
CIO Notification for Environmental Data Quality Issues Procedure

Directive No: CIO 2105-P-03.0

*Issued by the EPA Chief Information Officer,
Pursuant to Delegation 1-19, dated 07/07/2005*

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1. PURPOSE

This Procedure describes the comprehensive, coordinated due diligence process for evaluating environmental data quality issues that could have an adverse effect on the Environmental Protection Agency (EPA) organizations. It also describes the procedure for notifying all potentially affected EPA organizations.

The intent of the notification procedure is to communicate how the Agency plans to provide information about data of questionable quality to potentially affected organizations. This will allow potentially affected organizations to evaluate the impact of the data on its environmental decisions. Data quality issues may be attributed to lack of adequate Quality Assurance (QA) processes including: beginning data collection activities without an approved Quality Assurance Project Plan (QAPP) or other required QA documentation; improper chain-of-custody practices; inconsistent and/or incomplete entry of laboratory results in lab notebooks or other official records; manipulation of field/lab instrumentation results; and, lack of training and proficiency of staff generating the data. Data quality issues could also be attributed to improper QA practices for work acquired through an extramural funding vehicle. Management controls for data review and due diligence process should be documented in an organization's Quality Management Plan (QMP).

2. SCOPE

The Procedure applies to all EPA organizations having environmental data activities. This includes work supported by a contract, grant or other extramural agreement. Program and regional offices should invoke this due diligence process when made aware of questionable quality data submitted to EPA.

For this application "environmental data" is defined in the *Policy and Program Requirements for the Mandatory Agency-Wide Quality Management System (CIO 2105.0)* as any measurements or information that describe environmental processes, locations or conditions; ecological or health effects and consequences; or the performance of environmental technology. Environmental data activities that are covered by this procedure may include, but are not limited to, data sampling and collection; data testing, evaluation and validation; analyses and exposure studies that are the results of data manipulation; and, methods development.

This Procedure does not apply to suspected laboratory fraud. Report suspected laboratory fraud to the Office of Inspector General (OIG). Also, this procedure does not apply to investigations conducted by the Office of Enforcement and Compliance Assurance (OECA)/Office of Criminal Enforcement, Forensics and Training (OCEFT) because internal reporting procedures are in place to communicate fraud and other data quality issues to internal and external stakeholders.

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3. AUDIENCE

The audience of this Procedure is all Agency employees responsible for the generation and use of environmental data that support the EPA mission.

4. BACKGROUND

EPA's directive *Policy and Program Requirements for the Mandatory Agency-Wide Quality System* (CIO 2105.0) provides requirements for EPA organizations that collect, evaluate and use environmental data. This policy is supported by the *EPA Quality Manual for Environmental Programs* (CIO 2105-P-01), which provides a detailed description of how EPA organizations should implement the Agency's quality policy for environmental data operations.

The Office of Environmental Information (OEI), now Office of Mission Support – Environmental Information (OMS-EI) issued a *Quality Policy* (CIO 2106.0) for EPA disseminated products and services in 2008. This policy is supported by a *Quality Procedure* (CIO 2106-P-01). Section G of this Procedure includes a description of a CIO Notification Process. This process requires that:

1. EPA organizations have procedures in place to conduct an internal review of quality-related issues with any of their disseminated products or services;
2. The EPA organization's Senior Information Official (SIO) sends the OMS-EI Deputy Assistant Administrator (AA) and Chief Information Officer (CIO) information about any environmental data quality-related issue with a product or service that may adversely affect Agency operations; and
3. The OMS-EI Deputy AA and CIO notifies EPA SIOs of the quality-related issue and ensures that organizations are kept informed of the ongoing evaluation and the final outcome.

In 2010, OMS-EI issued a memorandum to clarify the scope and applicability of the *Quality Policy* (CIO 2106.0). This memorandum stated that the scope of the Quality Program encompasses quality activities concerning the collection, production and use of environmental data. This changed the focus of the EPA Quality Program from disseminated products and services to environmental data.

