Region 8

Core QA Training

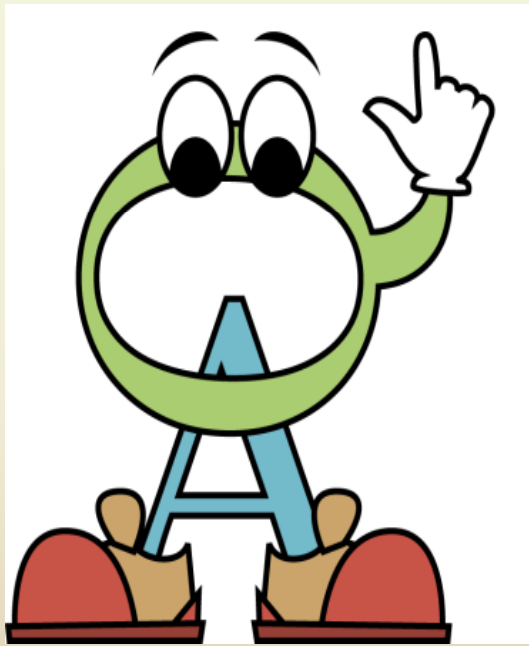**START**
3/25/13

Photo credits: "Loose Leashes" by Ron Schmidt

R8 Core QA Training Program 3-25-2013

Objectives:

- Highlight the main Statutes, EPA Orders, and Policies for Quality Assurance at EPA

- Locate and use available tools

- Emerging issues

"Who needs to take this training

Roles:
- Grant Project Officer (PO)
- Technical Project Officer
- Work Assignment Manager (WAM)
- Contracting Officer Technical Representative (COTR)
- Contracting Officer Representative (COR)
- Task Order Project Officer (TOPO)

Activity:
- Writing conditions (e.g. in permits, etc.)
- Writing reports using data or information involving/impacting an EPA decision
- Assisting/Participating in any sampling, data or information collection activities
- Conducting inspections
- Managing the databases, etc.

Organizations
- Technical Divisions (ECEJ, OEPR, OPRA)
- Montana Office
- TMS-Grants
- TMS-Lab

CIO 2106
Quality Policy
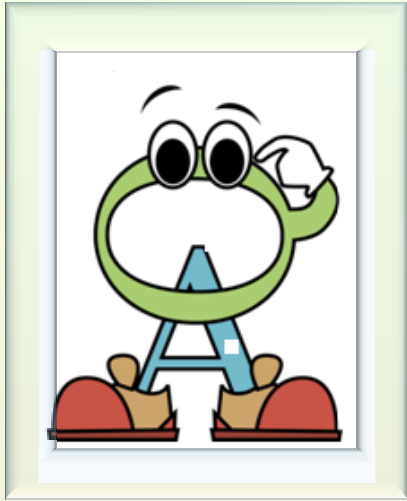
Applies to <u>all</u> <u>EPA</u> <u>employees</u> who are responsible for <u>developing,</u> <u>distributing</u> and <u>disseminating</u> products and services in support of EPA's mission.

Products and Services

   means environmental data collection, productions, and use. [1]

[1] 12/16/10 memo from Malcolm D. Jackson, Assistant Administrator and Chief Information Officer clarification on CIO 2106.

CIO 2105.0 * (formally 5360.1) (approved 5/5/2000)
CIO 2105P * (Quality Manual for Environmental Program)

establishes a policy for
mandatory

Quality System for all environmental programs performed by or directly for EPA through EPA-funded extramural agreements

The <u>Order</u> is to <u>ensure that environmental data</u> obtained/collected by the Region or delegated State, Local and Tribal Governments are of sufficient quantity and adequate quality <u>for their intended use</u> and are used consistent with such intentions.

These documents can be found in the QA website (http://www.epa.gov/region8/qa/).

EPA's Quality System puts in place
a process of checks and balances
to make sure that all of our programs and
projects involving the generation or use of
environmental data
address the appropriateness of data
and is defensible.

YOU are legally responsible
for complying with

Order 5700.7* **(Environmental Results under EPA Assistance Agreement)**

40 CFR 30* **(Requires the grantee to develop and implement quality**
40 CFR 31* **assurance practices to produce data of adequate quality to**
40 CFR 35* **meet project objectives).**

48 CFR 46* **(Contract quality requirements, i.e.,** Attention to organization, planning, work instructions, documentation control, and advanced metrology.)

