

Figure 3

Region 8 Quality Assurance Review Form For Extramural Actions

I. General Information		
A. Select <i>all</i> that apply: Initial Extramural Action <input type="checkbox"/> Contract <input type="checkbox"/> Sole Source <input type="checkbox"/> Grant <input type="checkbox"/> Assistance Agreement <input type="checkbox"/> IAG* (funds out) <input type="checkbox"/> IAG* (funds in) <input type="checkbox"/> Other:	Existing Vehicle Action <input type="checkbox"/> Contract No.: _____ <input type="checkbox"/> Work Assignment No.: _____ <input type="checkbox"/> Delivery/Task Order No.: _____ <input type="checkbox"/> Modification No.: _____ <input type="checkbox"/> Grant No. : _____ <input type="checkbox"/> COOP, IAG No.: _____ <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Other:	B. Specific or Descriptive Title:
<i>*If you are processing an IAG, the responsibility for QA must be negotiated within the agreement. The Project Officers (POs) in consultation with the QAMs in the various organizations must agree on, and document which organization will take the lead for QA, the names of the QAM and PO from each organization, and the QA requirements which will be adhered to during the agreement. Include this information in the IAG package.</i>		
C. Office, PO, and Phone	D. QA Category: <input type="checkbox"/> 1. Collection or Generation of Data <input type="checkbox"/> 2. Use of Secondary Data <input type="checkbox"/> 3. Use or Development of Software or Models <input type="checkbox"/> 4. Other:	
II. Scope of Work		
A. Does this extramural action involve the collection, generation, use, and/or reporting of environmental data; or development of software and/or models, or methods? <i>(If "No", skip to Section IV, and sign the form.)</i>		<input type="checkbox"/> Yes <input type="checkbox"/> No
B. For solicitations, will the activities in Section II.A account for greater than 15% of the cost or effort? If so, the QA documentation specified in the RFP or SOW and/or provided for in Section III.B.1 or III.B.2 shall be included in the technical evaluation at a weight of 10-20%, or pass/fail. <i>(*check N/A for existing vehicle actions)</i>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> *N/A
C. Will the SOW or any subsequent work assignments or task orders, or COOP, or IAG involve any cross-federal organizational efforts? If so, which organization will take the lead for QA?		<input type="checkbox"/> Yes <input type="checkbox"/> No
D. Has a QAPP already been approved for the activities specified in the SOW or RFP?		<input type="checkbox"/> Yes <input type="checkbox"/> No
1. Provide the title, date or revision number, approving official, and date of QA approval:		
2. Does the QAPP require <i>any</i> revision by the contractor or cooperator? <i>(*If II.D is "No", check N/A)</i>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> *N/A
E. Is an applicable QAPP in the process of being prepared or revised by EPA, the contractor, or grantee/cooperator? <i>(QAPP must be approved by EPA <u>before</u> the collection or use of environmental data.)</i> <i>(*If II.D is "No", check N/A)</i>		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> *N/A
1. Provide the expected title and approximate date for submission to QA staff for approval:		

III. Quality-Related Requirements		
A. Quality System Documents (Specifications): In Section III.B, “R-2” refers to <u>EPA Requirements for Quality Management Plans (QA/R-2)</u> (EPA/240/B-01/002) and “R-5” refers to <u>EPA Requirements for Quality Assurance Project Plans (QA/R-5)</u> (EPA/240/B-01/003). Copies of these documents are available at http://www.epa.gov/quality/ . The use of the R-2 and R-5 guidance documents is highly recommended.		
B. QA Documentation Options: <i>[For solicitations, complete items 1-4; for all actions other than solicitations, complete items 3-4. All documentation specified under “Other” must be defined in the Region 8 Quality Management Plan or National Program QMPs and be consistent with requirements defined in EPA Order CIO 2105.0. For all items checked below, there must be adequate information in the SOW (or its appendices) for the offeror to develop this documentation. Where applicable, reference a specific section of the SOW.]</i>		
Before Award Documentation		
1.a. <input type="checkbox"/> Documentation of an organization’s Quality System: Either	<input type="checkbox"/> QMP in accordance with EPA Order EPA CIO 2105-0 / ANSI/ASQC E4 , (R-2 as guidance). <input type="checkbox"/> Other: “Respondent Requirements Demonstrating Their Organization’s Quality Assurance and Quality Control System” attached to, and referenced from within the SOW or RFP).	
b. <input type="checkbox"/> Combined documentation of an organization’s Quality System and application of QA and QC to the single project covered by contract: Either developed IAW:	<input type="checkbox"/> R-2 <u>and</u> R-5 or <input type="checkbox"/> Other:	
2. a. <input type="checkbox"/> Programmatic QA Project Plan: Either developed in accordance with:	<input type="checkbox"/> R-5 or <input type="checkbox"/> Other:	
b. <input type="checkbox"/> Application of QA and QC activities to the single project covered by contract:	<input type="checkbox"/> QA Project Plan developed in accordance with R-5 or <input type="checkbox"/> Other:	
c. <input type="checkbox"/> Not applicable.		
After Award Documentation		
3. a. <input type="checkbox"/> Documentation of an organization’s Quality System: Either	<input type="checkbox"/> QMP developed in accordance with EPA Order CIO 2105.0 or ANSI/ASQC E4 <input type="checkbox"/> Other: “Respondent Requirements Demonstrating Their Organization’s Quality Assurance and Quality Control System” attached to, and referenced from within the SOW or RFP (found on page 3 of this document)	
b. <input type="checkbox"/> Combined documentation of an organization’s Quality System and application of QA and QC to the single project covered by the contract. Developed in accordance with:	<input type="checkbox"/> R-2 <u>and</u> R-5 or <input type="checkbox"/> Other:	
c. <input type="checkbox"/> Not applicable.		
4. a. <input type="checkbox"/> Documentation of the application of QA and QC activities to applicable project(s): Either developed in accordance with:	<input type="checkbox"/> R-5; <input type="checkbox"/> A supplement to the following Programmatic QA Project Plan ____ ; or <input type="checkbox"/> Other:	
b. <input type="checkbox"/> Programmatic QA Project Plan with supplements for each specific project: Developed in accordance with:		
c. <input type="checkbox"/> Existing documentation of the application of QA and QC activities will be used: Either	<input type="checkbox"/> Documentation developed pre-award; <input type="checkbox"/> Documentation will be identified in individual SOW or RFP, or <input type="checkbox"/> Documentation identified in Section ____ of the SOW or RFP	
C. Reports: Are quality reports or reports containing quality assurance information (for example, status of quality system implementation, review of a quality system, quality control data, etc.) required? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, identify the required reports and the time frame for submission:		
D. Assessments: Select all quality assessments that will be performed post-award by EPA staff:	<input type="checkbox"/> Readiness reviews; <input type="checkbox"/> PE samples; <input type="checkbox"/> Technical systems audits;	<input type="checkbox"/> Surveillance audits; <input type="checkbox"/> These and/or others are specified in the SOW/QAPP at some frequency.

