
Environmental Information Quality Procedure

Directive No: CIO 2105-P-01.1

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

Environmental Information Quality Procedure

1. PURPOSE

This Procedure supports the implementation of EPA's *Environmental Information Quality Policy* (CIO 2105.1). This Procedure establishes management principles and responsibilities for ensuring that EPA environmental information and technology products and operations meet Agency quality-related requirements, are of sufficient quality for their intended use, and support EPA's mission to protect human health and the environment.

This Procedure describes Policy implementation and the governance of EPA's Quality Program. It is intended to provide a comprehensive, coordinated approach for consistent implementation of the Quality Policy to ensure the continual improvement in the quality of EPA's environmental information and technology programs.

The quality tools and processes described in this Procedure are based on national and international consensus standards. They will assist the Office of Mission Support (OMS), Deputy Assistant Administrator (DAA) for Environmental Information (EI) and Chief Information Officer (CIO) in overseeing the Agency's Quality Program.

2. SCOPE

This Procedure defines the minimum requirements for the Quality Program supporting EPA environmental programs that encompass the collection, production, evaluation, or use of environmental information by or for EPA and the design, construction, and operation of environmental technology. Collectively these activities are referred to as environmental information operations.

3. AUDIENCE

The audience for this Procedure is all Agency employees responsible for environmental information operations that support the EPA mission. This includes Headquarters and Program Offices, Regions, and their sub-organizations. When cited in extramural agreements, this Procedure also applies to non-EPA organizations (e.g., states, tribes, localities, regulated parties, volunteer organizations, contractors, cooperative agreement holders, grantees, other federal governmental agencies, intergovernmental organizations, educational institutions, and other environmental information providers) performing work in support of EPA's mission or national program priorities as defined by and in accordance with federal laws, regulations, extramural agreements, or performing work on a voluntary basis under agreement with EPA.

4. BACKGROUND

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42 Since 1979, it has been an Agency requirement for all EPA organizations supporting
43 environmental programs and non-EPA organizations performing work on behalf of EPA to
44 participate in an Agency-wide Quality Program. Documentation of this requirement, with a
45 scope of primary environmental data collection, was first written in April 1984, in EPA
46 Order 5360.1, *Policy and Program Requirements for the Mandatory Agency-Wide Quality*
47 *Management System*.

48
49 On May 5, 2000, this Order was reissued and in 2008, renumbered as CIO 2105.0, and
50 was written with the intent for the Agency's Quality Program to be applicable to only
51 environmental data collection, production, or use. On October 20, 2008, CIO 2106, *Quality*
52 *Policy* and CIO 2106-P-01.0, *Procedure for Quality Policy* were published and addressed
53 all Agency products and services. The issuance of CIO 2106 did not rescind CIO 2105
54 and CIO 2105-P-01-0. As a result, there were two existing Quality Policies with an
55 undefined relationship.

56
57 A clarification memorandum issued December 12, 2010, by the Assistant Administrator
58 (AA)/CIO, restricted CIO 2106 to only be applicable to environmental data collection,
59 production, and use. The memorandum also directed that the Agency use the Federal
60 Managers Financial Integrity Act (FMFIA) process for administrative and financial quality-
61 related issues; and indicated use of the Information Quality Guidelines (IQG) process for
62 all other quality-related issues.

63
64 Subsequently, on August 1, 2017, the CIO's Strategic Advisory Council (SAC) made the
65 decision to rescind CIO 2106 and update CIO 2105 to be consistent with ASQ/ANSI E4
66 (2014) and current Agency directives that have quality components.
67

5. AUTHORITY

68
69 These citations are valid at the time of issuance of this Procedure. Since these documents
70 are subject to periodic review, users of this Procedure should refer to the most recent
71 version.
72

- 73
- 74 • [National Technology Transfer and Advancement Act \(NTTA\) \(PL 104-113\)](#)
- 75 • [Clinger-Cohen Act of 1996 \(PL 104-106\)](#)
- 76 • [Office of Management and Budget \(OMB\) Circular A-130, Management of Federal](#)
77 [Information Resources](#)
- 78 • [Information Quality Act \(IQA\), Section 515 of Treasury and Government](#)
79 [Appropriations Act, 2001 \(PL 106-554, 31 USC 3516\)](#)
- 80 • [2 CFR 1500.11: Uniform Administration Requirements, Cost Principles and Audit](#)
81 [Requirements for Federal Awards, Quality Assurance](#)
- 82 • [40 CFR Part 35: State and Local Assistance](#)
- 83 • [40 CFR Part 40: Research and Demonstration Grants \(EPA's Quality System-](#)
84 [Related Regulations\)](#)
- 85 • [48 CFR Part 46: Quality Assurance](#)
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6. PROCEDURE

This Procedure outlines EPA's Quality Program requirements to support EPA's mission to protect human health and the environment and to ensure environmental information operations are of known and documented quality for their intended use(s). It defines the DAA/CIO's role in leading the Agency Quality Program and recognizes and builds upon existing environmental information operations quality-related policies, procedures, and activities implemented across the Agency. This Procedure ensures a comprehensive and coordinated approach for consistent implementation of continual improvement in the quality of EPA's environmental information operations. Also, all environmental information operations performed for the Agency through extramural agreements must comply with this Procedure as defined in extramural agreements.

This Procedure requires organizations to develop, implement, and maintain a Quality Program. Each organization listed in Section 3 and covered by the scope of this Procedure must:

A. Assign a Quality Assurance Manager. The title of this position may vary by organizational structure [e.g., Director of Quality Assurance (DQA) and Regional Quality Assurance Manager (RQAM)]. For this Procedure, this position will be referred to as the Quality Assurance Manager (QAM). Organizations should identify and assign a QAM. This person will function independently of direct environmental information production, model development, or technology development for issues within their authority. The QAM must have Quality Management expertise, and the authority to conduct independent oversight of the organization's Quality Program. They will report on quality issues to senior managers having executive leadership authority for the organization. Refer to Section 7, Roles and Responsibilities, for a list of activities to be performed by QAMs.

Each EPA QAM will have their role specified in their position description and will have their responsibilities documented in their Performance Appraisal and Recognition System (PARS).

The QAM authority is independent of environmental information operations. The operations manager (e.g., program manager) will not have authority to sign QA documentation for the QAM, nor will the QAM have authority to sign QA documentation for the operations manager. The two functions, QA and operations, must remain independent; however, in small organizations outside of the EPA (e.g., small tribal departments), these two functions may be combined with approval from the EPA QAM serving this organization.

The QAM must have authority to access and discuss quality issues with their organization's senior leadership, outside of their direct supervisory chain as necessary. This delegation of authority to the QAM, from their management must be documented in the Quality Management Plan (QMP).

