College of Applied Medical Sciences

Department of Environmental Health

Quality Control

Lecture2



# **DEFINITION OF QA/QC**

**Quality assurance** (**QA**) refers to the overall management system which includes the organization, planning, data collection, quality control, documentation, evaluation, and reporting activities of your group. QA provides the information you need to ascertain the quality of your data and whether it meets the requirements of your project. QA ensures that your data will meet defined standards of quality with a stated level of confidence.

**Quality control (QC)** refers to the routine *technical activities* whose purpose is, essentially, error control. Since errors can occur in either the field, the laboratory or in the office, QC must be part of each of these functions. QC should include both internal and external measures. Together, QA and QC help you produce data of known quality, enhance the credibility of your group in reporting monitoring results, and ultimately save time and money. However, a good QA/QC program is only successful if everyone consents to follow it and if all project components are available in writing. The Quality Assurance Project Plan (QAPP) is the written record of your QA/QC program.

# **QC** Measures

Internal Quality Control (IQC) is a set of measures that the project undertakes among its own samplers and within its own lab to identify and correct analytical errors. Examples include lab analyst training and certification, proper equipment calibration and documentation, laboratory analysis of samples with known concentrations or repeated analysis of the same sample, and collection and analysis of multiple samples from the field.

**External Quality Control**(EQC) is a set of measures that involves *laboratories and people outside of the program*. These measures include performance audits by outside personnel, collection of samples by people outside of the program from a few of the same sites at the same time as the volunteers, and splitting some of the samples for analysis at another lab.

External and internal QC measures are described in more detail in the "QC Samples" box at the end of this chapter. This chapter is designed to introduce you to the terminology of quality assurance/quality control. The key terms we will be addressing are: precision, accuracy (sometimes referred to as bias), representativeness, completeness, comparability, and sensitivity. You will be seeing these terms again, so you may want to spend some time getting to know them.

In natural systems, such as streams, lakes, estuaries, and wetlands, variability is a factor of life. Changes in temperature, flow, sunlight, and many other factors affect these systems and the animals that inhabit them. Variability also occurs when we attempt to monitor such systems. Each of

us reads, measures, and interprets differently; we may also apply different levels of effort in how we monitor.

The equipment we use may be contaminated, broken or incorrectly calibrated. These and many other differences can lead to variability in monitoring results. Measures of precision, accuracy, representativeness, completeness, comparability, and sensitivity help us evaluate sources of variability and error and thereby increase confidence in our data.

Because all projects have different goals, data users and uses, capabilities, and methods, this document cannot tell you what levels of precision, accuracy, representativeness, completeness, comparability, and sensitivity are acceptable for your individual project. You will need to consult your advisory panel (in particular, your data users), the laboratory you deal with, and peer reviewers to determine acceptance criteria for your monitoring project.

# **Precision**

Precision is the degree of agreement among repeated measurements of the same characteristic on the same sample or on separate samples collected as close as possible in time and place.

Replicate samples are two or more samples taken from the same place at the same time. When you have many replicate samples, determine precision by calculating the **standard deviation(s)** of the samples. The standard deviation indicates the range of variation in the measurements you've taken. Many of today's calculators perform the standard deviation calculation.

**STANDARD DEVIATION** (s): The Project wants to determine the precision of its temperature assessment procedure. They have taken 4 replicate samples:

Replicate 1 (X1) =  $21.1 \, {}^{0}\text{C}$ 

Replicate 2 (X2) =  $21.1^{\circ}$ C

Replicate 3 (X3) =  $20.5 \, {}^{\circ}\text{C}$ 

Replicate 4 (X 4) =  $20.0 \, {}^{\circ}\text{C}$ 

To determine the **Standard Deviation** (s), use the following

formula:  $S = \sqrt{\sum_{i=1}^{n} \frac{(X_1 - \overline{X})^2}{n-1}}$ 

where xi = measured value of the replicate,  $\overline{x}$  = mean of replicate measurements,

 $\mathbf{n}$  = number of replicates,

 $\Sigma$ = the sum of the calculations for each measurement value--in this case,  $X_1$  through  $X_4$  First, figure out the mean, or average of the sample measurements.

Mean =  $(X_1 + X_2 + X_3 + X_4) \div 4$ . In this example, the mean is equal to  $20.68^0$  C.

Then, for each sample measurement (X1 through X4), calculate the next part of the formula. For  $X_1$  and  $X_2$ , the calculation would look like this:

$$\frac{(21.1 - 20.68)^2 = (-0.42)2}{4 - 1} = \frac{0.1764}{3} = 0.0588$$

For  $X_3$  the calculation would be 0.0108; and for  $X_4$  it would be 0.1541 Finally, add together the calculations for each measurement and find the square root of the sum: 0.0588 + 0.0588 + 0.0108 + 0.1541 = 0.2825. The square root of 0.2825 is 0.5315.So, the standard deviation for temperature is 0.532 (rounded off).

The **relative standard deviation (RSD)**, or coefficient of variation, expresses the standard deviation as a percentage. This is generally easier for others to understand. The smaller the relative standard deviation (or standard deviation), the more precise your measurements.