IV. Signatures**

The signatures below verify that the Statement of Work or Request for Proposal has been reviewed to ascertain the necessary QA and QC activities required to comply with EPA Order CIO 2105.0, that the Contracting Officer's Representative (COR), Designated Project Manager (DPM), and/or Project Officer (PO) understands these requirements, and that the COR/DPM/PO will ensure that the quality requirements indicated on the pages of this form are incorporated into all necessary sections of the SOW or RFP. *(Sign/date below, obtain a concurrence signature from the QA Manager, and submit the form along with the other extramural action documentation.)*

EPA Region 8 COR, DPM, or PO	Date	EPA Region 8 QA Manager	Date
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***If this form accompanies an incremental funding action, the signature of the Project Officer acknowledges that the assistance recipient has fulfilled any QA requirements identified in the initial funding decision memo and is current with any periodic QA/QC reports that are identified in the project's QAPP as specified in Section III.C, above.*

Respondent Requirements Demonstrating Their Organization's Quality Assurance and Quality Control System

In accordance with EPA Order CIO 2105.0, conformance to ANSI/ASQC E4 must be demonstrated by each solicitation respondent. Providing responses to the list of topics provided below are sufficient to demonstrate this conformance. Responding to the topics listed below provides a description of each respondent's Quality System that sets forth its capabilities in providing products (such as those described in the Statement of Work or Request for Proposals) of known and verifiable quality. Each respondent, as a separate and identifiable part of its technical proposal, shall submit its responses to these topics. The Quality System documentation of the respondent will become part of the evaluation. For more information on these requirements visit: <http://www.epa.gov/QUALITY/faq4.html>

For the successful respondent, the Quality System documentation will be reviewed by the EPA Quality Assurance Manager and approved following an acceptable response to his requested revisions. In addition, a project-specific Quality Assurance Project Plan (QAPP) (following directions in the Quality Management Plan of the originating NHEERL Division) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the successful respondent shall also implement it as written and approved by the Government.

Topics to be addressed in demonstrating an organization's Quality System

- (a) A statement of policy concerning the organization's commitment to implement a Quality Control/Quality Assurance program to assure generation of data of adequate quality to meet the requirements of the Request for Proposals (RFP) or Statement of Work (SOW).
- (b) An organizational chart showing the position of a QA function or person within the organization. It is highly desirable that the QA function or person be independent of the functional groups which generate measurement data.
- (c) A delineation of the authority and responsibilities of the QA function or person.
- (d) The type and degree of experience in developing and applying Quality Control/Quality Assurance procedures to the proposed methods needed for performance of the SOW or RFP.
- (e) The background and experience of the proposed personnel who will be assigned to the project.
- (f) The responder's general approach for accomplishing the QA specifications within the scope of the SOW or RFP, or their specific approach that would provide results of known and verifiable quality.

The respondents shall be aware of the following nonexclusive list of words and phrases that may indicate the need for a discussion of QA activities as they describe the various (a thru f) features of the particular application of their organization's Quality System to this SOW or RFP.

validation
audit procedures
system evaluation
Standard Reference Materials
Standard Operating Procedures

verification
positive/negative controls
configuration management
acceptance or QA/QC testing
surrogates

hardware/software evaluation
matrix spikes
change control
documenting software code