B. Develop a Quality Management Plan. Describe and document their Quality Program in a QMP consistent with the current version of EPA QA/R-2, *EPA Requirements for*

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136 *Quality Management Plans*¹. The QMP describes the organization's Quality Program.
137 It documents how the organization structures its Quality Program and describes its
138 quality policies and procedures; criteria for and areas of application; and roles,
139 responsibilities, and authorities. It also describes an organization's policies and
140 procedures for implementing and assessing the effectiveness of the Quality Program.
141 The QMP must document all technical activities to be performed under the Quality
142 Program and how the program will integrate QA and quality control (QC) procedures
143 and plans into all its environmental information operations activities. Approval of an
144 EPA organization's QMP requires signatures by their executive leadership. Depending
145 upon the level of the QMP, the OMS DAA/CIO or the Office of Enterprise Information
146 Programs (OEIP) Director will approve and sign the organization's QMP. The QMP
147 must include provisions for dispute resolution to include technical and management
148 systems disputes.
149

150 Each Agency organizational unit governed by the Quality Procedure shall document
151 its Quality Program in a QMP. When stated in extramural agreements, non-EPA
152 (extramural) organizations conducting environmental information operations funded by
153 or implemented on behalf of EPA (e.g., states, tribes, and contracts) also are required
154 to establish and document their Quality Program in a QMP or equivalent document
155 accepted and approved by EPA. Each extramural agreement that funds environmental
156 information or technology programs or projects shall include specific language, such
157 as contract clauses or assistance agreement terms and conditions, concerning
158 requirements for documentation of extramural Quality Programs; such language may
159 cite applicable regulations.
160

161 When preparing QMPs, organizations shall adhere to QMP development and content
162 requirements found in the current version of *EPA Requirements for Quality
163 Management Plans*, EPA QA/R-2². EPA QA/R-2 was originally intended for
164 organizations that conduct environmental information operations through contracts,
165 assistance agreements, and interagency agreements; however, it was designed so
166 that it could be used by EPA as well. Because EPA QA/R-2 contains the same QMP
167 requirements as EPA *Quality Manual for Environmental Programs*, CIO 2105-P-01-0,
168 which is being superseded by this Procedure, EPA and external organizations shall
169 now use EPA QA/R-2.
170

171 EPA QA/R-2 describes the quality management practices and QMP elements that are
172 normally considered to be critical to an effective Quality Program. If the QMP preparer
173 determines that additional quality management elements are useful or necessary for
174 an adequate Quality Program, these elements shall be developed and discussed in
175 the QMP.
176

177 When addressing the planning requirements of EPA QA/R-2, each organization shall
178 determine content requirements for Quality Assurance Project Plans (QAPPs) that
179 best suit its needs by project type where projects do not readily fit in the structure or
180 described contents of the current version of *EPA Requirements for Quality Assurance*

¹ The current version of this document is available at <https://www.epa.gov/sites/production/files/2016-06/documents/r2-final.pdf>

² The current version of this document is available at <https://www.epa.gov/sites/production/files/2016-06/documents/r2-final.pdf>

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181 *Project Plans*, EPA QA/R-5³ and document that determination. This Procedure does
182 not make recommendations on guidance or tools for QAPPs suitable for projects.

183
184 All QMPs shall be approved and signed by the senior management of the
185 organization, as described in EPA QA/R-2. EPA organizations shall submit their QMPs
186 to the EPA Enterprise Quality Management Division (EQMD) for review and approval.
187 Non-EPA organizations shall submit their QMPs to the EPA official responsible for the
188 work, as described in EPA QA/R-2. All organizations (EPA and non-EPA) shall review
189 their QMP at least annually to reconfirm the suitability and effectiveness of the
190 approved quality management practices.

191
192 In general, a copy of any QMP revision(s) made during the year should be submitted
193 to the approving authority as a report when such changes occur. However, if
194 significant changes have been made to the quality system that affect the performance
195 of work, it may be necessary to re-submit the entire QMP for re-approval. Conditions
196 requiring the revision of an approved QMP include:

- 197
198
- expiration of the five-year life span of the QMP;
 - major changes in mission and responsibilities, such as changes in the
199 delegation status of a program;
 - re-organization of existing functions that affect programs covered by the QMP;
200 and
 - assessment findings requiring corrective actions and response.
- 201
202
203
204

205 Refer to paragraph J, Conduct Reporting, of this Procedure for information on tracking
206 QMPs. When EPA QMPs are submitted to EQMD for review and approval, EQMD
207 shall use an EPA QA tracking tool as described in paragraph J of this Procedure to
208 track receipt, review, and approval of the QMP. EQMD also shall use the information
209 in the tracking tool to facilitate reporting metrics as part of the Agency-wide Quality
210 Program Management Reviews described in paragraph J of this Procedure.

211
212 When extramural QMPs are submitted to EPA organizations for review and approval,
213 the EPA QAM shall use an EPA approved tool to track and report receipt, review, and
214 approval of their extramural QMP.

- 215
216 **C. Provide for Resources.** Ensure resources are available to implement the Quality
217 Program as defined in their QMP, including QA resources required for extramural
218 activities in support of EPA. The Senior Manager having executive authority in the
219 organizations is responsible for providing resources. Resources are knowledgeable
220 personnel, funding, materials, supplies, and time.
- 221
222 **D. Conduct Systematic Planning.** Document the processes for systematic planning and
223 use them to develop acceptance or performance criteria and to perform design,
224 construction, and operations for all environmental information operations.

225
226 Environmental information and technology operations shall use a systematic planning
227 process that is based on the scientific method. The planning process shall be based

³ The current version of this document is available at <https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf>

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228 on a common sense, graded approach to ensure that the level of detail in planning is
229 commensurate with the importance and intended use of the work and the available
230 resources. Elements of a systematic planning approach that shall be documented
231 include:

- 232
- 233 • Identification and involvement of the project manager, sponsoring organization
234 and responsible official, project personnel, stakeholders, scientific experts, etc.
235 (*e.g., all customers and suppliers*);
- 236 • Description of the project goal, objectives, and questions and issues to be
237 addressed;
- 238 • Identification of project schedule, resources (including budget), milestones, and
239 any applicable requirements (e.g., regulatory requirements, contractual
240 requirements);
- 241 • Identification of the type of information needed and how the information will be
242 used to support the project's objectives;
- 243 • Determination of the quantity of information needed and specification of
244 performance criteria for measuring quality;
- 245 • Description of how, when, and where the information will be obtained (including
246 existing information) and identification of any constraints on information
247 collection;
- 248 • Specification of needed QA and QC activities to assess the quality performance
249 criteria (e.g., QC samples for both the field and laboratory, audits, technical
250 assessments, performance evaluations, sensitivity analysis of models, etc.);
- 251 • Description of how the acquired information will be analyzed (either in the field
252 or the laboratory), evaluated (i.e., QA review, validation, verification), and
253 assessed against its intended use and the quality performance criteria.

254
255 To the extent possible, the systematic planning process shall ensure that all
256 organizations and/or parties who contribute to the quality of the environmental project
257 or use the results are identified and that they participate in this process. The planning
258 process shall also provide for direct communication between the customer and the
259 supplier to ensure that there is a clear understanding by all participants of the needs
260 and expectations of the customer and the product or results to be provided by the
261 supplier. EPA has developed a systematic planning process called the Data Quality
262 Objectives (DQO) Process, or scientific method. While not mandatory, this process is
263 the recommended planning approach for many EPA information collection activities.

