

Laboratory Quality Manual Template

Revision Month YYYY

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1.3 ABC Quality Objectives

ABC sets the following Quality Objectives in the accomplishment of the laboratory's Mission and in the manner stated in its Values:

- Maintain a documented, internationally-recognized quality system that incorporates adequate review, and audit as well as quality assurance of laboratory data.
- Retain trained and appropriately supervised staff that demonstrate continuing proficiency to carry out assigned activities.
- Use only validated and appropriate test methods (and related work instructions) that incorporate adequate quality control.
- Produce results traceable to the SI, through a National Metrology Institute (NMI), and accorded uncertainties appropriate to requirements.
- Use only those facilities, equipment, supplies and services that are appropriate to the work of the laboratory. Ensure they are functioning properly and meet required specifications.
- Handle all samples, from acquisition to disposal, with adequate security, protection of integrity using defined processes for their acquisition or receipt, identification, checking, routing, storage and disposal.
- Maintain rigorous data/record management procedures that incorporates adequate procedures for the security, recording, calculation, validation, authorisation, transmittal, storage and disposal of all records generated within ABC.
- Manage the laboratory workload so as to sustain the ability to produce valid and competent results.

1.4 Identification

1.4.1 Form of Business (Legal Entity)

ABC was incorporated on June 1, 1989 under the **Canada Corporations Act** as a for-profit business. A copy of the ABC Articles of Incorporation are included at Appendix _____. [*Laboratories are encouraged to include some formal evidence of their establishment as a legal business entity in an appendix.*]

[Many laboratories are not an entity unto themselves, but will often form of a larger organisation. In these instances, the requirement for the demonstration of being a "legal" entity falls to the larger organisation. Laboratories are normally expected to provide the documentation showing the legal entity of the larger organisation within their quality system, if it is not already part of the quality system of the larger organisation.

In all cases, the laboratory should retain documentation in the form of an organisation chart or other, that shows how the laboratory fits into the larger organisation, the legal entity. This is especially true for public sector laboratories

4.7.1 Quality Control Samples

Quality Control Samples, as appropriate, are used to ensure that the measurement process is in control. The various types of quality control samples and the characteristics they monitor are summarised as follows:

<u>Type of QC Sample</u>	<u>Characteristic Monitored</u>
Control Standard ¹	calibration stability
Reference Sample ²	method / calibration accuracy
Duplicate Samples	method precision
Analyte or Surrogate Spike	method recovery
Reagent Blank	blank response (calibration)
Method Blank	blank response (method)
Control Sample	inappropriate toxicological response
Control Culture	inappropriate biological response

4.7.2 Level of Quality Control Effort

The specific minimum required frequency of QC samples is detailed in each individual method contained in the ABC Methods Manual. QC samples are typically be introduced into the analytical stream on a batch basis and normally comprise 20 - 30% of total sample throughput. For small batches of samples or single samples, at least one reference standard is always included.

For batch sizes of 15 - 20 the following QC samples are included:

Chemistry

one control standard, if applicable
one reference sample,
one analyte or surrogate spike, if applicable
one duplicate sample
one reagent blank, if applicable
one method blank, if applicable

Microbiology

one control culture providing a negative response
one control culture providing a positive response
one duplicate
one method blank

¹ Calibration standard shall be rerun, if appropriate, periodically throughout a batch to demonstrate process stability.

² Reference samples may be either certified reference materials or analyte-free materials to which the analyte has been added. Reference samples and test samples must be matrix matched.

5.0 MEASUREMENT TRACEABILITY AND CONFIDENCE LIMITS

5.1 Quality Objective

Produce results traceable to the SI, through a **National Metrology Institute** (NMI), and accorded uncertainties (confidence limits) appropriate to requirements.

5.2 Measurement Uncertainty (Confidence Limits)

5.2.1 Requirement

All quantitative measurements made in the laboratory are given associated confidence limits. This value is a determination of the confidence that the **Customer** may place in the derived value, and the size of that confidence region.