*this document and other QA related regulations can be found in the QA website
    (http://www.epa.gov/region8/qa/)

§ 31.45   Quality assurance **(Requirements for Grants and Cooperative Agreements to State and Local Governments)**

If the grantee's project involves environmentally related measurements or data generation, the grantee shall develop and implement quality assurance practices consisting of policies, procedures, specifications, standards, and documentation sufficient to produce data of quality adequate to meet project objectives and to minimize loss of data due to out-of-control conditions or malfunctions.

CIO 2105.0

Section 4. REFERENCES. The following documents contain provisions which… users of this Order should apply the most recent editions of the documents indicated below.

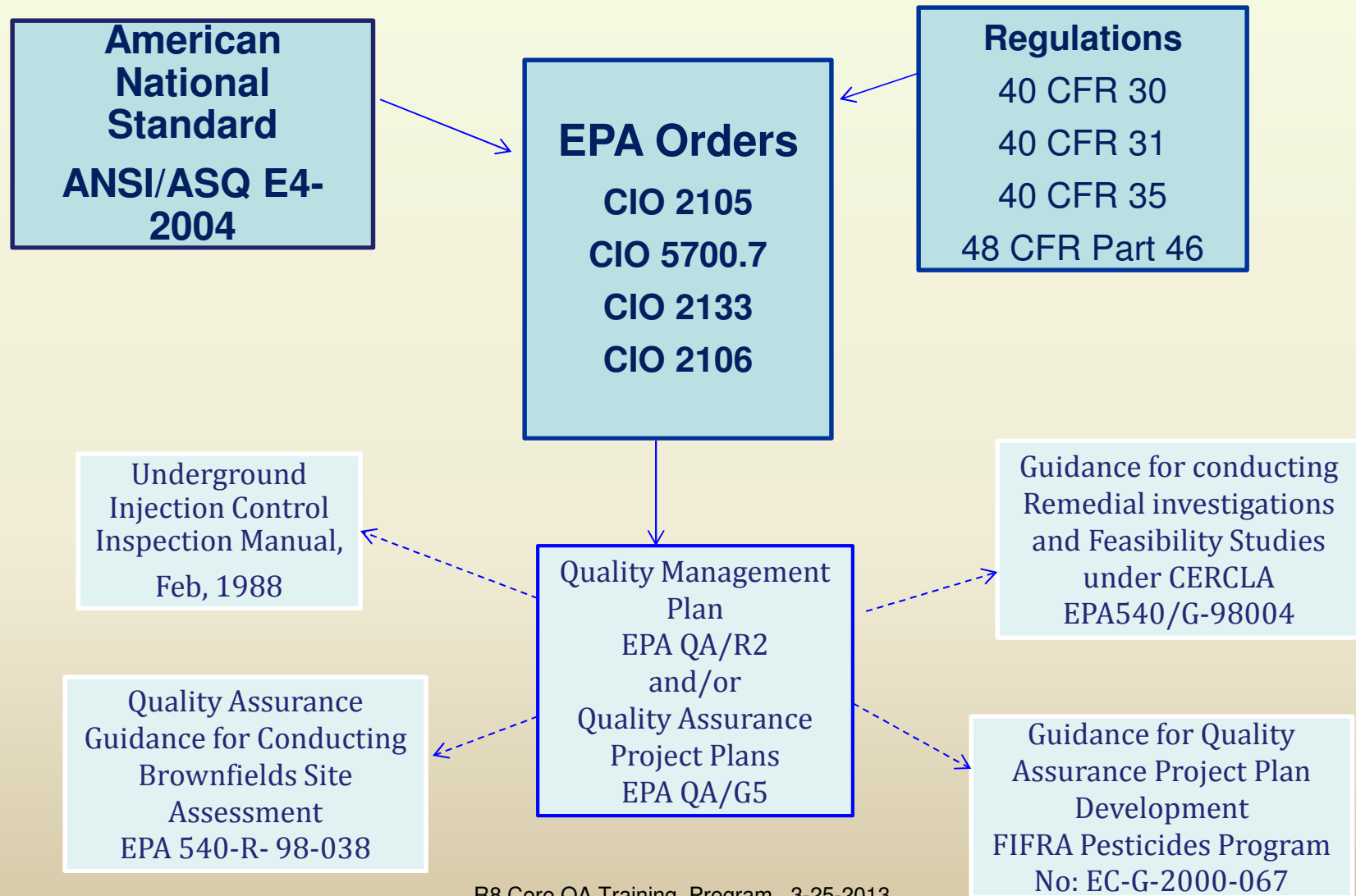   d. **48 CFR 46, "Quality Assurance**."

