

Issued by the EPA Chief Information Officer, Pursuant to Delegation 1-19

CIO Notification for Environmental Data Quality Issues Procedure

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 this 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, but not limited to: beginning environmental information operations without an approved QA 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 information. 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).

SCOPE

The Procedure applies to all EPA organizations having environmental information operations. This includes work supported by a contract, grant or other extramural agreement. EPA organizations shall invoke this due diligence process when questionable information is submitted to EPA.

For this application "environmental information" is defined in the current version of the <u>Environmental Information Quality Policy</u> to include data and information that describe environmental processes or conditions which support EPA's mission of protecting human health and the environment. Examples include but are not limited to:

- direct measurements of environmental parameters or processes;
- analytical testing results of environmental conditions (e.g., geophysical or hydrological conditions);



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- information on physical parameters or processes collected using environmental technologies;
- calculations or analyses of environmental information;
- information provided by models;
- information compiled or obtained from databases, software applications, decision support tools, websites, existing literature, and other sources;
- development of environmental software, tools, models, methods and applications; and
- design, construction, and operation or application of environmental technology.

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.

3. AUDIENCE

The audience of this Procedure is all Agency employees responsible for environmental information operations that support the EPA mission.

4. AUTHORITY

The current version of the Environmental Information Quality Policy establishes the authority for this Procedure.

5. PROCEDURE

5.1. Management Review

- 5.1.1. 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 information. This applies to each organization affected by the data quality issue.
- 5.1.2. If an individual or organization suspects fraud, it should be reported to the OIG Hotline. Additional information about fraud can be found on

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- 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.
- 5.1.3. If the organization finds that the environmental data quality issue would affect other EPA organizations, it shall complete the notification process found in Section 5.2. 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 QMP. Organizations should report results of the internal management review in the organization's Annual Quality Assurance Report to the Office of Mission Support (OMS), Office of Records, Administration, and e-Discovery (ORASE), Enterprise Quality Management Division (EQMD)I. The EQMD will review the implementation of corrective actions during scheduled Quality Program Assessments (QPAs).
- 5.1.4. 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 EPA Information Security Program Intranet site..

5.2. Notification Process

- 5.2.1. The organization's Senior Information Official (SIO) sends the Chief Information Officer (CIO) and Deputy Assistant Administrator (DAA) for Information Technology/Information Management (IT/IM) a memorandum with a courtesy copy to the ORASE and EQMD Directors, 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:
 - 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 information.
 - iv. The timeframe in which the environmental information was produced by the entity.

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- v. The timeframe of receipt of the environmental information produced by or for the Agency (if applicable).
- vi. A list of potentially affected EPA organizations.
- 5.2.2. The CIO and DAA for IT/IM issues the CIO Notification Memorandum to the EPA SIOs in response to the memorandum received from the affected organization.
- 5.2.3. The EQMD Director distributes the CIO Notification Memorandum to QA Community and uploads it to the QA Community SharePoint site.

5.3. OMS Evaluation Process

- 5.3.1. 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:
 - i. EQMD Director, who will chair the workgroup;
 - ii. representatives from affected EPA organization(s), including at a minimum, the QA Manager (QAM);
 - iii. representatives from the Office of General Counsel(OGC);
 - iv. representatives from the Office of Grants and Debarment (OGD) and/or the Office of Acquisition Solutions (OAS); and other representatives as needed.
- 5.3.2. The Evaluation Workgroup reviews the information sent to the CIO and DAA for IT/IM, to determine the potential risk and the impact of the data quality issue on the Agency's environmental information operations. If needed, the Evaluation Workgroup may obtain additional information to evaluate the data quality issue.
- 5.3.3. The EQMD Director provides the results of the Evaluation Workgroup's review to the CIO and DAA for IT/IM. The Evaluation Workgroup's report will include background information, a summary of the evaluation and recommendations for next steps if further action is required.
- 5.3.4. The CIO and DAA for IT/IM reviews the Evaluation Workgroup's report and provides direction to the EQMD Director on the content of the CIO Notification Findings Memorandum.
- 5.3.5. The EQMD Director prepares the draft CIO Notification Findings Memorandum.
- 5.3.6. The EQMD Director sends the draft CIO Notification Findings
 Memorandum to the ORASE Director for review and transmittal to the
 CIO and DAA for IT/IM.
- 5.3.7. The CIO and DAA for IT/IM reviews the draft CIO Notification Findings



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Memorandum, makes the appropriate edits and issues the final memorandum to EPA SIOs.

