides QA related expertise as requested.

There also are several variables related to the agency's use of these assessment tools:

- Not all IDEM programs gather samples.
- Most IDEM programs do not operate labs where some of these types of assessments may be more commonly practiced.
- Some assessment tools in use by IDEM program area office staff, may consist of the same basic practices as those recommended by U.S. EPA, but simply may be referred to by a different name than is used by U.S. EPA.
- Some IDEM programs that perform sampling export the lab work to contractors. Because of the limited number of IDEM labs, and hence the limited number of IDEM staff familiar with laboratory-oriented protocol and

assessments, these IDEM programs rely on their contract labs to be certified by a third party, such as the National Environmental Laboratory Accreditation Conference (NELAC), rather than sending IDEM staff to conduct laboratory audits.

- Since IDEM still is building its quality system, assessment (which is the third step of the plan, do, check, act cycle) may not be something that all programs are ready to tackle at this time.

9.1.2. Future Assessments

For more than twenty-five years, assistant commissioners (ACs) at IDEM have each been responsible for and in charge of their respective program area offices. Staff at IDEM, including QA staff, does not have authority over ACs. Staff assists, advises, suggests, and serves, but lines of authority run from the IDEM Commissioner and ACs to staff. In fact, in every quality system model, quality staff ultimately reports to management. However, that the IDEM ACs now are responsible for quality system development and improvement does not mean that IDEM QA staff will not be proactive in helping them build a viable quality system within the agency.

IDEM QA staff has been successfully building working relationships with program area office staff since well before the IDEM 2007 QMP was approved. During that time, IDEM QA staff has developed a solid understanding of the status of QA practices – both strengths and shortcomings – throughout the agency. QA staff has assisted with the development and review of program area offices' QMPs, SOPs, QAPPs, QAPP-related work plans, and QA Annual Reports. IDEM QA staff increasingly is viewed by program area office staff as a resource, which is one of the milestones listed in U.S. EPA's model of the four stages of quality system development.

As IDEM QA staff is increasingly relied upon to assist with these smaller quality system components, they will be able to assist with pulling these small pieces together into a more holistic quality system. For example, the U.S. EPA's QA presentations depict the QMP as the 'umbrella' under which QAPPs exist. But are the QAPPs the byproducts of the QMP, which must be put into place first before there can be QAPPs? Or, are QAPPs the building blocks which must be completed first, before there can be a QMP? The IDEM Quality Manager and QA staff maintain that the QMP and the QAPPs (and associated SOPs and reports) evolve together, each being developed and improved incrementally, and often times at different rates, until a mature system results. Of course, that means that perhaps not all of the elements of either the QAPP or the QMP come into existence, or function as intended, at the same time.

As program area office ACs and staff work to develop and improve QAPPs (and related SOPs) they will begin to see that in order to ensure that each QAPP is as complete and as effective as the last, they may need to have a larger system in place whose purpose is to consistently develop effective data gathering plans that will produce accurate, reliable data. To improve the system that produces such QAPPs, it is anticipated the ACs will rely on the same QA staff that became a staff resource with respect to developing and improving SOPs and then QAPPs. And, of course, assessment is generally the first step in systematic improvement.

IDEM QA staff is now reviewing and improving QAPPs more effectively than ever. Program area office staff is beginning to appreciate the knowledge and assistance QA staff offers. Although IDEM has been busy producing various types of quality documentation, IDEM QA staff believes the agency is now entering a phase where it is understood that to produce more effective QA project documentation (QAPPs, etc.), more attention will need to be directed to a systematic approach to developing that documentation.

IDEM QA staff will make efforts to assess the state of agency and program area office quality system components. When assessments are requested or ordered, IDEM QA staff will provide assistance, including access to assessment training as it is available. Also, additional staff resources have been committed to the quality program, specifically to perform these assessments. Meanwhile, QA staff will continue to gather and evaluate information about the level of QA-related activity in place, and to provide input to the IDEM Quality Manager to communicate to the other ACs, the Chief of Staff, and the Commissioner.

As previously stated in Sections 1.3.6 and 2.2.3 of this QMP, program area office management shall be responsible for ensuring and determining the following:

- Which program area office staff members will develop QA documentation or implement QA-related activities, including QAPPs, SOPs, and TSOPs; and which staff members will conduct QA document review.
- When QA assessments will be performed within the program area office to ensure that completed work follows the appropriate QAPP and/or SOP(s) and whether QA staff shall participate in those assessments.
- When agency QA staff will perform quality assessments of the overall program area office quality system, in conjunction with the IDEM Quality Manager.
- The extent of program area office staff participation in continuous improvement exercises, QA-related training, or other QA-related activities.

9.1.3. Frequency of assessments

As stated in agency Quality Assurance Policy (Section 1.1.1 of this document), agency assistant and deputy assistant commissioners are directly responsible to the commissioner for the development, implementation, and ongoing improvement of the agency quality system. Any overall quality system assessment – such as a quality system audit or management system review – must be requested by them. When requested, IDEM QA staff provides QA-related customer service to program area office management and staff. QA staff will not independently schedule random quality system assessments. Nonetheless, agency QA staff will regularly remind program area office management of their availability to assist with any aspect of QA-related development, including a QA system assessment. If the IDEM QA staff is tasked with conducting a quality system assessment by the IDEM Quality Manager, they will follow the recommendations in *U.S. EPA Guidance on Assessing Quality Systems QA/G-3* to the fullest extent possible.

The use of those types of assessments and assessment tools not intended for system-wide assessment, such as assignment of peer reviews, technical reviews,

performance evaluations, readiness reviews, ongoing managerial surveillance or other assessment, is solely at the discretion of program area office staff. IDEM QA staff recommends that there be some reasonable degree of separation between staff doing the work to be reviewed and staff performing the review. If IDEM QA staff has a role in these types of assessments, it is to ensure program area office staff has access to any available training from U.S. EPA or other appropriate entities.

9.1.4. Selection of assessment processes and personnel

If a quality system assessment is requested, IDEM's Quality Manager and QA staff will work with agency and program area office management to determine the type of assessment that is appropriate, which staff is most qualified to conduct the assessment, and what type of pre-assessment training(s) will be necessary. Management also may identify issues of particular interest or establish parameters for the review. However, all final decisions regarding any such quality system assessment will be made by program area office management. Any personnel recommendations made by QA staff will be based on the independence of staff from the managers requesting the assessment and on adequate separation of staff invited to participate in the assessment from staff performing the work to be assessed. QA staff also will make recommendations to program area office management regarding the assessment team's access to program area office staff and documents, as well as its degree of organizational independence to conduct the assessment. All such final decisions regarding quality system assessments belong to the program area office management requesting the assessment.

9.2. Response

9.2.1. Corrective actions

To date, IDEM QA staff has not issued corrective actions. IDEM QA staff have responded to those corrective actions required by U.S. EPA Region 5 QA managers in response to their 2005 management system review.

