QUALITY MANAGEMENT PLAN REVIEW CHECKLIST

ORGANIZATION:	

This checklist will be used to review the Quality Management Plans (QMPs) that are submitted to the Enterprise Quality Management Division (EQMD) of the Office of Mission Support, Environmental Information (OMS-EI) for Agency review under CIO 2105.0^a. Items from this checklist are discussed in detail in Chapter 3 of CIO 2105-P-01-0^b and in *EPA Requirements for Quality Management Plans (QA/R-2)*. Consult these resources for more information on the items below.

Note that all items below are required to be included or addressed in the QMP. If an item is not relevant, please provide an explanation about why this is not relevant in the comments column. Also note, that a process may either be described or referenced in the QMP; however, all references should be readily accessible within the organization and provided to the EQMD with the QMP.

Element	Section & Pages(s)	Comments (this column completed by QAM/DQA)	Recommended Change (this column completed by EQMD)
Management and Organization [Re	eference CIO 2	105-P-01-0 §3.3.2; EPA QA/R-2 §3.2]	
1) QMP Approved by senior manager (signed if hard copy or approved by separate cover memo if electronic QMP copy)?*			
2) Signed and dated by senior line management (for subordinate offices) as applicable (signed if hard copy or approved by separate cover memo if electronic QMP copy)?*			
3) Signed and dated by QA manager (signed if hard copy or approved by separate cover memo if electronic QMP copy)?*			
4) Includes statement of the organization's QA policy?			
a) QA policy statement includes			

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general objectives/goals?			
b) QA policy includes general discussion of management and staff responsibilities?			
5) Includes organizational chart?			
a) Organizational chart identifies all components of organization?			
b) Organizational Chart identifies position of QA manager?			
c) Organizational Chart identifies lines of reporting of the QA manager?			
d) Organization Chart identifies any other QA staff?			
6) Includes discussion of roles, responsibilities, and authorities of the QA manager and QA staff (QA Officers, Coordinators, etc.), as applicable?			
7) Documents the organizational independence of the QA manager?			
8) Describes procedures to ensure QA staff has access to appropriate levels of management?			
Discusses technical activities or programs that require application of quality management practices?			
10) Discusses where oversight of delegated (i.e., States, Tribes) and/or extramural programs is needed?			
11) Identifies where internal coordination of QA and QC activities among			

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organizations (e.g., divisions, offices, branches) is needed?			
12) Discusses how management assures understanding and implementation of quality practices in all programs and activities?			
13) Describes process for resolving disputes relating to quality issues?			
Quality System Components [Refer	ence CIO 2105	3-P-01-0 §3.3.3; EPA QA/R-2 §3.3]	
14) Includes description of the quality system as it pertains to the organization's mission?			
15) Addresses and describes principal quality system components and tools developed by the organization, including how they are implemented and by whom? (Note: list specific tools, such as SOPs, guidance, training, etc., in Column 3.)			
a) Planning work			
b) Implementing work.			
c) Assessing work performed.			
16) Identifies internal organizations (e.g., subordinate offices, divisions) that develop QMPs?			
17) Identifies review and approval procedures for these internal QMPs?			
18) Includes assurance that QA responsibility is incorporated into performance standards for QA Managers/Directors of Quality Assurance?			

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Personnel Qualifications and Train	ing [Reference	CIO 2105-P-01-0 §3.3.4; EPA QA/R-2 §3	.4]
19) States policy regarding QA training for management and staff?			
20) Describes minimum training for personnel necessary to implement the QMP?			
21) Describes process for identifying, ensuring, and documenting that personnel have necessary quality-related competencies?			
22) Describes process for ensuring personnel maintain quality-related competencies, including continuing education or refresher training?			
23) Describes roles, responsibilities, and authorities managers and staff relative to training planning and implementation?			
Procurement of Items and Services	[Reference CI	O 2105-P-01-0 §3.3.5; EPA QA/R-2 §3.5]	
24) Describes process for reviewing and approving all extramural agreements (grants, cooperative agreements and contracts), including use of the QA Review Form ^e ?			
a) Review process ensures documents are complete and accurate?			
b) Review process ensures agreement clearly describes the item or service needed?			
c) Review process ensures agreement describes the associated technical			

