

Air Monitoring Directive

CHAPTER 5: QUALITY SYSTEM

for Developing, Implementing and Maintaining a Quality Management System for Air Monitoring

[referred to as ‘the Quality System Chapter’ of the
Air Monitoring Directive]

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1.0 PURPOSE

This Quality System document is part (Chapter 5) of Alberta’s Air Monitoring Directive (Alberta Environment and Sustainable Resource Development 2014, as amended) and will hereafter be referred to as the ‘Quality System Chapter’. Refer to Chapter 1 of the AMD (Introduction) for requirements and definitions that apply to all parts of the AMD, a list of what components constitute the AMD, and details on review of and revisions to the AMD.

The purpose of the Quality System Chapter is to establish a set of consistent requirements for the documentation, implementation and maintenance of a Quality System to:

- verify the quality of air monitoring data;
- establish consistency in air monitoring practices;
- ensure comparability of data; and
- ensure that air monitoring, reporting and maintenance activities are delivered with consistent quality.

The requirements set out in the Quality System Chapter (Chapter 5) of the AMD apply to the person responsible, including:

- Alberta airsheds and industrial operations who conduct air monitoring or reporting; and
- Alberta airsheds or industrial operations who hire contractors to conduct air monitoring or reporting on their behalf.

For example, an industrial operation would not be required to have a QAP if they are not required to do air monitoring or reporting as per their approval requirements. However, if an industrial operation is required to report emissions, but is not required to do monitoring, they would still be required to have a QAP (although the QAP may be limited in scope). Refer to Section 6.2 (Contracted Services) for requirements when services are contracted out.

The Quality System Chapter does not include requirements for CEMS monitoring. The *CEMS Code* (Alberta Environmental Protection, 1998) includes requirements for a QAP for CEMS monitoring.

QS 1-A The person responsible must comply with the requirements set out in the Quality System Chapter of the AMD on or before June 20, 2015.

1.1 Amendments to the Air Monitoring Directive

The 2006 Amendments to the Air Monitoring Directive, 1989, also called the AMD 2006, (Alberta Environment 2006) is hereby amended as follows:

QS 1-B Sections 2.1 through 2.8 of the AMD 2006 are repealed and replaced with the Quality System Chapter.

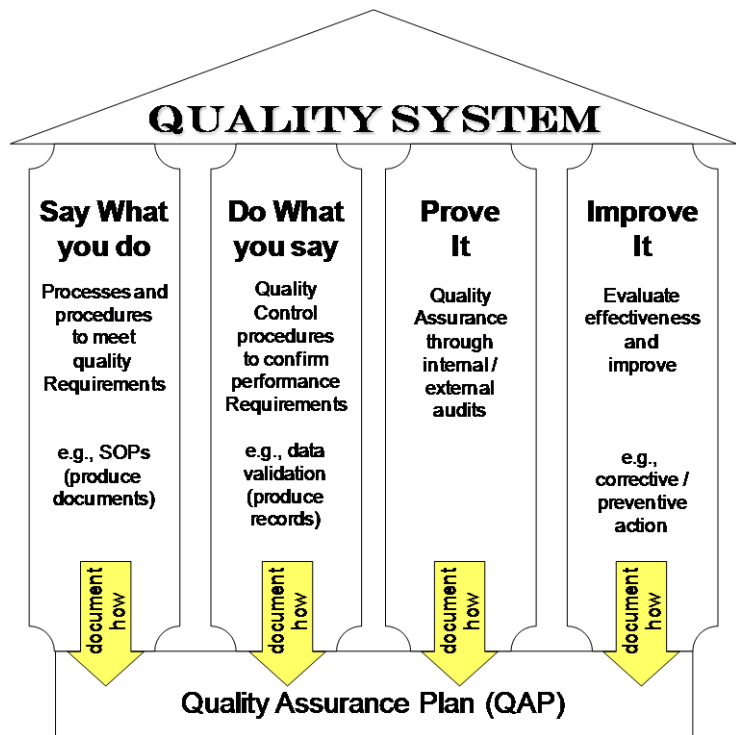
- QS 1-C Clauses 2.9.1 through 2.9.33 of the AMD 2006 are repealed and replaced with the Quality System Chapter.*
- QS 1-D Clauses 2.9.35, 2.9.36, 2.9.39 and 2.9.44 of the AMD 2006 are repealed and replaced with the Quality System Chapter.*
- QS 1-E Clauses 2.9.48 through 2.9.59 of the AMD 2006 are repealed and replaced with the Quality System Chapter.*

2.0 QUALITY SYSTEM

A Quality System consists of policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plans that an organization uses to ensure quality in its work processes, products and services. The Quality System provides the framework for planning, implementing, documenting, assessing and improving work performed by the organization, including Quality Assurance and Quality Control.