Any corrective actions written and presented to IDEM by U.S. EPA Region 5 and/or GLNPO QA manager(s) (e.g., from a management system review or QAPP assessment), will be a priority. IDEM QA staff will work to implement U.S. EPA-recommended corrective actions through direct involvement at the agency wide level, and will assist program area office staff to implement U.S. EPA-recommended quality system corrections if requested.

As IDEM conducts more assessments of the quality system, formal corrective actions may be needed. These will be addressed by IDEM's Quality Manager in cooperation with the applicable program area office management.

9.2.2. Dispute resolution

To date, no formal assessment of IDEM's quality system has been conducted, so no disputes have arisen. As with any agency dispute, resolution will be accomplished through elevating the issue through the management hierarchy, including IDEM's Commissioner, if necessary. As assessments become more common within the agency QA system, agency QA staff will develop a dispute resolution mechanism. One of IDEM's goals during the effective period of this 2012 QMP is to develop a dispute resolution protocol reflective of the agency's management structure (also see the discussion at Section 1.3.6. Resolving QA-related disputes and at Section 1.1.4 QA Goals and objectives: Develop dispute resolution processes).

9.3. Current Assessment Goal: Training

As the IDEM quality system continues to develop, quality system assessments will be needed and may be sought by agency program area office management and staff. IDEM QA staff is seeking assessment-related training on topics including but not limited to how to plan, implement, document, and report the findings of an assessment.

As agency QA staff focuses on strengthening the overall agency QA system, other assessment skills likely would be useful as well; these skills include how to assess QAPP development and implementation and the data quality assessment activities associated with QAPPs. The opportunity to participate with U.S. EPA staff in an assessment also may be beneficial.

10. Quality Improvement

Purpose – To document how IDEM will improve its quality system.

10.1. *Identifying Process Improvement Opportunities*

Responsibility for fostering a QA-based work culture within IDEM rests with the various program area office management and staff. The ideal work culture has program area office staff welcoming the assessment of their quality system and striving to promote ongoing QA-related improvements. Again, the agency has determined that program area office managers and staff should take ownership of their respective quality systems and begin to incorporate more QA into their work, rather than consider it something they do in addition to their work. It is the responsibility of agency QA staff to assist with this task, when requested, by providing QA-related experience and expertise.

Per *U.S. EPA Guidance for Developing Quality Systems for Environmental Programs, QA/G-1*, there are four stages to the development of a viable quality system:

- Initiation (characterized by denial and reluctance)
- Development (characterized by acceptance)
- Implementation (characterized by leadership)
- Ongoing Maintenance and Improvement (the ideal, steady state)

Working through each of these stages involves using the four steps of the Shewart Cycle, more often referred to as the PDCA Cycle:

- Plan – Analyze the situation, develop solutions
- Do – Implement the planned solutions
- Check – Assess the results of the implementation
- Act – Take corrective action after assessment

The importance of the PDCA Cycle with respect to U.S. EPA quality system requirements is highlighted by the fact the final four sections of the QMP template featured *in U.S. EPA Requirements for Quality Management Plans (QA/R-2)* are planning, implementation of work processes, assessment and response, and quality improvement.

IDEM's continuous improvement (CI) program has been working to help program area office staff and agency wide service staff streamline processes, improve efficiency, and improve the quality of work products for several years. As practiced at IDEM, CI focuses on providing value to the customer by delivering high-quality work products that meet customer needs within a reasonable time frame. The principles and practices of CI are firmly rooted in the PDCA cycle: recognize opportunities for improvement, make the changes, determine whether the desired results were achieved (and why or why not), and take action to make additional improvements. This makes IDEM's CI program a natural fit with quality assurance, management, and improvement.

10.2. *Working with Groups to Build Ownership*

The majority of CI activities have focused on assisting various IDEM program area office staff to map out, review, and reorganize work flow processes of their choosing, with the intent to improve those work processes and the resultant work products. As previously mentioned, the CI initiative was combined with the agency QA staff during reorganization of the Office of Compliance Support in the first part of 2011. Since then, the CI program has facilitated activities to assist QA staff in rebooting the role of QA as a service group for the agency. Results have included:

- Clarifying how QA and program area office staff work together in the development of agency nonrule policies and program area office SOPs,
- Determining a common-sense approach for when an SOP is needed, and
- Deciding what should be included as content in documents to ensure that they are useful to those who must use them.

Outside of the IDEM QA program, most CI activities to date have focused primarily on process improvement, but not the QA aspects of those processes directly. However, strong emphasis is placed on incorporating tools and practices in work processes that build in quality from the beginning in order to provide value to the customer. Tools such as guidance and checklists for external customers and internal staff, templates, and standard work instructions ensure that necessary information is provided, consistent work processes and products are completed, and mistakes are avoided. Practices such as peer reviews, spot checks, and performance metrics assist in ensuring problems with work processes and products are quickly identified and corrected.

The results of CI activities usually include the development of new or revised standard work instructions and tools, such as letter templates and checklists. It is anticipated that as more program area office staff request CI activities to streamline or improve work processes, the 'final results' of the CI exercise will continue to become SOPs or standard work instructions documenting work processes and the QA-related elements of those processes. Because CI is based on the idea that those who do the work know best how to do the work – and also have the best ideas for how to improve it – and CI activities focus heavily on their input and agreement, program area office staff take ownership of the processes they have improved and the resulting work products.

10.3. *Rooting Out Conditions Adverse to Quality*

It is anticipated that as program area office staff refine and document work processes, QA practices related to the work will be incorporated more thoroughly. This will cause conditions adverse to quality work outcomes to be a concern, and increasingly practices will be put into place to prevent adverse impacts on quality. Program area office staff invested in the refinement and accurate documentation of work processes is much more likely to have a similarly strong interest in promptly identifying and correcting the root causes of poor work practices or poor quality results.

Meanwhile, IDEM QA staff members meet periodically with program area office staff members to discuss the agency's quality system. A major component of these discussions is identifying conditions adverse to quality. The source of these adverse conditions has often been the administrative requirements of the quality system itself. QA staff and the quality manager work to address these problems with input from program area staff and management. As the quality manager, program area office managers, and QA staff identify the need for and conduct assessments, conditions adverse to quality will be uncovered. QA staff will examine the results of these assessments in conjunction with other feedback provided by program area office staff to identify the common root causes among these problems so they can be addressed throughout the agency.

As IDEM's individual program area office quality systems – and their equally importantly culture of quality assurance – are developed and refined, procedures to promptly identify and correct conditions adverse to quality will be developed, documented, and implemented. The need for such procedures will be most readily identified by program area office management and staff that most rely on, and will most benefit from, a quick return to conditions conducive to quality. As with other aspects of IDEM's quality system, such procedures will be most useful when tailored to the specific circumstances of the affected program area office. Meanwhile, any solution general enough to address identifying and correcting quality adverse conditions throughout the agency will likely not be specific enough to identify or correct such problems at the program-specific level.