264
265 **E. Prepare Quality Assurance Project or Program Plan Documentation.** Document
266 the output of systematic planning in QAPPs or equivalent document (in this Procedure
267 referred to as QAPPs) and approve them for use. Detailed information for QAPP
268 development is provided in the current version of EPA QA/R-5, *EPA Requirements for*
269 *Quality Assurance Project Plans*⁴, or in other tools or guidance developed by
270 organizations to support development of QAPPs for existing data projects as required.
271 QAPPs must describe the project DQOs, applicable QA procedures, QC

⁴ The current version of this document is available at https://www.epa.gov/sites/production/files/2016-06/documents/r5-final_0.pdf

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272 specifications, and implementation of other activities to ensure the expected quality of
273 the project results.

274
275 This Procedure requires that all work performed by or on behalf of EPA involving
276 environmental information and technology operations shall be implemented in
277 accordance with an Agency-approved QAPP. The QAPP is a critical planning
278 document for any environmental information operations since it documents how
279 environmental information operations are planned, implemented, documented, and
280 assessed during the life cycle of a program, project, or task. The ultimate success of
281 an environmental program or project depends on the adequacy and sufficiency of the
282 quality of the environmental information obtained for use in decision making. This may
283 depend significantly on the adequacy of the QAPP and its effective implementation.
284 Systematic planning is an essential component of project management, and the QAPP
285 provides the mechanism for documenting the results of the planning process. This
286 planning should include the “stakeholders” (e.g., decision makers, information
287 producers, gatherers, and users) to ensure that all needs are defined adequately at
288 the outset and that the planning for quality addresses the specific needs defined.
289

290 The current version of EPA QA/R-5, *EPA Requirements for Quality Assurance Project*
291 *Plans*, presents detailed specifications on the information that must be addressed in a
292 QAPP for environmental information operations performed by or on behalf of EPA;
293 these specifications are known as QAPP elements, and, as presented in EPA QA/R-5,
294 these elements represent the information generally required for many operations
295 involving the characterization of environmental processes and conditions, such as field
296 sampling and laboratory analyses. Because of the diversity of Agency programs,
297 some elements described in EPA QA/R-5 may not be applicable to all programs. The
298 final decision on the applicability or use of any or all these elements for QAPPs shall
299 be made by individual EPA organizations. Each EPA organization may tailor these
300 requirements in its own implementation documents (e.g., QMP, guidance documents,
301 standard operating procedures (SOPs), templates, etc.) to better fit its specific needs.
302

303 Guidance on developing QAPPs, including examples of addressing required QAPP
304 elements, may be found in the current version of several guidance documents and
305 other tools, such as:

- 307 • *Guidance for Quality Assurance Project Plans*, EPA QA/G-5⁵;
- 308 • *Guidance for Geospatial Data Quality Assurance Project Plans*, EPA QA/G-
309 5G⁶;
- 310 • *Guidance for Quality Assurance Project Plans for Modeling*, EPA QA/G-5M⁷;
- 311 • *EPA Council for Regulatory Environmental Modeling’s (CREM’s) Guidance on*
312 *the Development, Evaluation, and Application of Environmental Models*⁸; and

⁵ The current version of this document is available at <https://www.epa.gov/sites/production/files/2015-06/documents/g5-final.pdf>

⁶ The current version of this document is available at <https://www.epa.gov/sites/production/files/2015-06/documents/g5g-final.pdf>

⁷ The current version of this document is available at <https://www.epa.gov/sites/production/files/2015-06/documents/g5m-final.pdf>

⁸ The current version of this document is available at https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf

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- 359 • Standard Operating Procedures — SOPs contain mandatory, minimum
360 specifications or processes for use by EPA and non-EPA organizations that
361 must comply with Agency-wide Quality Program directives. An SOP is a set of
362 step-by-step instructions compiled by the organization to assist staff with
363 complex routine technical and quality operations. SOPs aim to achieve
364 efficiency, quality output, and uniformity of performance while reducing
365 miscommunication and failure to comply with directives.
366

367 All EPA quality-related directives and guidance documents and SOPs shall be valid for
368 a period of five (5) years from the approval date and are valid until formally rescinded
369 or revised. After five years, some action must be taken to reaffirm the document's
370 validity, revise it, or delete it from the Agency-wide Quality Program. Any changes to
371 approved documents must comply with the procedures used for the original review
372 and approval.
373

374 Additional user-specific QA and QC directives, guidance, and SOPs that are tailored
375 to an organization and its mission may be appropriate given the diversity of Agency
376 programs. For the purposes of this Procedure, "user-specific QA and QC guidance
377 and procedures" includes but is not limited to written documents, computer software,
378 and videos (if used to provide instructions). Such written documents must be
379 developed by the organization itself, consistent with Agency directives and the
380 organization's QMP.
381

382 Management shall ensure that all changes to the guidance and SOPs are available to
383 all personnel using that guidance, including active contractors and assistance
384 agreement recipients (e.g., grantees, cooperative agreement holders). The changes
385 do not become binding on contractors and assistance agreement holders until the
386 Office of Acquisition Management (OAM) or the Office of Grants and Debarment
387 revises the extramural agreement as applicable.
388

- 389 **G. Execute Assessments and Audits.** Plan, conduct, and document assessments
390 annually to provide information on the effectiveness of the Quality Program.
391

392 Describe in the QMP the frequency of assessments/audits, and how and by whom
393 assessments/audits of environmental information operations programs are planned,
394 conducted, evaluated, and documented. Describe the process by which management
395 in conjunction with the QAM chooses an assessment/audit tool, and the expected
396 frequency of their application to environmental information operations. Available
397 assessment/audit tools include but are not limited to data quality assessments (DQA);
398 management systems reviews (MSRs); peer, technical, and readiness reviews;
399 performance evaluations; technical systems audits; laboratory competency
400 assessments; and surveillances. Senior management shall assess (at least annually)
401 the adequacy of the Quality Program.
402

403 Discuss or address in the QMP the following items pertaining to management system
404 and technical assessments:
405

- 406 • How the process for the planning, scheduling, and implementation of
407 assessments/audits works, as well as how the organization shall respond to
408 needed changes;

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- 409 • Responsibilities, levels of participation, and authorities for all personnel and
410 staff participating in the assessment/audit process; and
411 • How, when, and by whom actions shall be taken in response to the findings of
412 the assessment/audit, and how the effectiveness of the response shall be
413 determined.

414
415 Describe how the level of competence, experience, and training necessary to ensure
416 the capability of personnel conducting assessments/audits are determined. Personnel
417 conducting assessments/audits shall be qualified, based on project-specific
418 requirements, to perform the assigned assessment. Management is responsible for
419 choosing the assessors, defining acceptance criteria, approving assessment/audit
420 procedures and check lists, and identifying goals prior to initiation of an
421 assessment/audit. Assessors shall be technically knowledgeable with no real or
422 perceived conflict of interest. If the assessors are chosen from within the organization,
423 they must have no direct involvement or responsibility for the work being assessed,
424 except for self-assessments.