ABC estimates the uncertainty of all quantitative tests conducted, where this is appropriate and possible. Estimation of uncertainty forms part of method validation. See Section 4.0 above.

ABC reports the expanded uncertainty (confidence limits) as part of the reported result :

- When required by the **Customer**, or
- To establish that the data is 'fit-for-purpose', or
- To establish compliance (of the body being represented by the analysed sample) with a requirement.

5.2.2 Effort

The confidence limits associated with any result depends on the method used and considers the method, the equipment, the sample, and **sampling** used to acquire test data. All of these factors contribute to the uncertainty (confidence limits) associated with each test result.

Supervisors may make use of proficiency testing and quality control data to generate standard uncertainties associated with groups of test results or test methods.

5.3 Traceability of Measurement

ABC calibrates all of its equipment in accordance with the requirements of **CAEAL A61 – CAEAL Traceability Policy**:

8.6 Data Validation

The appropriate **Section Head** ensures that:

- test results, where appropriate, are compared with expected values, ranges, or relationships,
- data calculations and transcriptions are independently checked and verified, and
- appropriate data validation records are kept.

[Provide suitable detail on who carries out the above steps, how the LIMS is used and the mechanisms, including sampling procedures, which are used. Indicate what records are kept.]

8.7 Specifications for Reported Results

8.7.1 Flagged Results

Flags (and explanatory comments) appear on the test reports if there are no results or if the data is otherwise qualified (see 9.3.2 and 9.3.3).

8.7.2 Significant Figures

Unless otherwise specified, the number of significant figures assigned to test data does not exceed 3 and no more decimal places appear on the report than have been derived in the method detection limit.

8.7.3 Low Level Data

Unless otherwise specified, test data which are below the established method detection limit (MDL) are reported as less than the MDL (< MDL, or <0.01mg/l).

8.8 Test Reports

8.8.1 Format and Content

Test reports contain the following information, as appropriate:

- unique test report ID,
- name and address of laboratory,
- name and address of **Customer**,
- unique sample ID,
- type of sample,
- sampling method, if applicable,
- location of sampling,
- time of sampling,

Master Document List				Today's Date: 12 Nov 06			
Code	Document / Record	Rev Date	Auth	Appr	Reviewed	Location (by copy #)	Needs Review?
Q	Quality Manual	Mar-06	QA	D	Mar-06	1 – D 2 – LM 3 – SM 4 – QA 5 – Chem 6 – Micro 7 – Tox	
Q01	ABC Articles of Incorporation	Mar-03	D	BD	Apr-06	With Quality Manual	Yes
Q02	Organisation chart and staff list	Feb-06	SM	D	May-06	With Quality Manual	
Q03	Floor Plan	Feb-06	SM	LM	Feb-06	With Quality Manual	
Q04	Scope of Accreditation and List of Routine Tests	Jan-06	QA	LM	Jan-06	With Quality Manual	
Q05	Master List (this record/list)	May-06	QA	QA	Mar-06	1 – QA	
A	Administration Manual	Mar-06	SM	D	Mar-06	1 – D 2 – LM 3 – SM 4 – QA 5 – FC 6 – MC 7 – OA 8 – R 9 – Chem 10 – Micro 11 – Tox	
S01	Financial Procedures	May 06	FC	SM	Sep 06	1 – D 2 – SM 3 – FC	
P	Procedures Manual	Mar-06	QA	D	Mar-06	1 – D 2 – LM 3 – SM 4 – QA 5 – Chem 6 – Micro 7 – Tox	

Laboratory Quality Manual Template Procedures

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An investigator of an ICAR root cause shall normally follow these steps:

- Ask the question, “What caused this condition to occur?” Answers will generally come in the form of, “Circumstance “X” caused condition “Y” to occur.” Very often, the circumstance we feel is the cause of the condition is just an intermediate effect of a more fundamental root cause. We are often required to repeat the question until we get to a cause that stands on its own.
- If our final answer is something like, “I got up and came to work,” we are missing something, or we should start looking for another job. Try to find a reasonable **cause** and **effect** relation.
- Root causes are what caused the problem, not just the symptoms. For example, waking up with a headache may be caused by an imposed requirement to wake up or it may be caused by the elevated amounts of alcohol ingested the previous evening. Blaming the headache on having to get up misses the significant effect of the activities of the previous evening. In another example, shivering due to feeling cold may not be caused by exposure. It may be caused by a cold or the flu. Shivering is just a symptom – the cause is the sickness.
- Document the root cause investigation.
- Anyone having any difficulty with the determination of the root cause of a non-conforming or potentially non-conforming condition should speak to the QA/QC Coordinator for assistance.

Once the root cause is identified:

- Determine a range of appropriate corrective action that will prevent the problem from recurring or appropriate preventive action that will prevent the problem from occurring in the first place.
- Establish an appropriate form of corrective/preventive action.
- Document the corrective/preventive action selected on the ICAR.

Consensus from all those that may be involved in implementing the solution and any supervisory or management is obtained at this stage. The signature of the investigator is the final step in the acquisition and articulation of this consensus. The ICAR is then submitted to the QA/QC Coordinator.

The QA/QC Coordinator signs and dates to indicate acceptance of the recommended Corrective / Preventative action. The form is then returned to the originator, or other person responsible, for implementation of the Corrective / Preventative action.

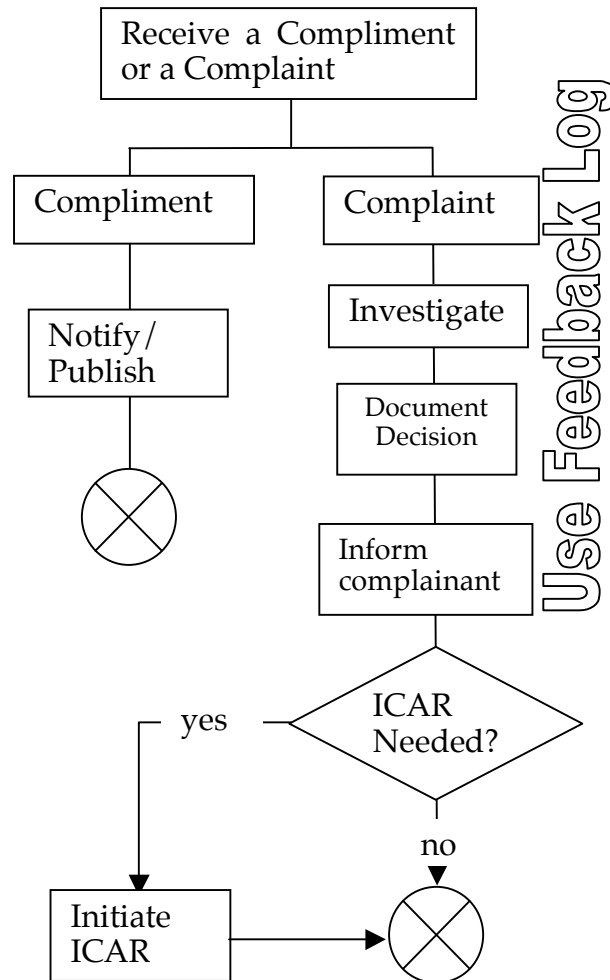
Corrective and Preventive Action

The person(s) implementing corrective/preventive actions follow these steps:

- Implement the selected corrective/preventive action.

Procedures

Overview



Start Points

Compliment. ABC receives a written compliment on any topic related to ABC. Compliments are acquired and tracked in the ABC Feedback Log. Compliments are distributed to staff, the Director, and the President of the Board whenever received.

Complaint. Complaints received by ABC are an indication that a problem may exist which has been perceived only from the outside. The actual problem may not be the one noted in the complaint, but acceptance of an outsider's perception of a problem goes a long way to finding good and enduring solutions.