10.4. Promoting Continuous Improvement

IDEM began implementing continuous improvement of the agency's business processes in 2007 through contracting with consultants to facilitate Lean/Six Sigma events. To reduce costs and integrate continuous improvement practices agency-wide, an internal Continuous Improvement Coordinator was designated to facilitate process improvement events and lead other activities to improve IDEM's operations. In 2012, the Continuous Improvement Coordinator assumed leadership of the QA program, formalizing the natural link between quality assurance and continuous improvement.

The very nature of a CI activity is consistent with the recommendations of the *U.S. EPA Requirements for Quality Management Plans QA/R-2*, that agency wide staff and program area office staff at all levels identify the customers (both external and internal) of the various outcomes of a process. The CI activity also provides an opportunity for all parties involved in a process to communicate their needs, identify process improvement opportunities, and offer and evaluate solutions to problems that disrupt the ideal work flow or undermine the quantity or quality or work results.

During the effective period of the IDEM 2012 QMP, the IDEM CI coordinator and staff shall continue to:

- Facilitate, upon request, the review of program area office staff work flow processes to improve work performance of that process.
- Suggest, when appropriate, that a quality component be added to any data gathering process being examined for work process improvements.
- Maintain a focus on providing value to the customer by producing high quality work products quickly and consistently.

During the effective period of the IDEM 2012 QMP, the IDEM QA staff shall promote continuous improvement of the agency QA system by:

- Providing additional QA training as available.
- Establishing a mechanism to remind/encourage program area office staff to continually check that QA-related activities, especially data gathering activities, are both implemented as planned and documented as such.
- Identifying additional opportunities to assist program area office staff (QA's customers) incorporate quality in their day-to-day work.
- Assisting each agency program area office to sensibly build and expand their respective QA system and documentation, following U.S. EPA guidances (while also employing the graded approach as appropriate to ensure the most robust development and use of QA practices for the time invested) to add value to and improve the quality of each program area work product.

Appendices

Appendix A: IDEM Senior Management Team's Fiscal Year 2012 Goals and Objectives

Environmental Goals

While all IDEM program work is important, the goals and objectives listed here are high priority for completion by June 30, 2012.

- Improve Land Quality:
 - Complete CFO/CAFO Rulemaking
 - Implement revised Remediation Closure Guidance
 - Complete Remediation Program Guidance
 - Develop and implement Operator Training Program for UST owners / operators
 - On average, issue all permits in less time than statutory requirements
 - Develop training modules for staff on solid and hazardous waste

- Improve Water Quality:
 - Issue remaining backlogged permits
 - On average, issue all permits in less time than statutory requirements
 - Complete antidegradation rulemaking
 - Work with other state agencies to develop and implement a strategy for consolidation of water regulatory programs
 - Convert rule-based general permits to administratively issue general permits
 - Complete rulemaking to establish water quality criteria for total phosphorus in lakes
 - Revise water quality standard for chlorides
 - Implement and evaluate new water quality monitoring strategy
 - Complete review and approval of long term control plans

- Improve Air Quality:
 - Obtain attainment designations for currently designated PM-2.5 nonattainment areas
 - Perform SO₂ modeling necessary to develop new limits for major SO₂ sources
 - On average, issue all permits in less time than statutory requirements
 - Conduct a study of the actual and potential air emissions created by the distillation of mint
 - Implement the requirements of the 2012 Air Monitoring Plan

- Improve Compliance Support:
 - Establish a systems-based safety management plan, audited for compliance with OSHA rules, and metrics that will drive behavior-based activities
 - Establish training for regulatory staff using observations and data from VL's and inspection notices to target areas for improvement
 - Re-purpose our quality system toward simplification and an orientation towards improvement rather than simply instituting rigid standards
 - Continue to increase participation in our stewardship and compliance assistance programs