All of the policies and practices used by an organization comprise that organization’s Quality System.

Establishing, implementing and maintaining a Quality System ensures that monitoring and reporting procedures are verified and documented, so that uncertainties in the reported data are known and can be controlled.



- QS 2-A The person responsible shall (a) establish, (b) implement, and (c) maintain a comprehensive Quality System that meets the requirements of the AMD.*
- QS 2-B The person responsible shall have a Quality Assurance Plan (QAP) that documents the Quality System required by clause QS 2-A.*

A comprehensive Quality system (QS 2-A) includes all phases of monitoring, reporting and maintenance activities. The QAP (QS 2-B) provides documentation of a Quality System and

should document how the person responsible intends to meet the requirements of the AMD. By following a QAP, the quality of the data being collected and reported is known and documented.

There are some procedures and processes which are not required to be documented. In these cases, the person responsible must be able to demonstrate that a consistent process or procedure is in place and that any person conducting the process or procedure is knowledgeable of the correct process or procedure.

A Quality System can be customized so that the system established is appropriate to the type, range, and volume of monitoring and reporting activities undertaken, as long as the minimum requirements set out in this Quality System Chapter are met. For this reason, development of a Quality Assurance Plan template is not feasible, as each organization will have its own unique processes.

3.0 DOCUMENT, RECORD AND DATA MANAGEMENT

3.1 Control of Documents

Documents are information in a particular supporting medium. For example, a QAP is a document (paper or electronic) outlining the components of a Quality System (outlining the processes in place and how things will be done).

QS 3-A The person responsible shall (a) establish, (b) implement, and (c) maintain documented procedures to control all documents that are necessary for the operation of the Quality System (internally generated or from external sources), so that these documents are:

- (i) accessible at known locations;*
- (ii) regularly reviewed, not to exceed a maximum interval of three years; and*
- (iii) revised when processes or systems change.*

QS 3-B The person responsible shall (a) establish, (b) implement, and (c) maintain documented procedures for the creation and modification of controlled documents such that:

- (i) all controlled documents are approved for use by authorized personnel, as designated by the person responsible, prior to issue; and*
- (ii) all approved changes to controlled documents are traceable.*

Traceability of changes to controlled documents could include keeping old versions of a document so that versions can be compared, or highlighting changes in most recent version of a document.

QS 3-C The person responsible shall a) communicate and b) make available the relevant Quality System documentation to all personnel identified pursuant to QS 6-A.

QS 3-D Current editions of applicable controlled documents shall be available at all locations where operations essential to the functioning of the air monitoring and reporting activities are performed.

3.2 Control of Records

Records state results achieved or provide evidence of activities performed. Records may include electronic, written, photographed, or otherwise recorded evidence, including data. Records can be used to assess whether a requirement of the AMD or Quality System has been fulfilled.

QS 3-E The person responsible shall (a) establish, (b) implement, and (c) maintain a documented procedure for the identification, storage, protection, retrieval, retention, and disposition of the records required in QS 3-F.

QS 3-F The person responsible shall (a) establish and (b) maintain records that:
(i) relate to the air monitoring, analysis, reporting, and maintenance activities;
(ii) enable determination of compliance with the AMD and the Quality System of the person responsible, including but not limited to, training, purchasing, audits, inspections, and reviews; and
(iii) are accessible as necessary for internal or external use or review.

Records (for example field sheets, station log books, etc.) must be maintained for all activities including, but not limited to, calibration, personnel/training, maintenance, monitoring methods, sample analysis, equipment identification, non-compliance, purchasing, corrective or preventive action, audits, inspections, system evaluation, and incidents.

QS 3-G The person responsible shall retain all records pursuant to clause QS 3-F for a minimum of three years unless otherwise specified in the AMD.