Section 5. SCOPE AND FIELD OF APPLICATION
    d. Organizational Applicability.
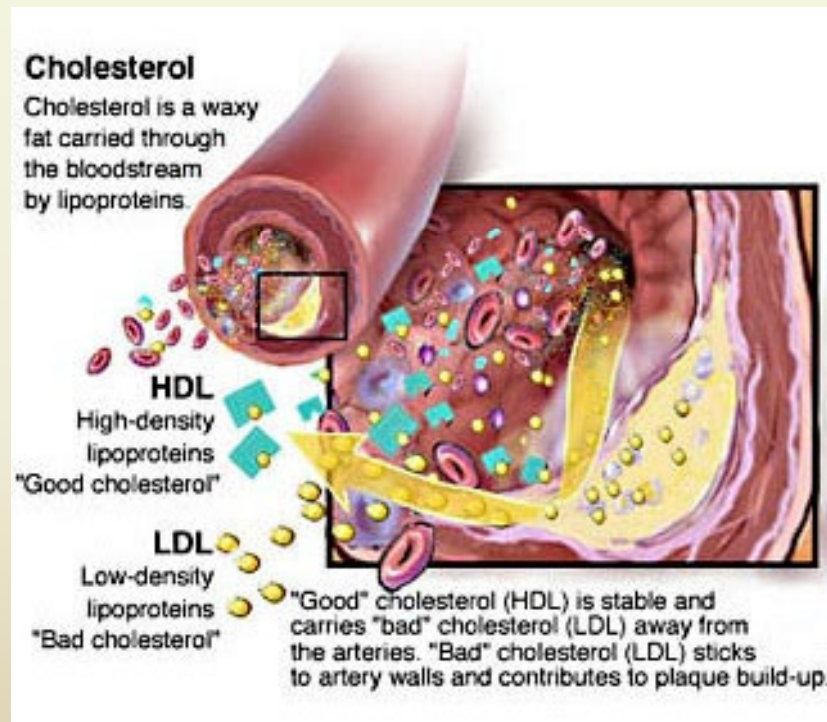   (2) **Extramural Agreements**
           (a) Any organization or individual under direct contract to EPA to furnish services or items or perform work (i.e., a **contractor)** under the authority of 48 CFR 46, (including applicable work assignments, delivery orders, and task orders)

Quality Assurance is a Regulatory Program

American National Standard

ANSI/ASQ E4-2004

EPA Orders

CIO 2105

CIO 5700.7

CIO 2133

CIO 2106

Regulations

40 CFR 30

40 CFR 31

40 CFR 35

48 CFR Part 46

Underground Injection Control Inspection Manual, Feb, 1988

Quality Assurance Guidance for Conducting Brownfields Site Assessment EPA 540-R- 98-038

Quality Management Plan EPA QA/R2 and/or Quality Assurance Project Plans EPA QA/G5

Guidance for conducting Remedial investigations and Feasibility Studies under CERCLA EPA540/G-98004

Guidance for Quality Assurance Project Plan Development FIFRA Pesticides Program No: EC-G-2000-067

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Your Health…

Cholesterol

Cholesterol is a waxy fat carried through the bloodstream by lipoproteins.

HDL
High-density lipoproteins "Good cholesterol"

LDL
Low-density lipoproteins "Bad cholesterol"

"Good" cholesterol (HDL) is stable and carries "bad" cholesterol (LDL) away from the arteries. "Bad" cholesterol (LDL) sticks to artery walls and contributes to plaque build-up.