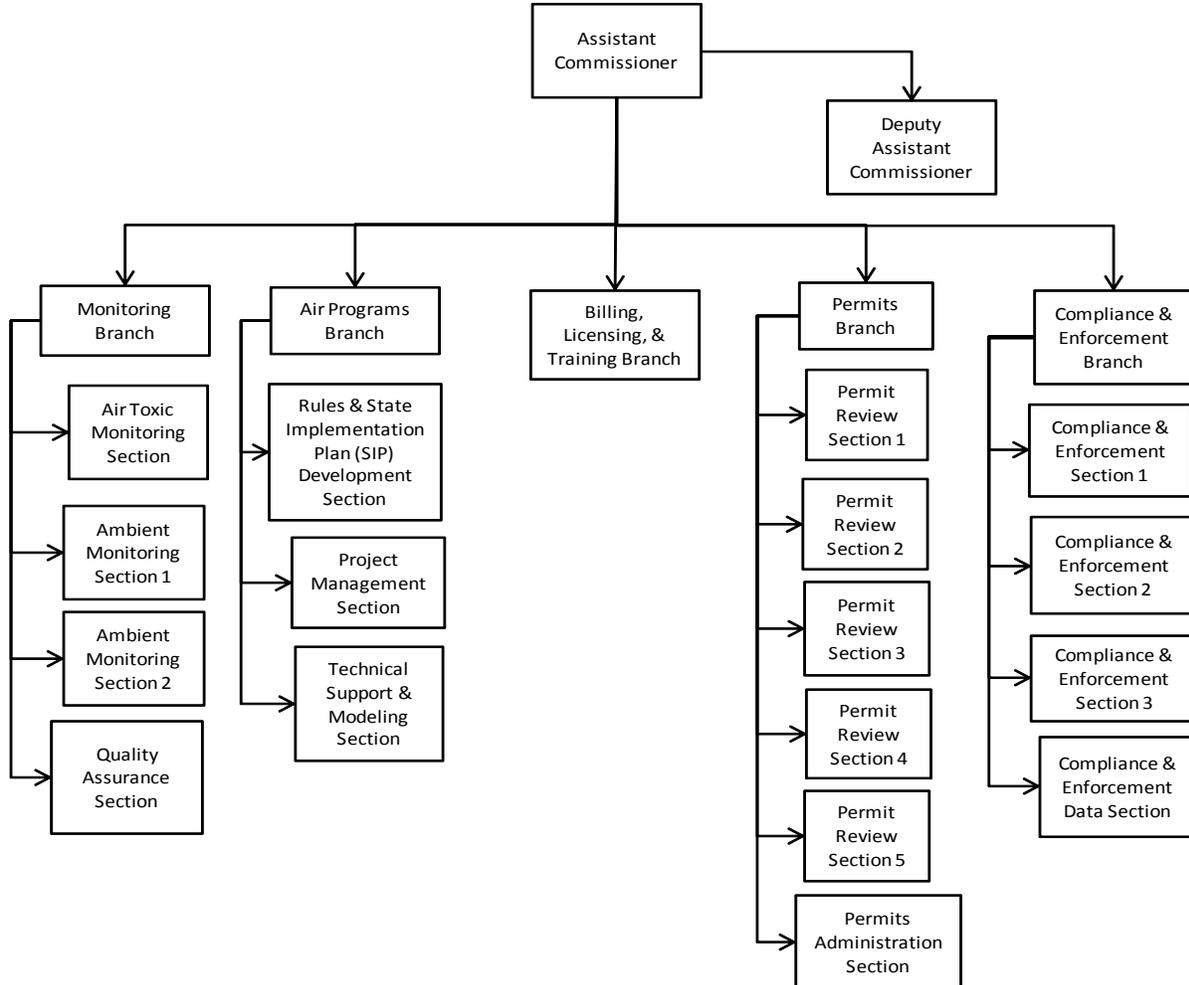
Administrative Goals

- Improve Internal Communications:
 - Commissioner

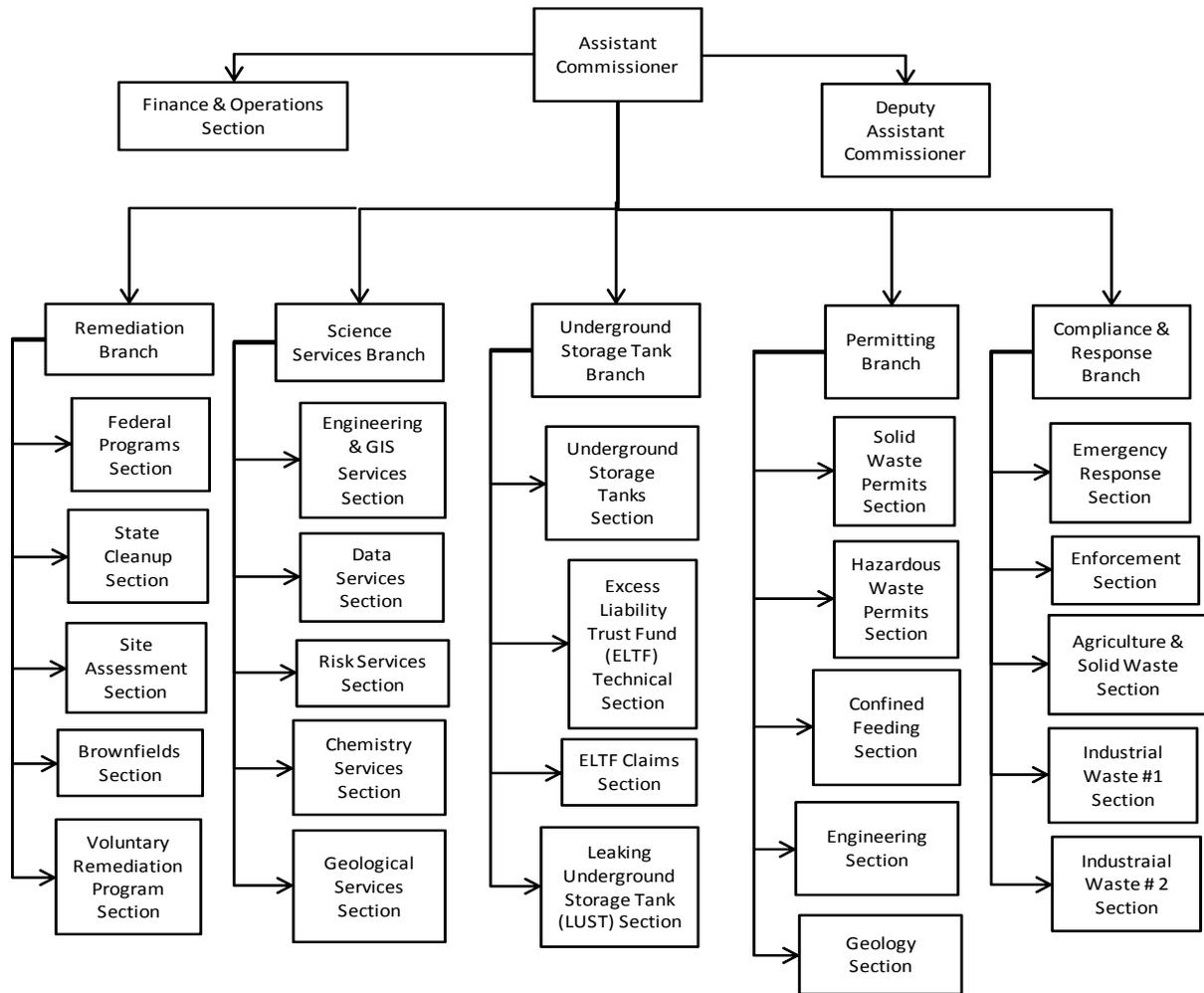
- Meet annually with all agency E7s and higher
 - Meet annually with all managers by office
 - Post quarterly letter on Extranet
 - Chief of Staff
 - Meet quarterly with all branch chiefs as a group
 - Assistant Commissioners/Deputy Assistant Commissioners
 - Meet with all staff at least annually
 - Post Bi-monthly letter on Extranet
 - Meet quarterly with Regional Office Directors
 - Restructure Extranet Front Page
- Improve External Communications:
 - Commissioner/Senior Management conduct meetings with editorial boards
 - Conduct regular meetings with stakeholders at program and agency level to enhance relationships
 - Participate in stakeholder meetings, trade conferences, and other group settings
 - Participate in inter-agency meetings at various levels
 - Revise metrics to ensure they better tell IDEM's story
 - Provide education and outreach (particularly as standards tighten) to increase understanding of relevant environmental topics
 - Identify significant changes for rules that go to boards for preliminary adoption
 - Update IDEM Internet site
- Maximize Value of Resources:
 - Identify agency wide needs for continuous improvement (kaizen events)
 - Establish working groups for major issues (as needed)
 - Prioritize and communicate status of IT initiatives including TEMPO, VFC, Digital Inspector, and SharePoint
- Training/Staff Development:
 - Organize formal, staff-level appropriate training sessions within program areas
 - Incorporate informal training as opportunities arise
 - Support inter- and/or intra-agency cross training
 - Conduct basic management/leadership training