425
426 Describe how personnel conducting assessments/audits shall have enough authority,
427 access to programs and managers, access to documents and records, and
428 organizational freedom to:

- 429
430 • Identify quality issues;
431 • Identify and cite noteworthy practices that may be shared with others to
432 improve the quality of their operations and products;
433 • Propose recommendations for resolving quality issues; and
434 • Independently confirm implementation and effectiveness of solutions.

435
436 The QMP or SOP must also discuss conditions under which a “stop work” order may
437 be needed and when and how authority for such decisions shall be made.

438
439 Describe in the QMP or SOP the roles and responsibilities of management and staff
440 for documenting, reporting and reviewing assessment/audit results. Describe the type
441 of assessment/audit findings (e.g., conformance, nonconformance, opportunity for
442 improvement, commendation) that may be used and the appropriate response to each
443 one. The organization shall base findings on objective evidence and shall retain the
444 documented information as part of quality records.

445
446 **H. Identify Corrective Actions and Improvements.** Perform and document corrective
447 actions and improvements.

448
449 Describe in the QMP or SOP how management shall respond to the results (or
450 findings) and recommendations from assessments/audits in a timely manner. When
451 conditions needing corrective action are identified, describe how the appropriate
452 response must be promptly made. Corrective actions shall include the identification of
453 root causes of problems, the determination of whether the problem is unique or has
454 systemic implications, and action(s) to prevent recurrence. As part of the corrective
455 action, indicate how follow-up actions shall be taken and documented to confirm the
456 implementation and effectiveness of the response action.

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458 Describe how disputes because of assessments/audits (if encountered) are addressed
459 and by whom.

460
461 The QMP or SOP must describe how staff at all levels are encouraged to identify and
462 establish communications among customers and suppliers, identify process
463 improvement opportunities, and identify issues.

464
465 **I. Hold Quality Program Management Reviews.** Plan, conduct, and document
466 management reviews of the Quality Program to assess its effectiveness, institute
467 improvements, and evaluate senior management’s commitment to implementation of
468 the Quality Program in accordance with the procedures described in the organization’s
469 QMP.

470
471 Annually, senior management must review, assure, and document the organization's
472 Quality Program to confirm its continuing suitability, adequacy, and effectiveness. This
473 management review process must be described in the QMP or SOP. The
474 management review must include consideration of:

- 475
476
 - The status of actions from previous management reviews;
 - 477 • Changes in external and internal issues that are relevant to the Quality
478 Program;
 - 479 • Information on Quality Program performance, including trends in:
 - 480 ○ Nonconformities and corrective actions;
 - 481 ○ Assessment/audit results, and opportunities for improvement; and
 - 482 • Suitability of Policies and SOPs.

483
484 The outputs of the management review shall include decisions related to continual
485 improvement opportunities and any need for changes to the Quality Program. The
486 organization must retain documented information as evidence of the results of
487 management reviews. This documentation will also serve as evidence that
488 management executed their due diligence responsibilities and have assured the data
489 used in their environmental information and technology products are of appropriate
490 quality.

491
492 **J. Conduct Reporting.** Report annually QA/QC activities for each fiscal year (FY) and
493 those activities planned for the upcoming FY to the CIO. Provide this information as
494 described in the annual reporting data call from the CIO. This reporting of QA activities
495 provides EPA managers access to information covering key QA/QC activities.

496
497 The following QA requirements will be annually reported to EQMD.

- 498
499
 1. QA course listing and training suppliers
 - 500 2. Total attending and date of QA training
 - 501 3. Assessments performed by the organization and date
 - 502 4. Number of implemented corrective actions/number of findings identified
 - 503 5. Total Number of QMPs received for approval.
 - 504 6. Total Number of QMPs approved.
 - 505 7. Total Number of all QAPPs received for review and approval.
 - 506 8. Total Number of all EPA approved QAPPs

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- 507 9. Total Number of all state and tribal QAPPs received for review and approval
508 (Applicable only to Regions)
509 10. Total Number of state and tribal QAPPs (each month) reviewed and approved
510 by EPA within 60 days – (Applicable only to Regions)
511 11. Total Number of Quality Assurance Review Forms (QARFs) or equivalent
512 documents received
513 12. Total Number of approved QARFs
514 13. List of QA Fields Activities (QAFAP) SOPs
515

516 In addition, EQMD will report on the following QA activities:
517

- 518 1. Assessments performed by EQMD and date
519 2. Number of implemented corrective actions/number of findings identified
520 3. Number of OMS approved QMPs with 124 days
521 4. Number of implemented corrective actions/number of findings identified
522 5. Number of IQG Request for Correction (RFCs) responded to within 120 days
523 6. Number IQG Request for Reconsideration (RFRs) responded to within 120
524 days
525

526 **K. Evaluate information using the Information Quality Guidelines (Pre-
527 Dissemination Review).**
528

529 Plan for and assess all environmental information (primary and existing) prior to use in
530 supporting Agency actions or decisions to verify the information is of sufficient quality,
531 objectivity, utility and integrity for their intended use and purpose.
532

533 Ensure information disseminated by or for EPA conforms with the *Guidelines for*
534 *Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information*
535 *Disseminated by the Environmental Protection Agency*¹⁰ (IQG) criteria for quality,
536 objectivity, utility, and integrity by evaluating the following during the administrative
537 review:
538

- 539 • Was the information collected under an Agency-approved Quality Program?
540 Is there an approved, current Quality Assurance Project Plan supporting the
541 information?
- 542 • Were EPA's *General Assessment Factors for Evaluating the Quality of*
543 *Scientific and Technical Information* considered in determining and
544 documenting the quality and relevance of the information used?
- 545 • Did information generated by or for EPA undergo appropriate peer review, in
546 accordance with the Agency's peer review policy and guidance?
- 547 • Has information that is presented from third-party sources (e.g., states,
548 tribes, other federal agencies, grantees) been subject to and collected under
549 EPA's Quality Program? If not, is the information of known quality? Did the
550 information undergo peer review? If EPA did not adopt or endorse the
551 information, is it appropriate to include a disclaimer indicating that EPA does
552 not endorse the information?

¹⁰ <https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information>

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- Does statistical or numerical information (including performance measurement data appearing in text or tables) include a characterization of statistical confidence and/or distribution, as appropriate?
 - Is there an adequate discussion of, or reference to, the suitability of the data for their use in the information product?

559 **Ensuring Transparency**—Sources of factual statements, data, statistics, tables,
560 charts, figures, and analytical methods should be described or referenced. In general,
561 references should be provided for the following kinds of information:
562

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- 570
- Sources of a significant and original statement.
 - Sources of information that are not familiar to ensure readers will readily recognize or locate them.
 - Sources of controversial matter and opposing views.
 - Sources of data, methods, models, calculations and statistics, tables, charts, etc.
 - Reports, studies, protocols, guidance, regulations, laws, etc. to which the information product refers.