- You may be weighting a health risk such as high cholesterol levels

  and

- Your concern about medication…

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Environmental Data

Any measurement or information that describes environmental processes, location, or condition; ecological or health effects and consequences, or the performance of environmental technology.[1]

Environmental data include any information collected directly from measurements or obtained from any other sources (i.e., existing/secondary data) such as those compiled from data bases, data reports, literature, surveys, or produced from models.[2]

[1] universal definition; as defined in ANSI/ASQ E4-2004
[2] EPA Quality Manual for Environmental Programs (CIO 2105-P-01-0)

QA is all about asking the **questions of:**

What,
Where,
When,
How, and
Why
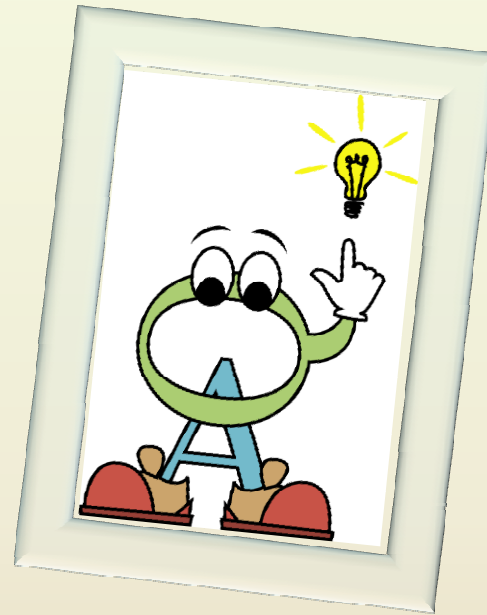
to help to organized your thoughts, to find out the risk, to **Plan** and THEN **make a truly informed decision.**

- You might be assessing the cleanup in your own back yard

- Is the cleanup good enough?
- Is it safe for the kids in the neighborhood?

- What is the definition of good?
- What is the definition of safe?

HAZARDOUS MATERIALS AND WASTE MANAGEMENT DIVISION
Colorado Department of Health and Environment
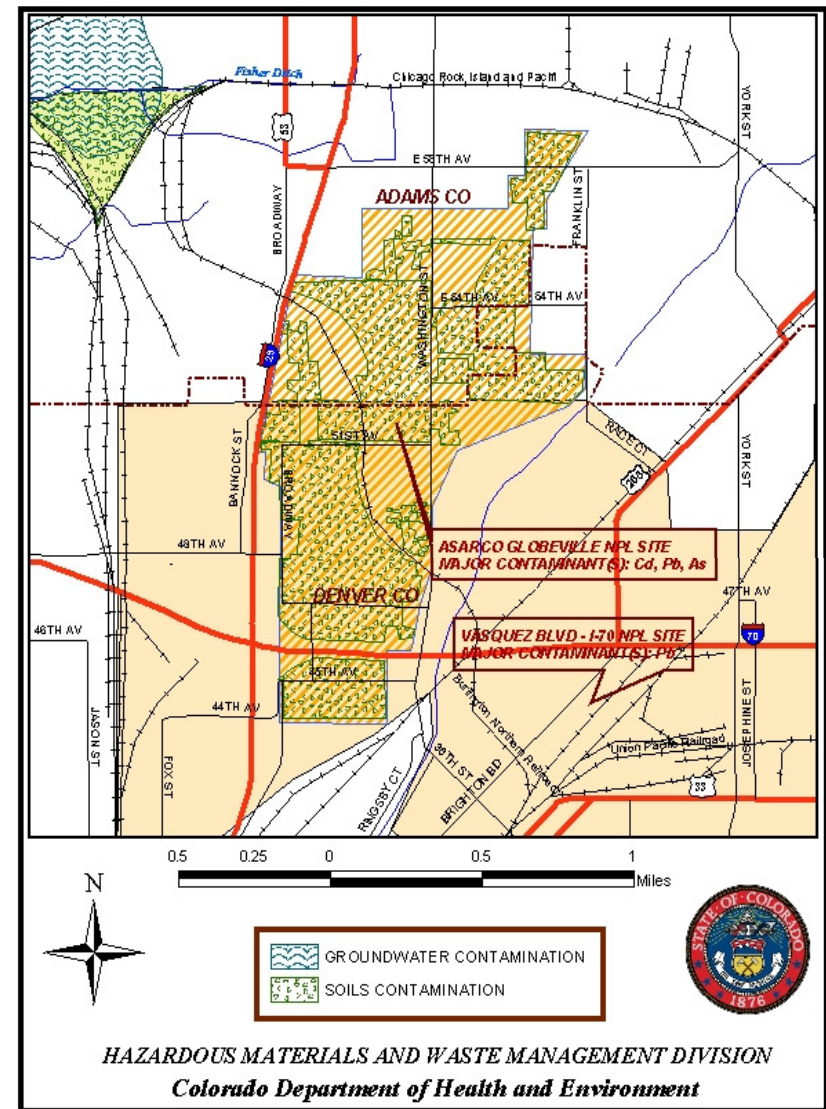
You might be concerned about the air you breathe.