QS 3-H The person responsible shall have a plan for record maintenance or transfer of the records in QS 3-F in the event that the person responsible's ownership is transferred or the person responsible goes out of business.

QS 3-I Where computers, automated equipment, microprocessors or other electronic equipment are used for the acquisition, processing, recording, reporting, storage, or retrieval of air monitoring or calibration data, the person responsible shall:
(a) (i) establish and (ii) implement procedures for protecting the data; and
(b) (i) establish and (ii) implement procedures for maintaining and securing data, including the prevention of unauthorized access to, and the unauthorized amendment of, electronic records.

QS 3-J When any corrections are made to the records in QA 3-F, the person responsible shall:

- (a)* cross out errors and enter the correction alongside, without erasing, deleting or making the original record illegible for hard copy records; and
- (b)* sign or initial any alteration to records pursuant to clause QS 3-J(a); or
- (c)* in the case of records stored electronically, take equivalent measures to avoid loss or change of original records.

3.3 Control of Data

QS 3-K The person responsible shall (a) establish, (b) implement, and (c) maintain documented procedures to verify that the data reported to the Regulator are free from error.

A documented validation process should be followed to identify errors in the data so that errors can be addressed before data are reported. A data treatment may need to be applied to address errors identified through the validation process.

QS 3-L The person responsible shall (a) establish, (b) implement, and (c) maintain documented procedures for demonstrating the validity of any data treatment(s) undertaken.

QS 3-M The person responsible shall (a) establish, (b) implement, and (c) maintain documented procedures for the development of data acceptance and rejection criteria where no method or regulatory criteria are specified in the AMD.

QS 3-N The person responsible shall retain all raw data for a minimum of three years.

QS 3-O The person responsible shall retain a copy of final reports and data summaries for a minimum of ten years.

The time for raw data retention is set to allow for a full internal or external audit of the data.

The Ambient Data Quality Chapter of the AMD (Chapter 6) outlines requirements for collecting, verifying and validating continuous ambient air quality and meteorological monitoring data.

4.0 INSPECTION AND AUDIT

An audit is a systematic and independent examination of records to determine whether activities and related results comply with defined specifications and requirements. An audit checks that a Quality System is working properly.

An internal audit is an examination performed by the person responsible to ensure that the AMD is adhered to, the Quality System is in place and adhered to, that corrective actions are taken when necessary, and there are no issues with data quality.

An inspection is a formal or official evaluation of the compliance of a property, commodity, or process with a specified requirement by observation or judgement. This will generally include measurement, testing, or gauging, as appropriate.

QS 4-A The person responsible shall conduct (a) internal audits and (b) inspections of air monitoring and reporting activities to verify that monitoring, reporting and maintenance operations continue to comply with the requirements of the person responsible's Quality System and the AMD.

QS 4-B The internal audits required under clause QS 4-A shall:
(a) be conducted in accordance with a predetermined schedule and procedure as determined by the person responsible; and
(b) include completion of a full Quality System audit a minimum of once every three years.

QS 4-C The internal inspections required under clause QS 4-A shall be conducted in accordance with a predetermined schedule and procedure as determined by the person responsible.

Internal audits (clauses QS 4-A and QS 4-B) may be completed through a single audit of the entire system or through multiple audits capturing portions of the overall system, provided all processes and procedures within the system are audited at least once every three years.

Internal inspections (clauses QS 4-A and QS 4-C) should be conducted to include the equipment and operations which are most significant to the success of air monitoring and reporting. The inspection frequency should be higher at monitoring startup, initiation of new monitoring or reporting activities, and with the introduction of new personnel. Inspection frequency should decrease over time, provided no non-compliances are discovered.

QS 4-D All internal audits shall be carried out by trained and qualified individuals who are, wherever resources permit, independent of the activity to be audited.

Audits do not necessarily need to be carried out by someone who is an 'independent source' (third party), but rather someone who is independent of the activity being audited and therefore not someone who regularly performs the tasks being audited.

Internal audits of the Quality System may be conducted by a third party if the person responsible so chooses, however this is not mandatory.