571

572 **Ensuring Reproducibility of Influential Information**—Supporting data, models,
573 methods, statistical/analytic procedures, assumptions employed, and calculations for
574 influential information (as defined in the IQGs) are adequately described and/or
575 referenced and are available to facilitate the reproducibility of the information by
576 qualified third parties. Information provided (either in the text or in a footnote) should
577 enable the public to access this information.
578

579 **L. Document Quality Program Requirements for Intra and Extramural Agreements.**

580 All EPA organizations shall identify projects, whether intramural or extramural, that
581 may be subject to the Quality Program Policy and Procedure and document this
582 determination. For projects that are identified, document the approval of Quality
583 Program documentation and strategies needed to support the project objectives. For
584 contracts, a QARF shall be used and it may be used with other types of extramural
585 agreements. A QARF is an internal EPA form that provides a means for EPA:
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- QA Personnel to identify, track, and report on individual projects that are subject to the Agency's Quality Program requirements;
 - Project Managers (PMs), Contract Officer Representatives (CORs), and Project Officers (POs) to broadly describe the quality management strategies they intend to employ for the projects they are responsible for managing or overseeing;
 - QA Personnel and Managers to review and document their concurrence with those strategies; and
 - National Program Offices (NPOs) and Regions to communicate the approved quality management strategies to officials responsible for executing extramural agreements.

599 For extramural projects, the broadly described QA requirements documented and
600 approved must be translated into specific requirements contained within the
601 procurement or financial assistance documents (e.g., contract, work assignment, task

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602 order or delivery order statements or scopes of work (SOW) and performance work
603 statements (PWS), applications for assistance, funding requests, and purchase
604 requests) that will be issued (e.g., contractor, interagency agreement partner).
605 Accordingly, EPA QA personnel must review the supporting documents to confirm the
606 need for the QA requirements specified, verify that those requirements have been
607 appropriately communicated to the organization in the corresponding documents and
608 provide any special language or conditions necessary for the QA requirements. If the
609 document undergoes revision, the EPA QA personnel must review the revised
610 document to ensure that revision has not necessitated a change in the QA
611 requirements or special language; if it has, they must adjust those accordingly.
612

613 **Internal EPA Projects**—An EPA project manager (PM), or equivalent, who is
614 responsible for planning and managing internal EPA projects shall document the
615 broad QA requirements necessary to support any environmental information and
616 technology operations that will be performed under the project. The Project Manager
617 shall submit the documentation to their QA Manager (or designee) for review and
618 approval, along with supporting documents that describe the goals of the project and
619 the environmental information and technology operations that will be performed (e.g.,
620 study plan, charter, memo).
621

622 The documentation provides confirmation that the appropriate QA and QC
623 requirements have been determined. It also communicates whether quality
624 requirements are necessary and, if so, which quality standards should be applied for
625 activities that involve the collection, generation, use, or reporting of environmental
626 information, and/or the design, construction, and operation of environmental
627 technologies.
628

629 **Contracts**—Requirements for QA and QC activities in contracts are given in 48 CFR
630 46 and in the EPA Acquisition Guide (EPAAG).
631

632 As stated in Federal Acquisition Regulation (FAR) 46.202-4, higher-level quality
633 requirements are those that apply to complex or critical items, or that are used when
634 the technical requirements of the contract require control of such things as work
635 operations, in-process controls, and inspection, or attention to such factors as
636 organization, planning, work instructions, documentation control, and advanced
637 metrology.
638

639 For EPA, this type of quality requirement will apply to the collection, generation, use,
640 or reporting of environmental information, and the design, construction, or operation of
641 environmental technologies. The requirements and specifications in this Procedure
642 extend to all contract forms involving environmental information. Accordingly,
643 approved QARFs are required for all solicitations, all PWSs or SOWs for contracts,
644 work assignments, task orders and delivery orders, and for any modifications to
645 existing work assignments, task orders, and delivery orders that involve a significant
646 change to the PWS/SOW.
647

648 Actions that do not affect the work performed by the contractor (e.g., incremental
649 funding or time extensions) do not require a QARF. As permitted in the EPA
650 organization's QMP, the QARF may not be required if technical direction is issued
651 under a project specific task order.

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652
653 OAM officials are responsible for incorporating the necessary standard clauses or
654 conditions into EPA contracts to assure that minimum specifications for compliance
655 with EPA policy are met. The specific SOW (or equivalent) may include additional
656 QA/QC specifications identified by the COR and approved by the organization's QAM
657 as described above. Since not all contract work assignments, delivery orders and task
658 orders involve environmental information operations, QA/QC specifications may not be
659 necessary. The QARF attached to the contract, work assignment, delivery order or
660 task order shall clearly identify whether QA/QC specifications are required and what
661 they are.

662
663 **Assistance Agreements**—The requirements and specifications set forth in this
664 Procedure extend to all assistance agreements involving environmental programs,
665 including but not limited to grants and cooperative agreements.

666
667 **Interagency Agreements**—EPA cannot unilaterally require other federal agencies to
668 comply with Agency-wide Quality Program requirements for interagency agreements
669 funded by EPA. Instead, QA/QC requirements for interagency agreements must be
670 negotiated between EPA and the other Agency. When agreement is reached on the
671 QA/QC specifications, the specifications must be included in the interagency
672 agreement.

673
674 When EPA receives funding from another Agency through an interagency agreement,
675 the EPA QA/QC requirements shall apply in addition to any specifications provided by
676 the funding organization. If the funding Agency does not specify any requirements,
677 EPA QA/QC requirements given by the Quality Program Policy and this Procedure
678 shall apply.

679
680 EPA organizations shall identify if projects are subject to the Quality Program Policy
681 and Procedure and document this determination. For projects that are, identify the
682 strategies needed to support the project objectives. This documentation shall describe
683 the QA/QC requirements established in each interagency agreement and shall be
684 routed to the EPA organization's QAM for review and approval before the agreement
685 is fully executed. This requirement applies to all interagency agreements, as it
686 provides a means for:

- 687
688
 - Identifying, tracking, and reporting on agreements that are subject to the
 - 689 Agency's Quality Program and
 - Documenting that the organization's QAM has approved the negotiated QA/QC
 - 690 strategies specified within the agreement.