5.3.8. The EQMD Director sends a copy of the CIO Notification Findings Memorandum to the QA Community 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 EQMD. EQMD will review the implementation of corrective actions during scheduled QPAs.

6. ROLES AND RESPONSIBILITIES

Assistant Administrators (AA) and Regional Administrators (RA)

AAs and RAs 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.

Chief Information Officer (CIO) and Deputy Assistant Administrator (DAA) for Information Technology/Information Management (IT/IM)

The CIO and DAA for IT/IM serves as the EPA Senior Management Official for EPA's Quality Program and is responsible for overseeing implementation of this Procedure. The CIO is responsible for informing AAs, RAs and Laboratory Directors of any issues related to the quality of Agency environmental information operations encompassed by this Procedure. The CIO and DAA for IT/IM 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 decides about the scope and impact of the data quality issue. If a data quality issue only affects that organization's environmental information operations, the SIO ensures that the appropriate corrective actions are taken. If the data quality issue potentially affects other EPA organizations, the SIO informs the CIO and DAA for IT/IM. The SIO is responsible for distributing the CIO Notification Findings Memorandum within their organization.

Office of General Counsel (OGC)



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The 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 data quality issue on the Agency's environmental data operations. If needed, the Workgroup may obtain additional information to evaluate the data quality issue. The Evaluation Workgroup makes recommendations to the CIO and DAA for IT/IM about the actions the Agency should take. Refer to Section 5.3.1 for the Evaluation Workgroup members.

Enterprise Quality Management Division (EQMD) Director

The EQMD Director leads the Evaluation Workgroup, develops the draft Notification Memorandum and CIO Findings Memorandum for the CIO and DAA for IT/IM 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 Grants and Debarment (OGD) and Office of Acquisition Solutions (OAS)Representatives

Representatives from OGD and OAS participate in the Evaluation Workgroup.

EPA QA Managers (QAM)

EPA QAMs 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.

7. RELATED INFORMATION

These citations are valid at the time of issuance of this Procedure. Since these documents are subject to periodic review, users of this Procedure should refer to the current version.

- Environmental Information Quality Policy
- Environmental Information Procedure
- ASQ/ANSI E4, Quality Management Systems for Environmental Information and Technology Programs – Requirements with Guidance for Use:2014 (R: 2019)
- <u>EPA has not Implemented Adequate Management Procedures to Address Potential</u> Fraudulent Environmental Data, Office of Inspector General Report, Report No. 14-



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P- 0270; May 29, 2014

8. **DEFINITIONS**

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

Environmental Information: Includes data and information that describe environmental processes or conditions which support EPA's mission of protecting human health and the environment. Examples include but are not limited to:

- direct measurements of environmental parameters or processes;
- analytical testing results of environmental conditions (e.g., geophysical
- or hydrological conditions);
- information on physical parameters or processes collected using
- environmental technologies;
- calculations or analyses of environmental information;
- information provided by models;
- information compiled or obtained from databases, software applications,
- decision support tools, websites, existing literature, and other sources;
- development of environmental software, tools, models, methods and
- applications; and
- design, construction, and operation or application of environmental technology.

Environmental Information Operations: A collective term for work performed to collect, produce, evaluate, or use environmental information and the design, construction, operation or application of environmental technology.

Fraud/Fraudulent Data: The deliberate falsification of analytical and QA 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.

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10. DIRECTIVE(S) SUPERSEDED

CIO Notification Procedure, CIO2105-P-03.0, August 10, 2020.

11. CONTACTS

For information about this Procedure contact the OMS/ORASE/EQMD or email quality@epa.gov. For information about the OECA/OCEFT reporting processes, please contact the OCEFT QAM.

Vaughn Noga, Chief Information Officer and Deputy Assistant Administrator for Information Technology and Information Management



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APPENDIX A:

ACRONYMS & ABBREVIATIONS

AA Assistant Administrator
CIO Chief Information Officer

DAA Deputy Assistance Administrator EPA Environmental Protection Agency

EQMD Enterprise Quality Management Division

IM Information ManagementIT Information TechnologyOAS Office of Acquisition Solutions

OCEFT Office of Criminal Enforcement, Forensics and Training OECA Office of Enforcement and Compliance Assurance

OGC Office of General Counsel

OGD Office of Grants and Debarments
OIG Office of Inspector General
OMS Office of Mission Support

ORASE Office of Records, Administrative Systems and e-Discovery

OSA Office of the Science Advisor

QA Quality Assurance

QAM Quality Assurance Manager
QAPP Quality Assurance Project Plan
QMP Quality Management Plan
QPA Quality Program Assessment
RA Regional Administrator
SIO Senior Information Official