Appendix B: IDEM Program Area and Support Office Organizational Charts

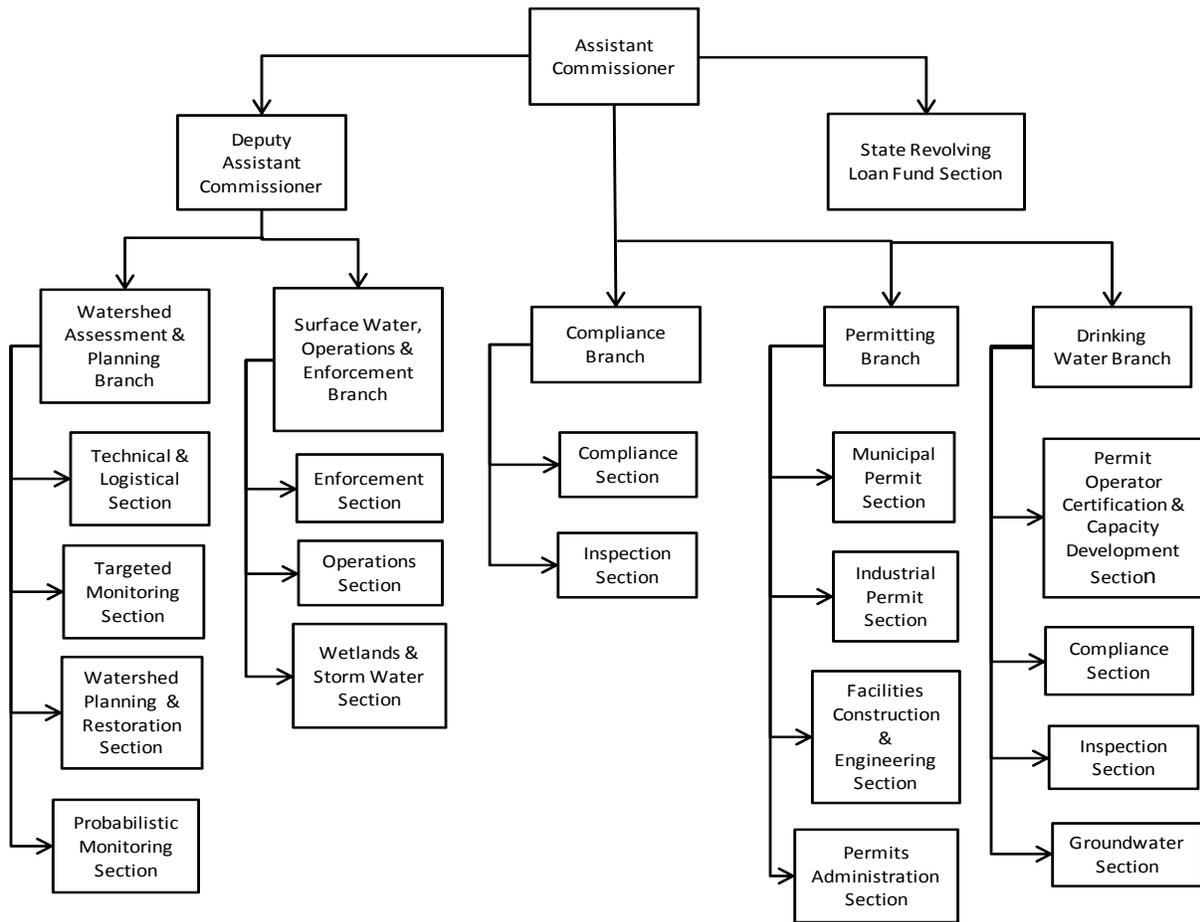
Office of Air Quality (OAQ) Organizational Chart



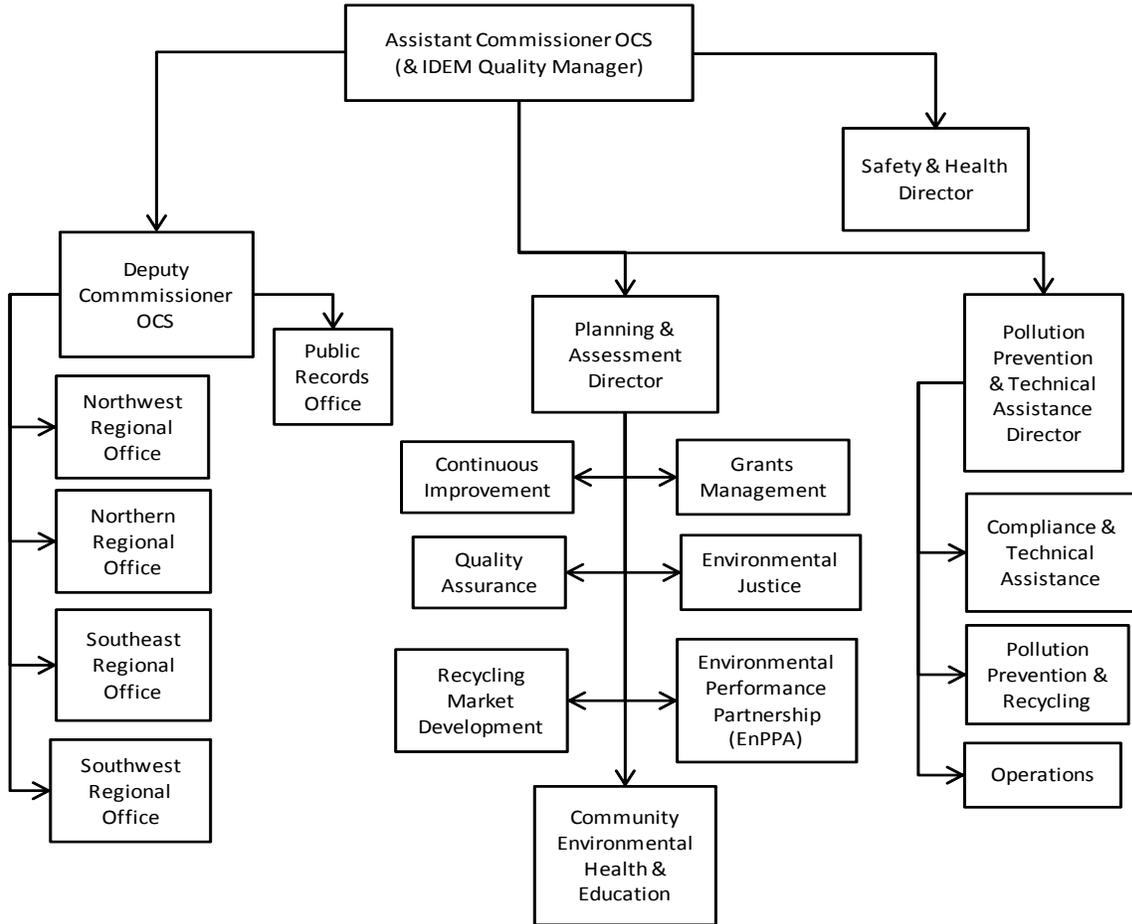
Office of Land Quality (OLQ) Organizational Chart