Air Pollution

respiratory, cancer, immune and other diseases

…acid rain
…harm the plant and animal life

influence land-use and transportation decisions

You might be concerned about your drinking water.

UIC Program - regulating the disposal of fluids into the subsurface from simple devices (floor drains) to complex system (injection wells).

QA Document Types

- The **QMP** describes processes and procedures at the organizational level, management and staff functional responsibilities and line of authority. Include all QMP elements (QA/R-2).

- The **QAPP** is the document that details the who, what, when, where, why and how of the project objectives (data quality objectives). Include all QAPP elements (QA/R-5 and QA/G-5).

- The **Field Sampling Plan** (**FSP**) provides the field sampling details for the sampling event(s).

- The **Sampling and Analyses Plan** (**SAP**) provides the field and analytical details for the sampling event(s).

- **Standard Operating Procedures** (**SOPs**) describe specific procedures (e.g., sampling techniques or field analytical methodologies) used. These are attached to the approved QA Document(s).

Note:
- FSPs, SAPs, and SOPs are subsets of a QAPP

- FSPs and SAPs may be addendums to a previously approved QAPP
  or
  a stand alone QA document, if all QAPP elements are included (QA/R-5 and QA/G-5)

Putting it all together…

QMP — Organization

QAPP — Project

FSPs/SAPs

SOPs
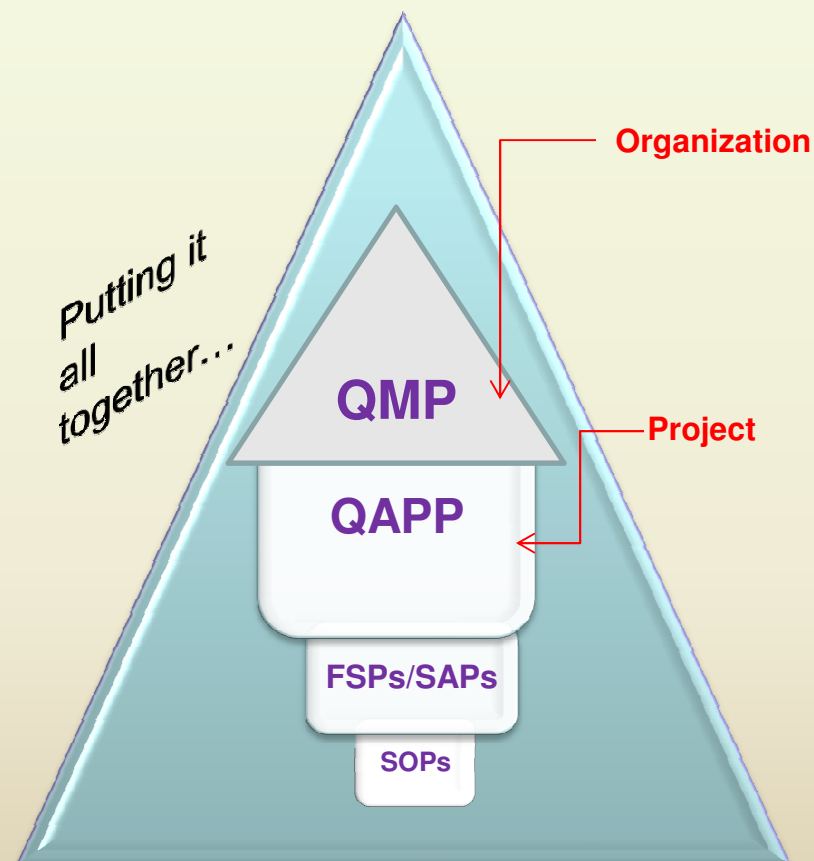
The QAPP is developed by
– The Grantee (for a grant)
– The Contractor (for a contract)
– EPA (for activities conducted/directed by EPA personnel).