691
692
693 **M. Address Environmental Information Quality Issues.** Identify laboratory
694 environmental information quality issues, other than fraud, and use the CIO
695 notification process described in the current version of CIO 2105-P-03.0, *CIO*
696 *Notification Procedure for Environmental Data Quality Issues*¹¹.
697

¹¹ The current version of this document is available at https://www.epa.gov/sites/production/files/2020-08/documents/cio_notificaton_for_environmental_data_quality_issues_procedure.pdf

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- 698 **N. Address Field Activities.** Describe how the organization's Quality Program is applied
699 to sampling and non-sampling field activities and use the process described in the
700 current version of CIO 2105-P-02.0, *EPA QA Field Activities Procedure*¹².
701
- 702 **O. Conduct Training.** Require appropriate training for all personnel to assure that QA
703 and QC responsibilities and requirements of the Quality Program are understood.
704 Organizations shall state their policy and procedures regarding training for
705 management and staff in their QMP. They shall describe the processes and the
706 management and/or staff responsible for:
707
- 708 • Identifying statutory, regulatory, or professional certifications that may be
709 required to perform certain operations;
 - 710 • Identifying, designing, performing, and documenting technical, quality, and
711 project management training; and
 - 712 • Describing how staff proficiency in critical technical disciplines is maintained
713 and documented.
714

7. ROLES AND RESPONSIBILITIES

715 **EPA Administrator:** Promotes and ensures quality is an integral part of the Agency's
716 mission by assuring that environmental information operations supporting EPA's programs
717 and activities are scientifically and legally defensible and meet our stakeholder needs. The
718 Administrator may re-delegate the responsibilities for this Procedure to Assistant
719 Administrators (AA) and Regional Administrators (RAs).
720

721 **Assistant Administrators (AA) and Regional Administrators (RA):** Each AA and RA is
722 responsible for the following QA activities:
723

- 724 • Implementing this Procedure in the context of the organizations' specific mission;
- 725 • Ensuring that adequate resources are devoted to QA activities to ensure
726 compliance with EPA's QA directives, to support the organization's mission and to
727 fully implement the organization's approved QMP;
- 728 • Ensuring that the organization's QMP includes activities that will help assure the
729 quality of the data and information the organization collects, manages, or uses in
730 carrying out its mission;
- 731 • Certifying annually to the DAA/CIO that the organization is implementing EPA's
732 QA directives and that the quality of data produced and utilized by the
733 organization is appropriate for its intended uses, including the use of data for
734 programmatic decision-making and regulatory development. Provide this
735 certification along with the organization's QA annual report to EQMD. Refer to
736 Appendix B for a copy of this certification; and
- 737 • Promoting continual improvement in QA activities across the organization.
738

739 **Office of Mission Support (OMS), Deputy Assistant Administrator (DAA) for**
740 **Environmental Information (EI)/Chief Information Officer (CIO):** Acts as the EPA
741 Senior Management Official for quality management and leads Agency-wide
742
743

¹² The current version of this document is available at <https://www.epa.gov/sites/production/files/2015-03/documents/2105-p-02.pdf>

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744 implementation of this Procedure and EPA's Quality Program. Informs AAs, RAs, and the
745 SAC of any issues related to the quality of Agency environmental information and
746 environmental information operations encompassed by this Procedure.

747
748 **Chief Information Officer's (CIO's) Strategic Advisory Committee (SAC):** Comprised
749 of Senior Information Officials (SIOs) and other senior managers. Advises and reports to
750 the DAA/CIO in developing and recommending actions to improve consistency in
751 implementing this Procedure. The SAC serves as a forum to discuss coordination of
752 cross-cutting Agency quality-related issues.

753
754 **Senior Information Officials (SIOs):** Oversee effective implementation, coordination, and
755 management of the organization's Quality Program for environmental information
756 operations. Located in each Program Office and Region, SIOs report to the Agency
757 DAA/CIO on quality-related issues.

758
759 **Mission Support Division Directors (MSDDs):** Manage issues related to information
760 technology and information management (IT/IM). Support the Region's Quality Program
761 and coordinate with Laboratory Services and Applied Science Division Directors
762 (LSASDDs).

763
764 **Laboratory Services and Applied Science Division Directors (LSASDDs):** Support the
765 Agency's Quality Program and provide technical assistance and expertise within the
766 Agency and with external partners.

767
768 **Science and Technology Policy Council (STPC):** Serves as a mechanism for
769 addressing EPA's science policy issues that go beyond regional and program boundaries,
770 with a goal of integrating policies that guide Agency decision-makers on their use of
771 scientific and technical information.

772
773 The STPC is an executive level council that is chaired by the Agency Science Advisor,
774 and provides a venue for identifying, coordinating, and, when appropriate, establishing
775 consensus for high priority, cross-Agency science and technology policy issues to assist
776 Programs and Regions. It focuses on issues that require high-level action and are relevant
777 to the Regions and Program Offices. The STPC is supported by the:

- 778
779
 - Forum on Environmental Measurements,
 - 780 • Laboratory Enterprise Forum,
 - 781 • Peer Review Advisory Group, and
 - 782 • Risk Assessment Forum.

783
784 **Office of General Counsel (OGC) and Office of Regional Counsel:** Provide legal
785 advice on issues related to environmental information operations.

786
787 **OMS/EI Office of Enterprise Information Programs (OEIP) and Enterprise Quality
788 Management Division (EQMD) Directors:** Serve as Office and Division Directors
789 respectively and are responsible for oversight of the Agency's Quality Program. Execute
790 actions on behalf of the DAA/CIO.

791

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792 **EPA Quality Assurance Managers (QAMs) and (QA) Personnel:** Have delegated
793 authority for the management of their Quality Program as described in their organization's
794 QMP. The QAM personnel roles and responsibilities below serve as a reference to assist
795 the QAM in identifying activities and best practices. These activities and best practices are
796 applicable to their organizations and may assist in continuous improvement. These
797 activities are not provided as performance measures for the organization but may be used
798 to guide the QAM in discussion with management on their roles and expectations for
799 implementing the Quality Program Policy and Procedure. These roles and responsibilities
800 focus on managing quality for environmental information and technology operations.

801
802 QAMs are individuals within the organization who are assigned specific quality
803 management duties and are delegated authority for quality management as defined in the
804 organization's QMP. The functions of the QA personnel may be totally related to Quality
805 Program activities or may be in conjunction with other functions and responsibilities within
806 the organization. It is the QAM's responsibility to determine whether a conflict of interest
807 exists. If these personnel have other functions to perform, there should be no conflict of
808 interest. Specific duties and responsibilities shall include:

- 809
- 810 • Facilitating QMP development and approval by the organization and preparing
- 811 updates to the approved QMP;
- 812 • Representing the organization on matters pertaining to quality management and
- 813 QA and QC activities;
- 814 • Providing expert assistance to the staff in the organization on QA and QC policies,
- 815 requirements, and procedures applicable to procurement and technical activities;
- 816 • Reviewing QMPs and QAPPs for all projects, work assignments, delivery orders,
- 817 task orders, grants, cooperative agreements, and interagency agreements
- 818 involving data acquisition, data generation, activities related to rulemaking, and/or
- 819 measurement activities that are performed by or on behalf of EPA that involve
- 820 performing activities within the scope of the Agency Quality Program Policy and
- 821 Procedure;
- 822 • Approving all QAPPs for implementation in all applicable projects, work
- 823 assignments, delivery orders, task orders, grants, cooperative agreements, and
- 824 interagency agreements performed on behalf of EPA;
- 825 • Coordinating the correction of deficient QAPPs with the PO and their
- 826 management;
- 827 • Identifying QA and QC training needs for the organization;
- 828 • Providing oversight of QA and QC implementation in the environmental programs
- 829 conducted by or for the organization;
- 830 • Performing assessments of environmental programs and confirming the
- 831 effectiveness of corrective actions;
- 832 • Managing the day-to-day implementation of the mandatory Quality Program;
- 833 • Acting as liaison between the organization and EQMD on matters of QA
- 834 requirements;
- 835 • Coordinating with senior management regarding changes to the Quality Program
- 836 as needed to assure its continued effectiveness and assisting in reporting the
- 837 results through an EPA QA tracking tool to EQMD;
- 838 • Managing organization resources designated for the Quality Program;
- 839 • Maintaining records of pertinent Quality Program activities performed by the
- 840 organization;

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- Reviewing environmental information products (i.e., project reports containing environmental information or reporting the results of environmental information activities), independently (i.e., by others than those who produced the information or the reports) to confirm that the information is presented correctly; and
 - Preparing reports approved by management prior to release, publication, or distribution.