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and quality requirements?			
d) Review process ensures agreement describes the quality system elements for which the supplier is responsible?			
e) Review process ensures that the supplier's conformance to requirements will be verified?			
25) Describes process for reviewing and approving applicable responses to solicitations and requests to ensure that they satisfy all technical and quality requirements?			
a) Review process includes the review of evidence of the supplier's capability to satisfy EPA quality requirements?			
b) Review process provides for ensuring that procured items and services are acceptable?			
26) Describes process for review and approval of suppliers' quality-related documentation (e.g., QA Project Plans and QMPs)?			
27) Includes discussion of any policy and criteria for delegations of review of QA Project Plans and QMPs?			
28) Describes process to ensure EPA extramural agreement policies, including quality, are satisfied?			
29) Describes roles, responsibilities, and authorities managers and staff relative to extramural agreement planning and			

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implementation? Documents and Records [Reference	CIO 2105-P-0	11_0 83 3 6· FPA OA/P_2 83 61			
30) Describes process for identifying quality-related documents and records (including electronic) requiring control (e.g., guidance, SOPs)?	. CIO 2103-1-0	1-0 §5.5.0, ETA QA/R-2 §5.0]			
31) Describes process for preparing, reviewing, approving, issuing, using, authenticating, and revising documents and records?					
32) Describes process for ensuring that records and documents accurately reflect completed work?					
33) Describes process for maintaining documents and records including transmittal, distribution, retention, access, preservation, traceability, retrieval, removal of obsolete documentation, and disposition?					
34) Describes process for establishing and implementing appropriate chain of custody and confidentiality procedures for evidentiary records?					
35) Records on environmental data and information comply with applicable EPA policies (e.g., locational data for samples, Agency records management)?					
36) Describes roles, responsibilities, and authorities managers and staff relative to documents and records?					
Computer Hardware and Software	Computer Hardware and Software [Reference CIO 2105-P-01-0 §3.3.7; EPA QA/R-2 §3.7] ^d				
37) Describes process for developing, installing, testing, using, maintaining,					

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controlling, and documenting computer hardware (e.g., computers, servers) and software, including software products like models, data bases, and programs?			
38) Describes process for assessing and documenting the impact of changes to user requirements and/or the hardware and software on performance?			
39) Describes process for evaluating purchased hardware and software?			
40) Describes process for ensuring that data and information produced from or collected by computers meet applicable EPA Orders, requirements, and standards?			
41) Describes roles, responsibilities, and authorities managers and staff relative to computer hardware, software, and information management?			
Planning [Reference CIO 2105-P-01	-0 §3.3.8; EPA	QA/R-2 §3.8]	
42) Includes a description of the systematic planning process for environmental information/data acquisition (e.g., direct measurement, compilation from other sources) and use?			
 a) Does this process include identification and involvement of relevant customers and suppliers? 			
b) Does this process include description of the project goal, objectives, and questions and issues to be addressed?			
c) Does this process include identification of project schedule,			

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	resources, milestones, and any applicable requirements?			
d)	Does this process include identification of the type and quantity of information/data needed and how the data will be used to support the project's objectives?			
e)	Does this process include specification of performance criteria for measuring quality?			
f)	Does this process include specification of needed QA and QC activities to assess the quality performance criteria?			
g)	Does this process include description of how, when, and where the data will be obtained (including existing data) and identification of any constraints on data collection?			
h)	Does this process include description of how the acquired data will be analyzed, evaluated, and assessed against its intended use and the quality performance criteria?			
rev	scribes process for developing, riewing, approving, implementing, d revising QA Project Plans?			
qua oth	scribes process for evaluating and alifying information acquired from the sources (e.g., States, other deral Agencies)?			