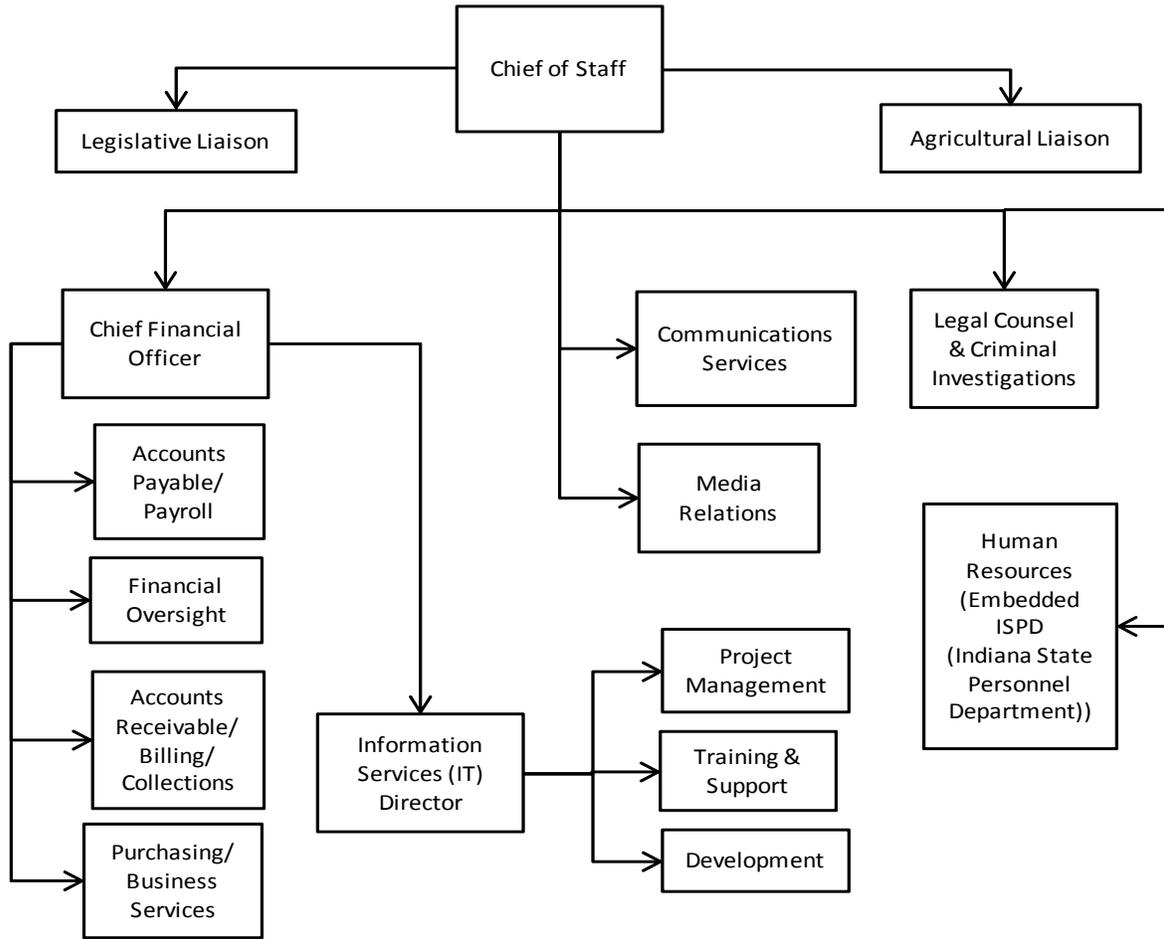
Office of Water Quality Organizational Chart



Office of Compliance Support (OCS) Organizational Chart



Office of the Chief of Staff Organizational Chart



Appendix C: IDEM Program Area Office Activities and Corresponding Federal Authorization

Listing of IDEM OAQ Programs and Their Corresponding Federal Authorization

Name of IDEM OAQ program, section, or branch	Brief description of the work completed	Authorizing Federal Statute
Permits Branch	Major source construction permits are issued to businesses seeking to build large new plants or major expansions at existing plants to meet the federal law requirement to have a major source construction permit before they break ground on a project. This program includes Prevention of Significant Deterioration (PSD) and Non-Attainment Area New Source Review (NA-NSR) permits.	The federal Clean Air Act, § 7410, requires Indiana to have a State Implementation Plan (SIP) that includes a permit program for the construction, modification and operation of new and existing businesses. Indiana's SIP is independently enforceable by the U.S. EPA, pursuant to 42 U.S.C. § 7413(a). U.S. EPA approved the PSD permit program into Indiana's SIP on March 3, 2003 (68 Federal Register 9892). EPA first approved the NA-NSR program into Indiana's SIP on February 16, 1982 (47 Federal Register 6621).
Permits Branch	Major source operating permits are issued to businesses that operate large sources of air pollution that are required by federal law to have a Part 70 operating permit, Title V Operating Permits (TVOP) for the very largest companies and Federally Enforceable State Operating Permits (FESOP) for businesses that can limit their emissions to less than 100 tons per year for each criteria pollutant. Each Part 70 permit sets out all the requirements that apply to the business and how it will stay in compliance with those requirements. Each permit contains emission limits and standards, testing, monitoring, record keeping and reporting requirements. OAQ is required to issue regular renewals of these permits.	The federal Clean Air Act (42 U.S.C. § 7661) requires that every major source have a TVOP or FESOP in order to operate. Indiana's FESOP program was approved in the Federal Register on August 18, 1995. EPA fully approved Indiana's TVOP program into Indiana's SIP on December 4, 2001 (66 Federal Register 629469).

Name of IDEM OAQ program, section, or branch	Brief description of the work completed	Authorizing Federal Statute
Permits Branch	The Air Permits Branch issues Source Specific Operating Agreements (SSOAs) to several specific types of businesses that would otherwise be required to have a Part 70 Operating Permit, if they agree to meet certain requirements.	The federal Clean Air Act (42 U.S.C. § 7661) requires that every major source have a TVOP or FESOP in order to operate. If a business did not have an SSOA it would be required to get a TVOP or FESOP. Indiana's SSOA program was approved as part of Indiana's SIP in the Federal Register on April 2, 1996.
Permits Branch	The Air Permits Branch issues Minor Source Operating Permits (MSOPs) to businesses that operate smaller sources of air pollution. Each MSOP sets out all the requirements that apply to that business and how the business will stay in compliance with those requirements. When smaller companies construct modifications or build new production plants they must have a modified or new MSOP before they may operate any new equipment or processes. In addition, OAQ is required to issue regular renewals of each MSOP.	The federal Clean Air Act, § 7410, requires Indiana to have a State Implementation Plan (SIP) that includes a permit program for the construction, modification and operation of new and existing businesses. The Indiana rule requiring MSOP permits, 326 IAC 2-5.1-4, was approved into Indiana's SIP by U.S. EPA in the Federal Register on June 18, 2007.
Permits Branch	The Air Permits Branch reviews information from businesses that may be eligible for a Permit By Rule. These businesses, that would otherwise be required to have a Part 70 Operating Permit, have the option of complying with requirements set out in the general Permit By Rule (PBR) or in specific PBR source categories. If a business meets the rule requirements it can operate without a Part 70 permit. Eligible sources prefer the PBR because there is no permit fee.	The federal Clean Air Act (42 U.S.C. § 7661) requires that every major source have a TVOP or FESOP in order to operate. If a business did not qualify for under the Permit By Rule program it would be required to get a TVOP or FESOP.