- QS 4-E When findings of non-compliance with the AMD or the person responsible's Quality System are identified during an audit or inspection, the person responsible shall take corrective action in accordance with QS 5-A and QS 5-B.*
- QS 4-F The person responsible shall record:*
- (a) the area of activity audited or inspected pursuant to QS 4-A, including references to the specific records reviewed;*
 - (b) any internal audit or inspection findings; and*
 - (c) corrective or preventive actions that arise from audit or inspection findings.*
- QS 4-G The person responsible shall conduct a management review of audit results to address any need to amend the Quality System and its policies and procedures in response to audit results or changing circumstances.*
- QS 4-H The management review of audit results in QS 4-G shall be documented by the person responsible.*

5.0 NON-COMPLIANCE, PREVENTIVE AND CORRECTIVE ACTION

Non-compliance is the failure to meet a requirement set out within the AMD or the person responsible's Quality System that is detected through internal or external quality control or quality assurance procedures.

Correction of data does not constitute corrective action. Correction is addressing a symptom or immediate problem, whereas corrective action is addressing the systemic root cause of a problem. For example, continually adding air to a leaky tire is a correction while repairing or replacing the tire is corrective action.

- QS 5-A The person responsible shall (a) establish, (b) implement, and (c) maintain documented processes for the following:*
- (i) handling and investigating actual and potential non-compliance;*
 - (ii) immediately commencing corrections; and*
 - (iii) identifying the root cause(s) of non-compliances.*

The processes identified in QS 5-A (i) through (iv) should be used when any aspect of air monitoring and reporting activities, or the results of these activities, do not comply with the AMD or the person responsible's Quality System.

- QS 5-B The person responsible shall (a) establish, (b) implement, and (c) maintain documented procedures for preventive action and corrective action to include the following requirements:*
- (i) corrective action is begun immediately upon determination of a root cause;*

- (ii) *corrective and preventive action is taken to eliminate the root causes of actual and potential non-compliance that is appropriate to the magnitude of the problem;*
- (iii) *where required by regulation, the Director is notified of any corrective or preventive action taken as a result of QS 5-B(i);*
- (iv) *corrected data are provided to the Regulator or anyone acting on its behalf;*
- (v) *any required changes to documented procedures resulting from corrective or preventive action are implemented; and*
- (vi) *verification activities are conducted as soon as practicable to evaluate the implementation and effectiveness of the corrective or preventive action taken.*

6.0 RESOURCES

The person responsible should provide all resources needed for establishing, implementing, and maintaining the Quality System, and for required air monitoring, reporting and maintenance activities.

Resources include, but are not limited to, personnel, financial, and technological resources.

6.1 Personnel

Personnel include anyone performing monitoring, maintenance or reporting activities, including, but not limited to employees and volunteers.

- QS 6-A The person responsible shall:*
- (a) *identify any personnel conducting monitoring, reporting or maintenance activities;*
 - (b) *define and document the responsibilities of all personnel that are involved with any of the following:*
 - (i) *the establishment, implementation, and maintenance of the Quality System; and*
 - (ii) *any air monitoring, reporting, and maintenance activities; and*
 - (c) *deploy competent personnel to perform tasks that are related to air monitoring, reporting or maintenance activities.*

Personnel competence refers to demonstrating that an activity can be adequately performed and should be based upon an appropriate combination of certification, education, training, and experience. Since the variety of different monitoring and reporting tasks require different competencies, the person responsible should define and document what skills and competencies are required for monitoring and reporting activities, and be able to demonstrate that personnel meet those requirements.

Demonstration of personnel competence can be an internal company process, unless external qualification or training requirements exist.

- QS 6-B The person responsible shall:*
- (a) identify training needs of personnel;*
 - (b) provide training for personnel;*
 - (c) supervise personnel who are in training;*
 - (d) keep training of personnel up-to-date; and*
 - (e) evaluate the effectiveness of personnel training.*

The person responsible is required to ensure that personnel performing the monitoring, reporting and maintenance tasks have adequate, up-to-date training and qualifications. This applies to all contractors, subcontractors and volunteers. In cases where the work is completed by a contractor, it is acceptable to refer to a contractor's QAP for specifics around how clause QS 6-B will be met. However, when this happens, the person responsible should have processes in place to verify that the requirements of QS 6-B are being followed by the contractor. This may include performing an audit or inspection. The person responsible is still responsible for meeting all requirements of the AMD, including any work undertaken by a contractor. Refer to Section 6.2 on contracted services.

The purpose of evaluating training effectiveness is to gauge whether or not personnel have mastered the skills and competencies required to perform the monitoring, reporting and maintenance activities. Evaluation could include testing or observation following training.