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The QAM and QA personnel roles and responsibilities reflect the activities that support systematic planning and life cycle management of EPA's environmental information products and services. Key criteria for success are the organization executive management endorsement of quality, sufficiency of quality resources, and empowerment /authority of the QAM to oversee the organization's Quality Program. The list above does not prescribe the roles of management, but instead presents them from the perspective of the QAM. Executive management actions and support are needed for success. The QAM is to be aware of the support needed by the organization and can communicate those needs to management.

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Agency Personnel: Perform work associated with environmental information technology operations as identified in their organization's QMP.

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Recipients of Extramural Agreements: Perform all environmental information operations in accordance with this Procedure's requirements as defined in their extramural agreements.

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8. RELATED INFORMATION

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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 most recent version.

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- 884
- ASQ/ANSI E4, *Quality management systems for environmental information and technology programs—Requirements with guidance for use* (2014)
 - *CIO Quality Policy* (CIO 2105.1, *Environmental Information Quality Policy*, 2020)
 - CIO 2105-P-02.0 *EPA QA Field Activities Procedure*¹³
 - CIO 2105-P-03.0 *CIO Notification Procedure for Environmental Data Quality Issues*¹⁴
 - [Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency](#)
 - [U.S. EPA Scientific Integrity Policy](#)
 - [U.S. EPA Peer Review Handbook](#)
 - [Enterprise Architecture Policy](#)
 - [Data Standards Policy](#)
 - [Enterprise Information Management Policy](#)

¹³ The current version of this document is available at <https://www.epa.gov/sites/production/files/2015-03/documents/2105-p-02.pdf>

¹⁴ The current version of this document is available at https://www.epa.gov/sites/production/files/2020-08/documents/cio_notificaton_for_environmental_data_quality_issues_procedure.pdf

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9. DEFINITIONS885
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While this Procedure uses multiple sources as the foundation for the terms defined, ASQ/ANSI E4 (2014) and CIO 2015.1 serve as primary references. The intent of this Procedure is to ensure consistency with these primary references and to make modifications where necessary to be applicable to the Agency.

Assessment—The evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management review, peer review, inspection, surveillance, or readiness review (including competency assessment, pre-award assessment of proposals, or technical assessment), peer consultation, product review (e.g., data inspection, software testing, pre-dissemination review, or review of contractor deliverables).

Audit—A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Consensus Standards—Standards that are developed and adopted by achieving agreement with all affected parties. These standards are developed in accordance with procedures used by the International Organization for Standardization or organizations accredited by the ANSI.

Data—A quantitative or qualitative representation of values, facts, observations, or ideas in a formalized manner capable of being transmitted, processed, stored, analyzed, interpreted, and/or communicated by some process, whether on paper or in electronic form.

- **Qualitative data**—is descriptive.
- **Quantitative data**—is numerical.
- **Primary data**—are data observed, collected, or generated directly for a specific purpose as defined by a QAPP.
- **Existing data**—are data that have been collected, derived, stored, or reported in the past or by other parties (for a different purpose and/or using different methods and quality criteria). Sometimes referred to as data from other sources.
- **Metadata**—is information about data required to facilitate its use, understanding, and management. Metadata should answer questions about data such as why they were collected, how they were collected, what was done to the data, what they were used for, and what were their limitations. Metadata makes tracking and working with specific data easier.

Data Quality Objectives (DQOs)—Qualitative and quantitative statements derived from the DQO Process that clarify study objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions.

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931 **Data Standard**—Documented consensus-based agreement on the format and definition
932 of common data.

933
934 **Environmental Information**—
935 Includes data and information that describe environmental processes or conditions which
936 support EPA’s mission of protecting human health and the environment. Examples include
937 but are not limited to:

- 938 • direct measurements of environmental parameters or processes;
- 939 • analytical testing results of environmental conditions (e.g., geophysical or
940 hydrological conditions);
- 941 • data on physical parameters or processes collected using environmental
942 technologies;
- 943 • calculations or analyses of environmental data;
- 944 • data provided by environmental data models; and
- 945 • environmental data compiled or obtained from databases, software applications,
946 decision support tools, websites, existing literature, and other sources.

947
948 **Environmental Information Operations**—A collective term for work performed to collect,
949 produce, evaluate, or use environmental information and the design, construction, and
950 operation of environmental technology.

951
952 **Environmental Measurement**—A subgroup of Environmental Information that includes or
953 produces values derived from tools, instruments, observational results, laboratory
954 operations on environmental samples, or other sampling and testing equipment. It is any
955 data collection activity or investigation involving the assessment of chemical, physical, or
956 biological factors in the environment which affect human health or the quality of life.

957
958 **Environmental Processes**—Manufactured or natural processes that produce discharges
959 or that impact human health and the environment.

960
961 **Environmental Programs**—Work or activities involving the environment, including but not
962 limited to characterization of environmental processes and conditions; environmental
963 monitoring; environmental research and development; the design, construction, and
964 operation of environmental technologies; and laboratory operations on environmental
965 samples.

966
967 **Environmental Technology**—An all-inclusive term used to describe pollution monitoring,
968 measurement and control devices and systems, treatment processes and storage facilities
969 and site remediation processes and their components, and site remediation technologies
970 and their components that may be utilized to remove pollutants or contaminants or prevent
971 them from entering the environment.. Examples include, but are not limited to:

- 972 • wet scrubbers (air),
- 973 • soil washing (soil),
- 974 • granulated activated carbon unit (water), and
- 975 • filtration (air, water).