Name of IDEM OAQ program, section, or branch	Brief description of the work completed	Authorizing Federal Statute
Compliance and Enforcement Branch	Conduct compliance monitoring and enforcement activities including full and partial compliance evaluations, inspections, investigations stack test observations, report review reviews, and complaint investigations	Clean Air Act, Titles I-V
Programs Branch	The Programs Branch is responsible for the following: the development of State Implementation Plans (SIP), criteria pollutant and air toxics emission inventory development, Tox-Watch screening, data analysis projects, Photochemical and Prevention of Significant Deterioration (PSD) modeling, rule development, oversight of the Inspection and Maintenance (I/M) program, Transportation Conformity, mobile source modeling, and Diesel Wise Indiana.	Clean Air Act (CAA)

Name of IDEM OAQ program, section, or branch	Brief description of the work completed	Authorizing Federal Statute								
Monitoring Branch	<p>The mission of the Air Monitoring Branch is to obtain and provide timely and accurate data relating to Indiana's ambient air quality to enable informed decisions to be made regarding appropriate preventive and corrective actions that should be taken to safeguard the health of its citizens and the welfare of its environment.</p> <ul style="list-style-type: none"> • Determine NAAQS compliance for criteria pollutants (O3, SO2, NO2, CO, Pb, PM) • Conduct effective non-criteria pollutant monitoring • Conduct compliance, complaint, or research monitoring activities • Implement air monitoring network modifications outlined in the "2012 Indiana Ambient Air Monitoring Annual Network Plan". • Implement the monitoring requirements for the new Lead Standard at all required sites. • Conduct Technical Systems Audits on all Indiana industrial air monitoring networks by 12/31/12. • Continue the air toxics special studies in 2012. • Continue Indianapolis area BioWatch network operation including special events monitoring. 	<p>The Clean Air Act - Title 40 Protection of the Environment</p> <p>Part 50 National Primary and Secondary Ambient Air Quality Standards</p> <p>Part 53 Ambient Air Monitoring Reference and Equivalent Methods</p> <p>Part 58 Ambient Air Quality Surveillance</p> <p>Grants:</p> <table border="0"> <tr> <td>Air Operating</td> <td>5-409-105</td> </tr> <tr> <td>Title V</td> <td>5-500-000</td> </tr> <tr> <td>PM2.5</td> <td>5-498-103</td> </tr> <tr> <td>BioWatch</td> <td>5-542-091</td> </tr> </table>	Air Operating	5-409-105	Title V	5-500-000	PM2.5	5-498-103	BioWatch	5-542-091
Air Operating	5-409-105									
Title V	5-500-000									
PM2.5	5-498-103									
BioWatch	5-542-091									

Listing of IDEM OLQ Programs and Their Corresponding Federal Authorization

Name of IDEM OLQ program, section, or branch	Brief description of the work completed	Authorizing Federal Statute
RCRA Authorized Hazardous Management Program is implemented by the Hazardous Waste Permit Section of the Permits Branch, the Compliance and Enforcement Sections of the Compliance and Enforcement Branch, and the Planning and Assessment Office and Pollution Prevention and Technical Assurances Office in the Office of Compliance Support.	Core Program activities in the Office of Land Quality include: hazardous waste facility (generators and TSDs) compliance inspection and enforcement of the hazardous waste management statutes and rules; the issuance of hazardous waste operating and post closure permits, the closure and post closure management of regulated units and corrective action for Solid Waste Management Units (SWMUS) and Areas of Concern (AOCs) at RCRA TSD facilities. The Office of Compliance Support also receives RCRA federal funding under the EnPPA for grants management in the Planning and Assessment Office; and pollution Prevention (P2) and recycling, and compliance and technical assistance in the Pollution Prevention and Technical Assistance Office.	Resource Conservation and Recovery Act (RCRA) Section 3006(b), 42 United State Code (U.S.C.) 6926(b)
Industrial Waste Compliance Section 1	Facility inspections to determine compliance with hazardous waste TSD requirements	RCRA Subtitle C Yes, receive federal funding
Industrial Waste Compliance Section 1	Facility inspections to determine compliance with registered waste tire facility requirements	RCRA Subtitle D
Industrial Waste Compliance Section 1	Facility inspections to determine compliance with permitted restricted waste landfill requirements	RCRA Subtitle D
Industrial Waste Compliance Section 1	Facility inspections to determine compliance with auto salvage requirements	RCRA Subtitle D & C, CAA, CWA Yes, receive federal funding
Industrial Waste Compliance Section 1	Issue PCB remediation and disposal approvals	TSCA
Industrial Waste Compliance Section 1	Issue waste classifications for waste disposed in a restricted waste landfill or legitimately reused	RCRA Subtitle D
Industrial Waste Compliance Section 1	Issue approvals for legitimate reuse of waste	RCRA Subtitle D
Industrial Waste Compliance Section 2	Facility inspections to determine compliance with Hazardous Waste, Used Oil, and E-waste regulations	RCRA Subtitle C Yes, receive federal funding

Name of IDEM OLQ program, section, or branch	Brief description of the work completed	Authorizing Federal Statute
Industrial Waste Compliance Section 2	Facility inspections to determine compliance with PCB equipment storage requirements	TSCA
OLQ Enforcement Section	Issue, negotiate, and resolve enforcement actions for hazardous waste generator and TSD violations, used oil violations, and e-waste violations.	RCRA Subtitle C Yes, receive federal funding
OLQ Enforcement Section	Issue, negotiate, and resolve enforcement actions for restricted waste site and waste classification violations.	RCRA Subtitle D
OLQ Enforcement Section	Issue, negotiate, and resolve enforcement actions for waste tire facility violations.	RCRA Subtitle D
OLQ Enforcement Section	Issue, negotiate, and resolve enforcement actions for solid waste landfill, transfer facility, processor, and open dump violations.	RCRA Subtitle D
OLQ Enforcement Section	Issue, negotiate, and resolve enforcement actions for auto salvage facility violations.	RCRA Subtitle C and D and CWA Yes, receive federal funding
OLQ Enforcement Section	Issue, negotiate, and resolve enforcement actions for UST and LUST violations.	RCRA Subtitle I Yes, receive federal funding
OLQ Enforcement Section	Issue, negotiate, and resolve enforcement actions for confined feeding operation violations.	CWA
OLQ Enforcement Section	Issue, negotiate, and resolve enforcement actions for land application violations.	CWA
OLQ Enforcement Section	Issue, negotiate, and resolve enforcement actions for emergency spill response violations.	CWA and CERCLA
OLQ Enforcement Section	Issue, negotiate, and resolve enforcement actions for hazardous substance information request violations.	CERCLA
Emergency Response Section	Responds to calls that are made to the 24 hr. spill line	No authorizing federal statute, just state statute