In 2014, the Office of the Inspector General issued Report No. 14-P-0270, *EPA Has Not Implemented Adequate Management Procedures to Address Potential Fraudulent Environmental Data* (May 2014). This Quality Procedure helps to address this OIG report by providing a more detailed description of the CIO Notification Process. It also describes the due diligence process the Agency plans to follow to evaluate environmental data quality issues.

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5. AUTHORITY

Policy and Program Requirements for the Mandatory Agency-Wide Quality Management System (CIO 2105.0, May 2000) and the Quality Policy (CIO 2106.0, October 2008), establish the authority for this Procedure.

6. PROCEDURE**6.1 Management Review**

- 6.1.1 EPA organizations should have established procedures for conducting a management review of environmental data quality issues. At a minimum, these procedures should determine the 1) potential impact of the environmental data quality issue on the organization and 2) the corrective actions needed to address any concerns regarding the continued use of the environmental data. This applies to each organization affected by the data quality issue.
- 6.1.2 If an individual or organization suspects fraud, it should be reported to the OIG Hotline. Additional information about fraud can be found on the OIG Resource Page at <http://intranet.epa.gov/oig/>. By default, the following steps are not pursued for cases where fraud is suspected, unless otherwise indicated by the OIG.
- 6.1.3 If the organization finds that the environmental data quality issue would affect other EPA organizations, it should complete the notification process found in Section 6.2. If the environmental data quality issue only affects the EPA organization that discovered the issue, it should document the findings of the management review and implement the appropriate corrective actions in accordance with the procedures found in the organization's Quality Management Plan (QMP). Organizations should report results of the internal management review in the organization's Annual Quality Assurance Report to OMS-EI. The Enterprise Quality Management Division (EQMD) will review the implementation of corrective actions during scheduled Quality System Assessments (QSAs).
- 6.1.4 If an individual in an organization suspects cybersecurity violations, then the suspected violations should also be reported to the organization's Information Security Officer or the EPA Call Center (866-411-4372). If it is determined that there are no cybersecurity violations, then the organization should document this finding in its records. Additional information about cybersecurity can be found on the EPA Information Security Program intranet site at <http://intranet.epa.gov/oei/cybersecurity.html>.

6.2 Notification Process

- 6.2.1 The organization's SIO sends the OMS-EI Deputy AA and CIO a memorandum with a courtesy copy to the OMS-EI Office of Enterprise Information Programs (OEIP) Director, the OMS-EI OEIP EQMD Director, and EPA's Scientific Integrity Official in the Office of the Science Advisor (OSA). At a minimum, the memorandum from the SIO should include the following information:

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- i. A description of the issue or suspected issue
 - ii. The scope of potential impacts of the environmental data quality issues
 - iii. The name of the entity that produced the environmental data
 - iv. The timeframe in which the environmental data was produced by the entity
 - v. The timeframe of receipt of the environmental data produced by or for the Agency (if applicable)
 - vi. A list of potentially affected EPA organizations
- 6.2.2 The OMS-EI Deputy AA and CIO issues the CIO Notification Memorandum to the EPA SIOs in response to the memorandum received from the affected organization.
- 6.2.3 The EQMD Director distributes the CIO Notification Memorandum to QA Community Leads and uploads it to the QA Community SharePoint site.