976
977 Usually, this term applies to hardware-based systems; however, it also applies to methods
978 or techniques used for pollution prevention, pollutant reduction, or containment of
979 contamination to prevent further movement of the contaminants, such as capping,

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980 solidification or vitrification, and biological treatment.
981
982 Environmental Technology does not include or incorporate the development and design of
983 IT systems.
984
985 **Extramural Agreement**—A legal agreement between EPA and an organization outside
986 EPA. Such agreements include but are not limited to contracts, work assignments,
987 delivery orders, task orders, cooperative agreements, research grants, state and local
988 grants, and EPA-funded interagency agreements.
989
990 **Information Quality Guidelines**—An Agency document that establishes EPA’s policy
991 and procedural guidance for ensuring and maximizing the quality of agency disseminated
992 information. The Guidelines outline EPA’s pre-dissemination review of information
993 products and describe administrative mechanisms to enable affected persons to seek and
994 obtain corrections from EPA regarding disseminated information that they believe do not
995 comply with EPA guidelines.
996
997 **Information System**—An organized collection, storage, and presentation system of data
998 for decision making, progress reporting, and for planning and evaluation of programs. It
999 can be manual or computerized, or a combination of both.
1000
1001 **Intergovernmental**—Between the EPA and international, other federal, state, tribal,
1002 territorial, area-wide, regional or local governments and agencies.
1003
1004 **Management System**—A management system may describe the polices, objectives,
1005 principles, organizational authority, responsibilities, accountability, and implementation
1006 plan of an organization.
1007
1008 **Operations Manager**—The Operations Manager is independent of the QAM. In some
1009 organizations this individual may also be referred to as the PM or person responsible for
1010 the activity.
1011
1012 **Organization**—An EPA organization is an office, region, national center, or laboratory. An
1013 external organization is a state, tribe, company, corporation, firm, enterprise, or institution,
1014 or part thereof, whether incorporated or not, public or private, that has its own functions
1015 and administration.
1016
1017 **Process**—A set of interrelated resources and activities which transforms inputs into
1018 outputs. Examples of processes include analysis, design, data collection, operation,
1019 fabrication, and calculation.
1020
1021 **Product**—The intended result or final output of an activity or process that is disseminated
1022 or distributed among EPA organizations or outside of EPA.
1023
1024 **Quality**—The totality of processes, procedures, features, and characteristics of a product
1025 or service that bear on its ability to meet the stated or implied needs and expectations of
1026 the user.
1027
1028 **Quality Assurance (QA)**—Management of an integrated system of activities involving
1029 planning, implementation, documentation, assessment, reporting, and quality

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1030 improvement to ensure that a process, item, or service is of the type and quality needed
1031 and expected by the organization.
1032
1033 **Quality Assurance Manager (QAM)**—The individual designated as the principal manager
1034 within the organization having oversight authority and responsibilities for planning,
1035 documenting, coordinating, and assessing the effectiveness of the Quality Program for the
1036 organization.
1037
1038 **Quality Assurance Project or Program Plan (QAPP)**—A planning document related to a
1039 project or program that describes in comprehensive detail the necessary QA/QC
1040 requirements and other technical activities that must be implemented to ensure that the
1041 results of the work performed will satisfy the DQOs and stated performance criteria.
1042
1043 **Quality Assurance Review Form (QARF)**—The document that describes QA
1044 requirements for contracts and documents the review and approval by the QAM. This
1045 document must be included with all contract packages.
1046
1047 **Quality Control (QC)**—The overall system of technical activities that measures the
1048 attributes and performance of a process, item, or service against defined standards to
1049 verify that they meet the stated requirements established by the customer; operational
1050 techniques and activities that are used to fulfill requirements for quality.
1051
1052 **Quality Management**—The aspects of the organization’s overall management system
1053 that drive the implementation of an organization’s Quality Program. Quality Management
1054 includes strategic planning, allocation of resources, and other systematic activities (e.g.,
1055 planning, implementation, documentation, and assessment) pertaining to an organization’s
1056 Quality Program.
1057
1058 **Quality Management Plan (QMP)**—A formal document that describes a Quality Program
1059 in terms of the organizational structure, functional responsibilities of management and
1060 staff, lines of authority, and required interfaces for those planning, implementing, and
1061 assessing all activities conducted.
1062
1063 **Quality Program**—The totality of management controls, processes, and documentation in
1064 EPA’s planning, implementation, and assessment of applying quality in the creation of
1065 Agency environmental information and technology products and services.
1066

1067 **10. WAIVERS**
1068
1069 N/A
1070

1071 **11. MATERIAL SUPERSEDED**
1072
1073 • *Policy and Program Requirements for the Mandatory Agency-Wide Quality*
1074 *Management System* (CIO 2105.0, May 5, 2000)
1075 • *EPA Quality Manual for Environmental Programs* (CIO 2105-P-01-0, May 5, 2000)
1076 • *Quality Policy* (CIO 2106.0, October 20, 2008)
1077 • *Procedure for Quality Policy* (CIO 2106-P-01.0, October 20, 2008)

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1141**APPENDIX A:
ACRONYMS & ABBREVIATIONS**

AA	Assistant Administrator
ANSI	American National Standards Institute
ASQ	American Society for Quality
CFR	Code of Federal Regulations
CIO	Chief Information Officer
CO	Contracting Officer
COR	Contracting Officer Representative
CREM	Council for Regulatory Environmental Modeling
DAA	Deputy Assistant Administrator
DQA	Data Quality Assessment
DQA	Director of Quality Assurance
DQOs	Data Quality Objectives
EI	Environmental Information
EPA	Environmental Protection Agency
EPAAG	EPA's Acquisition Guide
EPAAR	EPA's Acquisition Regulation
EQMD	Enterprise Quality Management Division
FAR	Federal Acquisition Regulation
FMFIA	Federal Managers Financial Integrity Act
FY	Fiscal Year
IGMS	Integrated Grants Management System
IM	Information Management
IQA	Information Quality Act
IQG	Information Quality Guidelines
IT	Information Technology
LSASDD	Laboratory Services and Applied Sciences Division Director
MSDD	Mission Support Division Director
MSR	Management System Review
NPO	National Program Office
NTTA	National Technology Transfer and Advancement Act
OAM	Office of Acquisition Management
OEIP	Office of Enterprise Information Programs
OGC	Office of General Counsel
OMB	Office of Management and Budget
OMS	Office of Mission Support
PARS	Performance Appraisal and Recognition System
PM	Project Manager
PO	Project Officer
PWS	Performance Work Statement
QA	Quality Assurance
QAM	Quality Assurance Manager
QAPP	Quality Assurance Project or Program Plan
QARF	Quality Assurance Review Form
QC	Quality Control
QMP	Quality Management Plan
QSA	Quality System Assessment
RA	Regional Administrator

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1142	RFC	Request for Correction
1143	RFR	Request for Reconsideration
1144	RQAM	Regional Quality Assurance Manager
1145	SAC	Strategic Advisory Committee
1146	SIO	Senior Information Official
1147	SOP	Standard Operating Procedure
1148	SOW	Statement of Work
1149	STPC	Science and Technology Policy Council
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**APPENDIX B:
QUALITY ASSURANCE ANNUAL CERTIFICATION**

I certify that *(provide your organization's name)* _____ is implementing EPA's QA directives and the quality of data produced and utilized by the organization is appropriate for its intended uses, including the use of data for programmatic decision-making and regulatory development.

(Provide an electronic signature and date to include the name, title and organization)