Name of IDEM OLQ program, section, or branch	Brief description of the work completed	Authorizing Federal Statute
Solid Waste – Ag & SW Compliance Section	Facility inspections to determine compliance with solid waste landfill and processing facility requirements	RCRA Subtitle D
Solid Waste – Ag & SW Compliance Section	Facility inspections to determine compliance with small and medium Concentrated Feeding Operations	State program
Solid Waste – Ag & SW Compliance Section	Facility inspections to determine compliance with Large Concentrated Animal Feeding Operations	NPDES *IDEM receives federal funding for NPDES program but OLQ Branch doesn't
Solid Waste – Ag & SW Compliance Section	Facility inspections to determine compliance with Septage Hauler permits	State program
Site Investigation Program	The Site Investigation program was established to evaluate, assess, and investigate uncontrolled or abandoned hazardous waste sites that pose a potential or real threat to human health and/or the environment. This section determines if sites require immediate response actions, qualify as federal Superfund sites, or should be referred to another state or federal program. The program is funded through a cooperative agreement with the U.S. EPA.	CERCLA, as amended by SARA (42 USC Sec. 9601 et seq) National Contingency Plan (40 CFR Pt. 300)
Defense Environmental Restoration Program (DERP)	The purpose of the DERP program is protection of human health and the environment through the investigation and cleanup of active, closing or formerly used military installations at which hazardous substances and/or petroleum products were used, stored, or disposed of during past operations.	BRAC Law CERCLA, as amended by SARA (42 USC Sec. 9601 et seq) National Contingency Plan (40 CFR Pt. 300) Non-NPL sites may use state rules and policies as authorized by the above federal statutes.
RCRA Authorized Underground Tanks Program is implemented by the Underground Tank Section , the Leaking Underground Tank of the Underground Tank Branch, and the Enforcement Section of the Compliance and Response Branch.	Tank registration activities, compliance inspection and enforcement of the underground tank statutes and rules; management of regulated tanks and corrective action for leaking USTs	Resource Conservation and Recovery Act (RCRA) Section 9004. 42 US Code 6991b as amended.

Name of IDEM OLQ program, section, or branch	Brief description of the work completed	Authorizing Federal Statute
Indiana Brownfields Program	The Indiana Brownfields Program (Program), managed by the Indiana Finance Authority (Authority) and including IDEM staff, works in partnership with the U.S. EPA and other Indiana agencies through a goal-oriented approach to assist in the assessment, cleanup, and reuse of brownfields by helping communities and/or other parties to identify and mitigate environmental barriers that impede sustainable redevelopment and local economic growth. Under the directive of federal and state brownfields-related laws, regulations, and policies, the Program's main goal is to partner with communities to help promote the reuse of existing properties, recognize and clean up brownfields, and revitalize economically depressed areas, while being protective of human health and the environment. Federal funding supports technical oversight of state and federal grant-funded assessment and cleanup activities and other Program expenses (e.g., training, outreach). Through the Authority, state legislation allows for the provision of services and the distribution of grant and low-interest loan funds to eligible communities for environmental assessment and cleanup of brownfield properties. In addition, the Program offers Comfort Letters, Site Status Letters, and No Further Action Letters to eligible entities to address liability and environmental	CERCLA, as amended by SARA (42 USC Sec. 9601 et seq) National Contingency Plan (40 CFR Pt. 300) UST regs (40 CFR Pt. 280)
Superfund Program	The purpose of the Superfund Program is protection of human health and the environment through the cleanup and management of uncontrolled or abandoned hazardous waste sites listed or eligible to be listed on the federal Superfund National Priorities List (NPL) as mandated by Superfund Law	CERCLA, as amended by SARA (42 USC Sec. 9601 et seq) National Contingency Plan (40 CFR Pt. 300)
State Cleanup Program (SCP)	The primary purpose of SCP is the protection of human health and the environment through the management of short-term (immediate removal) to long-term remediation (<i>i.e. cleanup</i>) of petroleum sites and hazardous waste sites.	Indiana Code (IC) 13-24-1 and IC 13-25-4 This program is state administered and has no federal involvement or funding.

Name of IDEM OLQ program, section, or branch	Brief description of the work completed	Authorizing Federal Statute
Voluntary Remediation Program (VRP)	The VRP was established to provide 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 the site investigation and, if necessary, remediation to ensure that cleanups are health-protective and consistent with agency goals and regulations. At the successful conclusion of the project, IDEM issues a Certificate of Completion, and the Indiana Governor's office issues a Covenant Not to Sue to the VRP participant for the property.	Indiana Code IC 13-25-5 This program is state administered and has no federal involvement or funding.

Listing of IDEM OWQ Programs and Their Corresponding Federal Authorization

Name of IDEM OWQ program, section, or branch	Brief description of the work completed	Authorizing Federal Statute
Surface Water, Operations and Enforcement Branch, Enforcement Section	Enforce violations of the CWA and SDWA.	Clean Water Act Safe Drinking Water Act
Surface Water, Operations and Enforcement Branch, Stormwater and Wetlands Section	Storm Water Permitting, Industrial Storm Water Permitting and Municipal Separate Storm Sewer Systems Wetlands 401 Water Quality Certifications.	Clean Water Act
Surface Water, Operations and Enforcement Branch, Operations Section	Oversees the budget, contracts, purchasing OWQ, regional sewer districts and geothermal certifications	Clean Water Act
Watershed Assessment and Planning Branch, Probabilistic and Targeted Monitoring Sections	Water quality monitoring to provide data for assessing all waters of the state including trophic status of lakes and reservoirs, to support development of water quality criteria/standards, to support public health advisories, to support NPDES and DW permitting activities, to develop TMDLs, to support watershed planning and restoration activities and to ascertain performance measures.	Clean Water Act
Drinking Water Branch, Public Water Supply System program	Implement the Safe Drinking Water Act at Indiana Public Water Systems	Safe Drinking Water Act
Drinking Water Branch, Ground Water Section	Implementation of the Ground Water Component of Indiana's Water Monitoring Strategy.	Section 305(b) of the Clean Water Act
Permits Branch, NPDES General Permits Program	Processing of NOIs for coverage under general permits.	Clean Water Act, Section 402

Name of IDEM OWQ program, section, or branch	Brief description of the work completed	Authorizing Federal Statute
Permits Branch, Industrial Wastewater Pretreatment Permits	Processing of applications for Significant Industrial Users that discharge into POTWs, except for those POTWs which have federally delegated pretreatment programs.	Clean Water Act, Section 402
Permits Branch, Combined Sewer Overflow Program	Review and approve Long Term Control Plans and Plan Updates for the 108 CSO communities in the state.	Clean Water Act, Section 402