6.3 OMS-EI Evaluation Process

- 6.3.1 EQMD will evaluate the reported information and convene an Evaluation Workgroup to determine the impact and risk to the Agency from the reported information. The Evaluation Workgroup will consist of the following representatives:
- i. the EQMD Director, who will chair the workgroup;
 - ii. representatives from affected EPA organization(s), including at a minimum, the QA Manager (QAM) or Director of Quality Assurance (DQA);
 - iii. a representative(s) from the Office of General Counsel (OGC);
 - iv. representatives from the Office of Administration and Resources Management (OARM), including representatives from the Office of Grants and Debarment and the Office of Acquisition Management; and other representatives as needed.
- 6.3.2 The Evaluation Workgroup reviews the information sent to the OMS-EI Deputy AA and CIO, to determine the potential risk and the impact of the data quality issue on the Agency's environmental data quality activities. If needed, the Evaluation Workgroup may obtain additional information to evaluate the data quality issue.
- 6.3.3 The EQMD Director provides the results of the Evaluation Workgroup's review to the OMS-EI Deputy AA and CIO. The Evaluation Workgroup's report will include background information, a summary of the evaluation and recommendations for next steps if further action is required.
- 6.3.4 The OMS-EI Deputy AA and CIO reviews the report of the Evaluation Workgroup's review and provides direction to the EQMD Director on the content of the CIO Notification Findings Memorandum.
- 6.3.5 The EQMD Director prepares the draft CIO Notification Findings Memorandum.
- 6.3.6 The EQMD Director sends the draft CIO Notification Findings Memorandum to the OEIP Office Director for review and transmittal to the OMS-EI Deputy AA and CIO.
- 6.3.7 The OMS-EI Deputy AA and CIO reviews the draft CIO Notification Findings Memorandum, makes the appropriate edits and issues the final memorandum to EPA SIOs.

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- 6.3.8 The EQMD Director sends a copy of the CIO Notification Findings Memorandum to the QA Community Leads for distribution and posts the CIO Notification Findings Memorandum on the EPA QA Community SharePoint site. All affected organizations are to report the results of internal management reviews in their respective Annual Quality Assurance Report to OMS-EI. EQMD will review the implementation of corrective actions during scheduled QSAs.

7. ROLES AND RESPONSIBILITIES**Assistant Administrators (AA) and Regional Administrators (RA)**

Assistant Administrators (AA) and Regional Administrators (RA) ensure that policies and procedures defined in this Procedure are developed and implemented consistently throughout their programs and will dedicate sufficient resources to support the effective implementation of this Procedure within their organizations. Each AA or RA may re-delegate the responsibilities for this Procedure to appropriate senior managers. OMS-EI recommends that AAs and/or RAs give one or more individuals the responsibility and authority to ensure that this Procedure is implemented and followed consistently.

Deputy Assistant Administrator for the Office of Mission Support - Environmental Information (OMS-EI) and Chief Information Officer (CIO)

OMS-EI's Deputy Assistant Administrator and Chief Information Officer (Deputy AA/CIO) acts as the EPA Senior Management Official for Quality Management and is responsible for overseeing the agency's Quality Program and this Quality Procedure. The Deputy AA and CIO is responsible for informing AAs, RAs and Laboratory Directors of any issues related to the quality of Agency environmental data encompassed by this Procedure. The Deputy AA and CIO will review the Evaluation Workgroup recommendations and issue the CIO Notification Memorandum.

Senior Information Official (SIO)

Agency SIOs ensure that their environmental programs conduct a management review when they receive information about environmental data quality issues that could potentially affect programmatic decisions. The SIO reviews the results of these internal management reviews and makes a decision about the scope and impact of the quality issue. If a quality issue only affects that organization's environmental data activities, the SIO ensures that the appropriate corrective actions are taken. If the quality issue potentially affects other EPA organizations, the SIO informs the OMS-EI Deputy AA and CIO. The SIO is responsible for distributing the OMS-EI Deputy AA and CIO Notification Findings Memorandum within the organization.

Office of General Counsel (OGC)

The Office of General Counsel (OGC) participates on the Evaluation Workgroup and provides advice on legal aspects related to data quality issues.

Evaluation Workgroup

The Evaluation Workgroup reviews the information found in the CIO Notification Memorandum to determine the potential risk and impacts of the quality issue on the Agency's environmental data operations. If needed, the Workgroup may obtain additional information to evaluate the quality issue. The Evaluation Workgroup makes

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recommendations to the OMS-EI Deputy AA and CIO about the actions the Agency should take. Refer to Section 6.3.1 for the Evaluation Workgroup members.