- QS 6-C The person responsible shall (a) establish, (b) implement, and (c) maintain procedures to inform all personnel identified under clause QS 6-A of all of the following:*
- (i) the importance of compliance with the requirements of the AMD and the person responsible's Quality System;*
 - (ii) their roles and responsibilities in achieving compliance with the AMD and the person responsible's Quality System; and*
 - (iii) the potential consequences for variance from specified procedures.*
- QS 6-D The person responsible shall maintain records (pursuant to clauses QS 3-E to QS 3-J) of the following:*
- (a) the relevant certification(s), including the date(s) on which certification or competence was confirmed for personnel identified in clause QS 6-A; and*
 - (b) the competence, educational and professional qualifications, training, skills, and experience of all personnel identified under clause QS 6-A.*

The person responsible can verify that a contractor maintains records on personnel certification or competence by reviewing these records during an audit or inspection. Refer to Section 6.2 on contracted services.

An example of relevant professional development is for personnel performing stack sampling holding membership in an accredited source evaluation organization such as the Source Evaluation Society (SES).

6.2 Contracted Services

A contractor may be hired by the person responsible to perform monitoring, reporting and maintenance activities on behalf of the person responsible. This will include documentation of these processes and keeping of relevant records pertaining to these activities. In this case, the contractor should have a QAP that complies with AMD requirements.

QS 6-E The person responsible is responsible for any and all air monitoring, analysis, reporting or maintenance activities conducted by a contractor on its behalf.

QS 6-F The person responsible shall (a) establish, (b) implement, and (c) maintain procedures to verify that air monitoring, analysis, reporting, or maintenance activities completed by a contractor meet the requirements of the AMD and the person responsible's Quality System.

Procedures established by the person responsible in QS 6-F may include, but are not limited to:

- reviewing the contractor's quality assurance inspection and audit reports;
- conducting inspections and/or audits of the contractor performing the monitoring activities; or
- receiving status reports from the contractor regarding compliance and non-compliance during the monitoring activities.

This is not an exhaustive list, and the options provided are not designed to be mutually exclusive. The determining factor is the confidence that the person responsible has in the contractor meeting the requirements of the AMD and agreements in place between the person responsible and the contractor.

Contractor activities are not directly enforceable under the AMD, however they can be enforced by the person responsible through a contract or service agreement.

QS 6-G The person responsible shall maintain a record, pursuant to clauses QS 3-E to QS 3-J, of all contractors performing air monitoring, analysis, reporting, or maintenance activities on behalf of the person responsible.

6.3 Purchasing of Services and Supplies

QS 6-H The person responsible shall (a) establish, (b) implement, and (c) maintain procedures for the selection and purchasing of the services and supplies used that affect or may affect the quality of the air monitoring and reporting.

Procedures for selecting and purchasing services and supplies may include having an approved vendor list or a procedure for authorization or sign-off on purchases.

QS 6-I The person responsible shall (a) establish, (b) implement, and (c) maintain procedures to verify that purchased supplies, reagents, and consumable materials that affect or may affect the quality of air monitoring comply with specifications or requirements defined in the monitoring and analysis method(s) for all monitoring methods identified in QS 7-A.

6.4 Equipment

QS 6-J The person responsible shall (a) establish, (b) implement, and (c) maintain documented procedures for:

- (i) identification, operation, maintenance and calibration of all relevant air monitoring equipment and software;*
- (ii) physically locating all air monitoring equipment at locations and in conditions that meet or exceed the operational requirements for the particular environmental monitoring equipment;*
- (iii) collection, handling, and preparation of samples, in accordance with QS 9-B, where the absence of such instructions could adversely affect the quality or consistency of the results of air monitoring or reporting;*
- (iv) safeguarding of all monitoring equipment and software from tampering or adjustments that could invalidate the monitoring results; and*
- (v) preventing the use of equipment or software that is defective or operating outside specified limits until it has been repaired and shown by calibration or test to perform within acceptable limits.*

QS 6-K For equipment or software that are modified for specific purposes outside the original intended use, the person responsible must validate this equipment or software in accordance with QS 7-D and QS 7-E.

7.0 AIR MONITORING METHODS

QS 7-A The person responsible shall accurately document all air monitoring methods and associated procedures used by them.