The QAPP must be complete, addressing all QAPP components, regardless of project size.

Important Requirement/Guidance/Assistance*

- QA/G-5 is the guidance on developing Quality Assurance Project Plans that meet EPA specifications. http://www.epa.gov/quality/qs-docs/g5-final.pdf

- QA/R-5, "EPA Requirements for QA Project Plans", describes how we plan a project. http://epa.gov/quality/qs-docs/r5-final.pdf

- Region 8 QAPP Checklist is based on QA/R5 for QAPP development. *Region 8 QA Document Review Crosswalk*

- Uniform Federal Policy for Quality Assurance Project Plans. http://www.epa.gov/swerffrr/documents/qualityassurance.htm

** these documents can be found in the QA website (*http://www.epa.gov/region8/qa/*)*

- Project Officers and/or Project Managers need to use the checklist* to ensure all elements of the QAPP are included.

EPA Region 8 QA Document Review Crosswalk

this document can be found in the QA website (http://www.epa.gov/region8/qa/)

The **QAPP must be**:
- **Reviewed by EPA program(s)** for contract, grants, and program requirements and consistency.

- **Reviewed by the QA staff and/or Delegate completing the R8 Crosswalk.**

- **Signed-off by the representatives of all major project participants**, at a minimum:
  - the grantee's/contractor Project Manager,
  - the grantee's/contractor individual with QA management responsibilities,
  - EPA Project Officer/Tribal Coordinator/Program Coordinator, and
  - the EPA Region 8 QA Director or Delegate.

- Final signed copies must be distributed to all involved parties.

- **Document control** is required for all QA documents reviewed and signed.
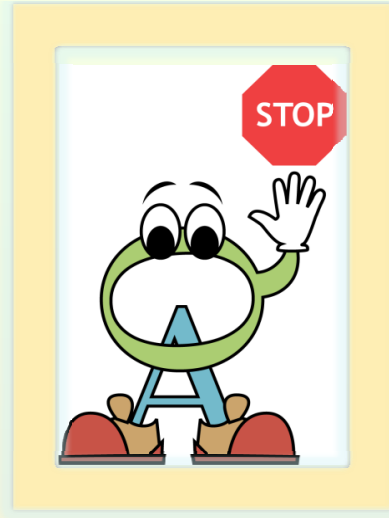
No data/information collection may begin until the QAPP (or UFP QAPP) has been approved!!!

- **IGMS**
  B.5 Quality Assurance

B.5. Quality Assurance: Does this program or project include generation of environmental data, or use of existing environmental data?	
	B.5.a. Are the proposed measurement activities covered by an existing or draft Quality Management Plan (QMP), or Quality Assurance Project Plan (QAPP)?
	B.5.b. Are the QA Plans or QA documents required for this assistance award approved?

- The purpose of a QA program is to assure the accuracy of environmental data on which environmental decisions may be made.

- Considering the definition of environmental data, you should assure the answer to Question B.5. is correct. If Question B.5. is answered "Yes", Questions B.5.a. and B.5.b. will open and, based on the responses to those, the appropriate terms and conditions **must** be added to the award.

http://intranet.epa.gov/OGD/course_library/manager/0.1-09-INFO-FR.html

```
Grant Application Received
 And
FR Form Initiated
```

```
Grants
Provide
Grantee
List to QA
```

```
FR (question B.5)
states Data/Info
Collection in
Workplan?
```

Yes

```
FR (question
B.5.a ) states
QAPP
Available and
QAPP Approved
demonstration
provided?
```

Yes

Grant Approved

No

No

```
Grant Issued.
No Further QA
Review
```

```
QA will
evaluate all
grants
categorized as
"No Data"
```

```
Grants
Places
Condition
on Grant
(i.e., 60 to
90 day
Review
Period)
```

```
Notify PO
of Grant
Condition
```

```
PO
acknowledges
grant
condition
```

```
Notify QA
for
Technical
Assistance
```

```
Project /Tribal
Manager
work with
grantee on
QMP/QAPP
```

```
QAPP
Approved
(QA and
Program
Signatures
obtained)
```

Yes

No

```
Program/Tribal
Manager provides
demonstration
Grants Program
Condition met
```

```
Notify Grants Program
condition not met
```

```
Grants Program
Notify Applicant
application Not
Approved
```

```
Work with Applicant
to submit
approvable QAPP
```

→ Grant Process Path Flow

--→ Coordination with QA

--→ Communication Requirement for PO and PM/TM

QARFs

The **QA Review Form* (**QARF) provides confirmation … that appropriate QA and QC requirements have been determined.