#### **RELATIVE STANDARD DEVIATION (RSD).**

If we use the same replicate measurements as above in the standard deviation example, we can determine the **Relative Standard Deviation** (**RSD**), or coefficient of variation, using the following formula:

$$RSD = \underline{s} \times 100$$

 $\underline{\mathbf{X}}$ 

where s = Standard deviation and x = mean of Replicate samples. We know s = 0.5315 and that x = 20.68. So, the RSD = 2.57. This means that our measurements deviate by about 2.57%. When you have only two replicate samples, determine precision by calculating the **relative percent difference** (**RPD**) of the two samples.

Again, the smaller the relative percent difference, the more precise your measurements.

# RELATIVE PERCENT DIFFERENCE (RPD).

If the Volunteer Creek project had only two replicates (21.10 C and 20.50 C) they would use **Relative Percent Difference (RPD)** to determine precision.

$$RPD = \underbrace{(X1-X2)\times 100}_{(X1+X2)\div 2}$$

where  $X_1$  = the larger of the two values and  $X_2$  = the smaller of the two values. In this example,  $X_1 = 21.1^0$  and  $X_2 = 20.5^{-0}$ 

RPD = 
$$\underline{(21.1-20.5)} \times \underline{100} = \underline{60.00} = 2.88$$
  
 $(21.1+20.5) \div 2 \qquad 20.8$ 

So, in this example, the RPD between our sample measurements is 2.88%.

# PRACTICAL CONSIDERATIONS IN DEVELOPING QA/QC SYSTEMS

Implementing QA/QC procedures requires resources, expertise and time. In developing any QA/QC system, it is expected that judgements will need to be made on the following:

- 1• Resources allocated to QC for different source categories and the compilation process .
- 2• Time allocated to conduct the checks and reviews of emissions estimates.
- 3• Availability and access to information on activity data and emission factors, including data quality .
- 4• Procedures to ensure confidentiality of inventory and source category information, when required .
- 5• Requirements for archiving information.
- 6• Frequency of QA/QC checks on different parts of the inventory.
- 7. The level of QC appropriate for each source category.
- 8• Whether increased effort on QC will result in improved emissions estimates and reduced uncertainties .
- 9• Whether sufficient expertise is available to conduct the checks and reviews.

#### **ELEMENTS OF A QA/QC SYSTEM**

The following are the major elements to be considered in the development of a QA/QC system to be implemented in tracking inventory compilation:

- 1. An inventory agency responsible for coordinating QA/QC activities;
- 2• A QA/QC plan;
- 3• General QC procedures (Tier 1);
- 4. Source category-specific QC procedures (Tier 2);
- 5• QA review procedures;
- 6• Reporting, documentation, and archiving procedures.

For purposes of the QA/QC system, the Tier 2 QC approach includes all procedures in Tier 1 plus additional source category-specific activities.

# **QA/QC Program Requirements**

## **Basic Requirement**

Each plant shall have a program with three basic elements:

## **QA/QC Plan**

The producer will prepare a written quality control plan. The plan may be generic but must be site-specific. The plan will describe in detail how the producer proposes to control the equipment, materials and production methods to insure that the specified products are obtained. The plan will list the personnel responsible for production and quality control at the site. The following specific information will also be included in the plan:

**1•** Identification of the physical location the plant, to include a description of the property site and references to the nearest identifiable points such as highways and towns.

- **2•** The method of identification of each lot of product during manufacturing, testing storage and shipment. Some specifying agencies may require special means of identifying and segregating product.
- **3•** The method of sampling, conditioning and testing of raw materials and finished product including lot sizes and type of tests performed as well as a description of equipment used to perform the tests. This plan will also include a method to trace the raw material lot to the finished product.
- **4•** A plan for dealing with quality control sample failures. This plan will include how the producer plans to initiate an immediate investigation and implement corrective actions to remedy the cause of the problem. This plan will also include the tests performed, the methods used to determine what tests are performed, and the person responsible for making the determination
- 5• A loading and shipping control plan which includes a description of the methods by which the products are to be loaded and shipped. The plan will also include methods of ensuring that all products are properly identified.

## ISO AS A DATA QUALITY MANAGEMENT SYSTEM

The International Organization for Standardization (ISO) series programme provides standards for data documentation and audits as part of a quality management system. Though the ISO series is not designed explicitly for emissions data development, many of the principles may be applied to ensure the production of a quality inventory. Inventory agencies may find these documents useful source material for developing QA/QC plans for greenhouse gas inventories. Some countries (e.g. the

United Kingdom and the Netherlands) have already applied some elements of the ISO

standards for their inventory development process and data management.

The following standards and guidelines published under the ISO series may supplement source category-specific QA/QC procedures for inventory development and provide practical guidance for ensuring data quality and a transparent reporting system.

**ISO 9004-1:** General quality guidelines to implement a quality system.

**ISO 9004-4:** Guidelines for implementing continuous quality improvement within the organisation, using tools and techniques based on data collection and analysis.

**ISO 10005:** Guidance on how to prepare quality plans for the control of specific projects.

**ISO 10011-1:** Guidelines for auditing a quality system.

**ISO 10011-2:** Guidance on the qualification criteria for quality systems auditors.

**ISO 10011-3:** Guidelines for managing quality system audit programmes.

**ISO 10012:** Guidelines on calibration systems and statistical controls to ensure that measurements are made with the intended accuracy.

**ISO 10013:** Guidelines for developing quality manuals to meet specific needs.