OMS-EI Office of Enterprise Information Programs (OEIP) Enterprise Quality Management Division (EQMD) Director

The EQMD Director leads the Evaluation Workgroup, develops the draft Notification Memorandum and CIO Findings Memorandum for the Deputy AA and CIO approval, and maintains all records associated with the CIO Notification Procedure. The EQMD Director posts information and correspondence about the data quality issue to the QA Community SharePoint site.

Office of Administration and Resources Management (OARM)

Representatives from the OARM Office of Grants and Debarment (OGD) and the Office of Acquisition Management (OAM) participate in the Evaluation Workgroup.

EPA Quality Assurance Managers (QAM) and Directors of Quality Assurance (DQA)

EPA Quality Assurance Managers (QAMs) and Directors of Quality Assurance (DQAs) should develop their organization's management review procedures, and they may participate in their organization's management review, review the results and/or oversee the completion of any corrective actions. They may also participate on the Evaluation Workgroup.

8. RELATED INFORMATION

- *Policy and Program Requirements for the Mandatory Agency-Wide Quality Management System* (CIO 2105.0, May 5, 2000)
- *EPA Quality Manual for Environmental Programs* (CIO 2105-P-01-0, May 5, 2000)
- *Quality Policy* (CIO 2106.0, October 20, 2008)
- CIO Clarification Memorandum, Subject: EPA Quality Policy (CIO 2016.0, December 10, 2010)
- *Quality Procedure* (CIO 2106-P-01.0, October 20, 2008)
- ASQ/ANSI E4, *Quality Management Systems for Environmental Information and Technology Programs – Requirements with Guidance for Use* (2014)
- *EPA has not Implemented Adequate Management Procedures to Address Potential Fraudulent Environmental Data*, Office of Inspector General Report, Report No. 14-P-0270; May 29, 2014

9. DEFINITIONS

Due Diligence Process: A review to determine the procedure for managing the communications and actions addressing environmental data quality issues.

Environmental Data: Any measurements or information that describe environmental processes, locations, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include

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information collected directly from measurements, produced from models, and compiled from other sources such as databases or the literature.

Fraud/Fraudulent Data: The deliberate falsification of analytical and quality assurance results. A number of practices may constitute fraud and include, but are not limited to:

- fabricating data;
- intentionally calibrating equipment using other than accepted procedures;
- modifying samples to alter characteristics;
- manipulating analytical results; and
- substituting samples, files or data.

10. WAIVERS

N/A

11. MATERIAL SUPERSEDED

N/A

12. CONTACTS

For information about this Procedure or the Quality Program, please contact the Office of Mission Support – Environmental Information, Office of Enterprise Information Programs, Enterprise Quality Management Division. For information about the OECA/OCEFT reporting processes, please contact the OCEFT QAM.

Vaughn Noga
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and Chief Information Officer***
U.S. Environmental Protection Agency

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APPENDIX A:

ACRONYMS & ABBREVIATIONS

AA	Assistant Administrator
CIO	Chief Information Officer
DQA	Director of Quality Assurance
EPA	Environmental Protection Agency
EQMD	Enterprise Quality Management Division
OAM	Office of Acquisition Management
OARM	Office of Administration and Resources Management
OCEFT	Office of Criminal Enforcement, Forensics and Training
OECA	Office of Enforcement and Compliance Assurance
OEIP	Office of Enterprise Information Programs
OGC	Office of General Counsel
OGD	Office of Grants and Debarments
OIG	Office of Inspector General
OMS-EI	Office of Mission Support – Environmental Information
OSA	Office of the Science Advisor
QA	Quality Assurance
QAM	Quality Assurance Manager
QAPP	Quality Assurance Project Plan
QMP	Quality Management Plan
QSA	Quality System Assessment
RA	Regional Administrator
SIO	Senior Information Official

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APPENDIX B:

CIO NOTIFICATION PROCEDURE PROCESS DIAGRAM