The QARF attached to the work assignment shall identify clearly those work assignments that need QA and QC specifications and shall identify the necessary requirements.

*CIO 2105P, CHAPTER 2, QUALITY SYSTEM IMPLEMENTATION
  2.4.1 Contracts

For Contracts:

The **QA Review Form (QARF) is required for all contracts** and must be **signed by** the **Project Officer** <u>and</u> the **Region 8 QA Director** <u>prior</u> to funding (e.g. in EAS).

The Task Order Statement of Work must be provided with the QARF.

The QARF is a legal document. The Region 8 QA Director is the last signature.

See Delegation Training for more information.

APPENDIX 46.1D U.S. EPA QUALITY ASSURANCE REVIEW FORM FOR CONTRACT ACTIONS

I.   General Information

a. Vehicle Type:

[ ] Solicitation/Sole Source (RFP #: _____)

[ ] Delivery Order/Work Assignment /Task Order
(SOW #: _____) and Contract #: _____)

b. Descriptive Title: _____

c. Sponsoring Organization (e.g., Branch, Division, Office, etc.): _____

d. Project Duration: _____

e. Is this a new [ ] or continuation of an existing [ ] project?

II.   Scope of Work

[For example activities, see www.epa.gov/quality/examples.html.]

a.   Does the work involve:

• the collection, generation, use, and/or reporting of environmental data? (Environmental data are defined as any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such

Yes   No

[ ]   [ ]

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QAPP is a living document

- A re-write is not necessary if no significant changes
  - ✓ Make changes directly on document
  - ✓ Initial and date the change(s)
  - ✓ Make changes <u>before</u> activity is conducted
  - ✓ Maintain a log of the changes throughout the year

- **Must be approved prior to** any data gathering work or use

Annual Review
- ✓ QAPPs <u>shall</u> be reviewed at least annually

Emerging QA Issues

- OIG Audit of Regional QAPPs
- New QA Requirements
  - Quality Standard in Federal Register
  - Handbooks will replace guidelines
- External Reviews of QAPPs
  - Congressional interest in QAPPs
 - Lawsuits regarding enforcement cases

How to Reach the Region 8 QA Staff

- **Regional QA Program Director**
  - Linda Himmelbauer, 303-312-6020, himmelbauer.linda@epa.gov
- **QA Staff**
  - Tom Brooks, 303-312-7291, brooks.tom@epa.gov
  - Jennifer Berig, 303-312-6262, berig,jennifer@epa.gov
  - Lee Hanley, 303-312-6555, hanley.lee@epa.gov
  - Bill Monson, 303-312-6985, monson.bill@epa.gov
  - Jeff Pritt, 303-312-7077, pritt.jeff@epa.gov
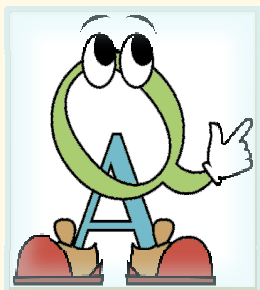
Additional Information

§ 31.40   Monitoring and reporting program performance

(a) *Monitoring by grantees.* Grantees are responsible for managing the day-to-day operations of grant and subgrant supported activities. Grantees must monitor grant and subgrant supported activities to assure compliance with applicable Federal requirements and that performance goals are being achieved. Grantee monitoring must cover each program, function or activity.

Four Main Parts of a QAPP

- ## A. Project Management

  project history and objectives, roles and responsibilities of the participants, etc.

- ## B. Data Generation/Acquisition

  project design and implementation (sampling methods, measurement and analysis, data collection or generation, data handling

- ## C. Assessment and Oversight

  assessing project implementation effectiveness and QA/QC activities

- ## D. Data Validation and Usability

  addresses the QA activities after the data collection, ensures data conform to the project criteria and objectives