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45) Describes roles, responsibilities, and authorities managers and staff relative to planning?			
Implementation of Work Processes	[Reference CI	O 2105-P-01-0 §3.3.9; EPA QA/R-2 §3.9]	
46) Describes process for ensuring that work is performed according to planning and technical documents (e.g., SOPs, approved methods and protocols)?			
47) Describes process for identifying operations needing procedures (e.g., SOPs)?			
48) Describes process for preparation, review, approval, revision, and withdrawal of these procedures?			
49) Describes policy for use of these procedures?			
50) Describes process for controlling and documenting the release, change, and use of planned procedures?			
a) Process includes description of necessary approvals?			
b) Process includes removal of obsolete documentation from work areas?			
c) Process includes verification that the changes are made as prescribed?			
51) Describes roles, responsibilities, and authorities managers and staff relative to implementing work processes.			
Assessment and Response [Reference	ce CIO 2105-P-	-01-0 §3.3.10; EPA QA/R-2 §3.10]	

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52) Describes the process for assessing the adequacy of the quality management system at least annually?			
53) Describes the process for planning assessments?			
a) Process includes selecting an assessment tool, the expected frequency, and the roles and responsibilities of assessors?			
b) Process includes determining the competence of assessment personnel?			
c) Process includes ensuring that personnel have no real or perceived conflict of interest, and have no direct involvement or responsibility for the work being assessed?			
d) Process includes ensuring that personnel conducting assessments have sufficient authority, access to programs and managers, access to documents and records, and organizational freedom?			
54) Describes the process for implementing and documenting assessments and reporting results to management?			
a) Describes the process for completing assessment reports in a timely manner, including appropriate levels of review and approval?			
55) Describes process for management's			

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review of, and response to, findings?			
56) Describes process for identifying how and when corrective actions are to be taken in response to the findings of the assessment?			
Process includes ensuring corrective actions are made promptly?			
b) Process includes confirming the implementation and effectiveness of any corrective action?			
c) Process includes documenting effectiveness of the corrective actions implemented?			
57) Describes process for addressing disputes encountered as a result of assessments?			
58) Describes roles, responsibilities, and authorities managers and staff relative to planning and implementing assessments and responses to assessments?			
Quality Improvement [Reference C	IO 2105-P-01-0	0 §3.3.11; EPA QA/R-2 §3.11]	
59) Describes process for ensuring that conditions adverse to quality are prevented, identified promptly, corrected promptly and that actions are taken toward prevention, documented and actions tracked to closure?			
60) Describes process for encouraging staff to establish communications between customers and suppliers, identify process improvement opportunities, and identify and propose solutions for			

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problems?			
61) Describes roles, responsibilities, and authorities managers and staff relative to quality improvement?			
Other Review Criteria			
62) Are regulatory or other citations in the QMP current and accurate?			
63) Are there any inconsistencies in the text?			
64) Is the writing clear?			
65) Are organizational units identified consistent with the most recent reorganization?			
66) Are activities described in the QMP consistent with QA Annual Report and Work Plans? ^e			
67) Are tasks proposed for other organizations not covered solely by this QMP documented elsewhere (e.g., in another organization's QMP)?			
Information Quality Guidelines ^f			
68) Does the QMP identify criteria for information products that are subject to Information Quality Guidelines?			
69) Is the process for pre-dissemination review discussed?			
70) Does the pre-dissemination process description include protocols for clearance review, requirements for clear disclaimer language; identify roles and responsibilities of management and staff?			

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^a Formerly EPA Order 5360.1 A2

^b Formerly EPA Order 5360.1 A2

^c Quality Assurance Review Form (QA Review Form) is required for EPA Organizations.

^d This may be a statement of compliance with Agency standards and practices if no specialized hardware or software are purchased or used by the organization.

^e Quality Assurance Annual Report and Work Plans are for EPA Organizations.

f Information Quality Guidelines apply to EPA Organizations and are optional element.