QS 7-B The documentation required in QS 7-A includes all of the following, where applicable, for each environmental monitoring method:

- (a) a description;*
- (b) a reference to the authority or source of method;*
- (c) the applicable matrix or media (e.g., gas, liquid, solid);*
- (d) the method detection limit(s);*

- (e) the scope and application, including the components to be analyzed;
- (f) definitions;
- (g) interferences;
- (h) the equipment and supplies required;
- (i) the linear range;
- (j) reagents and standards;
- (k) sample collection, preservation, shipment, and storage procedures;
- (l) Quality Control procedures;
- (m) calibration and standardization procedures;
- (n) calculation procedures;
- (o) data assessment and acceptance criteria for Quality Control measures;
- (p) corrective actions for out-of-control data;
- (q) references;
- (r) any tables, diagrams, flowcharts, and validation data; and
- (s) anything else requested or required in writing from the Director.

QS 7-C The person responsible shall not deviate from the air monitoring methods specified in the AMD unless the deviation has been documented, technically justified, validated as per QS 7-D and QS 7-E, and authorized in advance, in writing, by the Director.

Technical justification required for Director authorization includes a description of the monitoring method which deviates from the AMD, rationale for the deviation, and the monitoring method specifications.

The person responsible should select appropriate methods that, preferably, have been published in either national or international standards, by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment.

QS 7-D The person responsible shall validate all (a) non-standard methods, (b) standard methods used outside their intended scope, and (c) modifications of standard methods to confirm that the methods are suitable for the intended use.

Validation of non-standard methods could include comparing results from the non-standard method to those of a standard method to show that comparable data are produced.

QS 7-E The person responsible shall (a) establish, (b) implement, and (c) maintain a documented procedure to record:

- (i) the protocol used for validation in QS 7-D; and*
- (ii) the results obtained from the method validation performed in QS 7-D.*

When validating or assessing a non-standard method or a method used outside of the intended scope, the person responsible should estimate the uncertainty in the non-standard method. Uncertainty of measurement should be determined under conditions that are representative for the monitoring planned (e.g., meteorology, geography, location, etc.).

An example of how to calculate uncertainty of measurement is provided in the Appendix.

8.0 CALIBRATION

<i>QS 8-A</i>	<i>The person responsible shall (a) establish, (b) implement, and (c) maintain documented procedures for the calibration of all air monitoring equipment.</i>
<i>QS 8-B</i>	<i>If specific calibration requirements are specified as part of an air monitoring method, the person responsible shall meet those requirements in accordance with QS 7-C.</i>
<i>QS 8-C</i>	<i>Where a calibration gives rise to a set of correction factors, the person responsible shall (a) establish, (b) implement, and (c) maintain documented procedures for:</i> <i>(i) the use of correction factors;</i> <i>(ii) updating calibration records; and</i> <i>(iii) updating data records.</i>
<i>QS 8-D</i>	<i>When intermediate calibration checks are needed to maintain confidence in the calibration status of the equipment, the person responsible shall (a) establish, (b) implement, and (c) maintain a documented procedure to carry out these checks.</i>

An intermediate calibration check is performing a single point or possibly multi-point calibration response check to ensure that an analyzer is functioning properly. This is done when anomalies are noted in the data, for example an unexplained reading, baseline shift or when a daily span check reads different compared to the established value from the last full monthly multi point calibration. Normally no adjustments are made in response to intermediate calibration checks. These checks should be flagged as a maintenance check.

For detailed calibration requirements see the Calibration Chapter of the AMD (Chapter 7).

9.0 SAMPLING

Sampling is the process of obtaining a subset of measurements from a population. In the context of air quality monitoring this includes, but is not limited to, collecting a sample manually (e.g., using a canister or Tedlar bag, sampling vegetation, sampling precipitation) or passively, where a sample is sent to a laboratory for analysis. This section (9.0) applies to situations where:

- manual or passive sampling is conducted as a part of routine monitoring activities; or
- manual or passive sampling is conducted as part of special studies, investigations, confirmation of modelling results and other non-routine monitoring.

QS 9-A The person responsible shall (a) establish, (b) implement, and (c) maintain documented sampling plans and procedures whenever environmental sampling is conducted in support of air quality monitoring.

When implementing a sampling plan, the following should be recorded:

- the sampling procedure used,
- identification of the monitoring equipment used;
- environmental conditions at the time of sample collection;
- diagrams or other equivalent means to identify the sampling location(s); and
- the statistics upon which the sampling procedures are based, as applicable.

The person responsible should estimate the uncertainty of measurement when a new method is used for sampling or when an established sampling method is modified (see Section 7.0).

QS 9-B The person responsible shall (a) establish, (b) implement, and (c) maintain documented procedures for sample handling that protect the:
(i) integrity of the sample;
(ii) traceability of the sample; and
(iii) identity of the sample.

QS 9-C The person responsible shall (a) establish, (b) implement, and (c) maintain a documented sample acceptance procedure that outlines the circumstances and criteria under which samples are accepted or rejected.

QS 9-D The sample acceptance procedure in QS 9-C shall outline circumstances and criteria, in accordance with the manufacturer's directions for the specific monitoring equipment, or monitoring method, and with the AMD.

QS 9-E The person responsible shall regularly (a) assess, (b) evaluate, and (c) document the sample acceptance procedure referred to in QS 9-C.

QS 9-F The person responsible shall have all samples analyzed in a laboratory that adheres to the Laboratory Data Quality Assurance Policy (Alberta Environment, 2001), as amended, for the specific parameter(s) to be analyzed, unless otherwise authorized in writing by the Director.

The Laboratory Data Quality Assurance Policy can be found on the AMD website.

10.0 EVALUATION AND IMPROVEMENT

QS 10-A The person responsible shall (a) establish, (b) implement, and (c) maintain a documented process for regular evaluation of the Quality System effectiveness and applicability.

QS 10-B The person responsible shall (a) record the results of the evaluation in QS 10-A, and (b) continually improve the effectiveness of the Quality System based on the results of the evaluation in clause QS 10-A.

Opportunities for continual improvement are typically identified from audit results, analysis of records, corrective and preventive actions, and management reviews.

The effectiveness of the Quality System should be regularly evaluated by management. A QAP should continually be updated over time as processes change in order to keep it effective. Review of the Quality System ensures that audit findings are resolved and corrective actions are carried out.

APPENDIX CALCULATING UNCERTAINTY OF MEASUREMENT

A number of samples, say n , are collected from a given condition for which measurement uncertainty is to be assessed. The purpose is to express measurement uncertainty in a confidence interval with a certain probability, say 95 per cent. In this instance, the wider the confidence interval, the greater is the measurement uncertainty for the method in question.

For practical reasons, $n = 6$ is considered applicable and the following parameters are to be computed:

$$\bar{x} = \sum_{i=1}^n x_i / n \quad \text{the sample mean,}$$

$$\bar{x}_L = \bar{x} - t_{\alpha/2, n-1} \times s_{\bar{x}} \quad \text{the upper confidence limit of the sample mean,}$$

$$\bar{x}_U = \bar{x} + t_{\alpha/2, n-1} \times s_{\bar{x}} \quad \text{the lower confidence limit of the sample mean,}$$

$$s = \sqrt{\sum_{i=1}^n (x_i - \bar{x})^2 / (n-1)} \quad \text{the sample standard deviation,}$$

$$s_{\bar{x}} = s / \sqrt{n} \quad \text{the standard deviation of the sample mean.}$$

For 95 % confidence interval ($\alpha = 0.05$) and a sample of $n = 6$, the test statistic (t-value) is

$$t_{\alpha/2, n-1} = 2.571.$$

The measurement uncertainty is represented by $\bar{x} \pm t_{\alpha/2, n-1} \times s / \sqrt{n}$. This is $\bar{x} \pm 1.05s$ in this case.

As an example: for a sample of 6 observations: $x_1 = 0.61$, $x_2 = 0.95$, $x_3 = 0.91$, $x_4 = 1.16$, $x_5 = 0.72$, $x_6 = 0.59$. The mean is 0.82. The standard deviation s is 0.22. The resulting measurement uncertainty is 0.82 ± 0.23 .

As a rough general rule, it is recommended that the minimum sample size be $n=6$ for an adequate estimation of uncertainty. The larger the sample size, the more precise the estimation in measurement uncertainty.

Note: As the sample size changes, the t-value needs to be changed accordingly. The above calculation is appropriate for a sample size of six. For a larger sample size, other values of the test statistic need to be used.