QUALITY ASSURANCE GUIDELINES FOR THE SELECTION AND MONITORING OF CONTRACT LABORATORIES FOR CHEMICAL ANALYSIS OF ENVIRONMENTAL SAMPLES

by

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NWRI Contribution 87-66

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May 1986

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INTRODUCTION

Environment Canada generates a considerable amount of chemical analytical data under contract with private and university laboratories. One of the responsibilities of contract managers must be to ensure that the data collected are reliable and compatible on a regional, national and international basis. The analysis of environmental samples is more complex than many other chemical analyses due to the low concentrations of contaminants normally encountered. Frequently, the parameters of interest are present in the low parts per billion or parts per trillion range. At these concentrations many factors which are of little concern for normal analyses become critically important and can severely affect the reliability of the data.

Stringent quality assurance (QA) and quality control (QC) procedures and protocols must become an integral part of all analytical contracts if reliable, traceable and compatible data are to be generated. These procedure must ensure, and clearly demonstrate, the integrity of samples throughout collection, handling and analysis. Only by collecting and using data of known quality can we be sure that spatial and temporal trends are statistically significant or that data from different laboratories are comparable. Data of mediocre quality can often be meaningfully interpreted providing the limitations are known, whereas data without associated error limits are open to misinterpretation.

Project managers are responsible for ensuring that contracts contain sufficient quality control to define the precision and accuracy of the data generated to meet the project objectives. In general terms, intralaboratory quality control defines laboratory precision, interlaboratory round robins determine between-laboratory comparability and the use of certified reference materials determines the degree of accuracy. Without the knowledge of precision and accuracy the quality of data is difficult to define. Hence provision for all three activities should be included in all analytical contracts.

The purpose of this short document is to provide project managers with a set of quality assurance protocols for use in preparing, selecting and managing analytical contracts. The protocols are equally applicable to departmental laboratories as they are to those in the private sector. They are written in general terms and project managers should modify them to meet their specific requirements. Staff of the Quality Assurance and Methods Section, NWRI are willing to assist project managers with this task should this be necessary. Recommended quality assurance clauses for inclusion in contracts are provided for reference.

Phase One - Pre-Contract Period

At the outset, the project manager must clearly define the project objectives and the data quality required to meet these

objectives. Adequate quality assurance clauses must be included in all contracts (examples are provided in Appendix 1).

Prior to any consideration of a contract, a laboratory must be able to provide the following evidence or information for review:

1. Clear documentation of analytical and sample handling methodologies (see check list) including, wherever applicable, extraction/digestion, cleanup, derivatization, evaporation, and quantitation procedures used. Such methodologies must be available for reivew at any time.

2. Statements of method detection limits (MDL's) and laboratory performance (i.e., precision and accuracy) on replicate analyses of samples fortified at or close to MDL's as well as at higher levels.

3. The availability of relevant laboratory instrumentation and analytical standards.

4. Records of instrumentation performance, e.g., calibration curves, response factors, detector linearity, resolution, instrument detection limit, etc.

5. Documented in-house QA protocols and where appropriate records of in-house QA data for previous contracts on the same parameters in the same matrices at similar concentration levels.

6. Performance on previous interlab comparison studies or participation in a qualifying pre-contract QC study.

CHECK LIST FOR SAMPLE HANDLING AND ANALYTICAL METHODOLOGY

(A) Sample

1. Sample handling procedure.
2. Sample holding time until analysis.
3. Sample preservation procedure (if needed).
4. Sample storage condition.

(B) Analytical Method

1. Method documentation.
2. Ruggedness*.
3. Application.*
4. Specificity.*
5. Sensitivity.*

6. Detection limit (definition and statement).
7. Precision data at min. 2 levels.*
8. Accuracy data (or recovery) at min. 2 levels.*
9. Description of how the above method specifications were generated.

* Demonstration at realistic levels.

Phase Two: During the Contract Period

During the contract period, the project manager must ensure that the following activities are carried out by the contractor:

1. To demonstrate the precision of data generated, the contract laboratory should perform duplicate analyses on every 10th, 15th, or 20th sample, depending on the situation.

2. To demonstrate the accuracy of data generated, the contract laboratory should analyse a CRM (if available) or a check sample provided by the scientific authority once every 10, 15, or 20 samples. The agreement with the "true value" must be ±25 or better, or must meet the defined objectives of the Scientific Authority.

3. For big contracts, the contractor should provide preliminary results or data sheets to the Scientific Authority at regular intervals (e.g., monthly) rather than just a final report at the end of the contract. If obvious analytical errors are found the Scientific Authority has the right to reject all or part of a batch of analyses and request re-analysis, in whole or in part, of the batch of samples.

4. Blind samples in the form of CRMs, RMs, field split samples, sample extracts etc. (incorporated in the sample set by the Scientific Authority) must be aanalyzed and reported with the data set.

5. All sample data and chromatograms (or digitally stored data sufficient to regenerate the original chromatograms) should be retained by the contractor for all analyses unless otherwise authorized in writing by the Scientific Authority.

6. The contractor should participate in relevant interlab QC studies whenever possible during the contract.

7. The contract laboratory should not change analytical methodologies in the middle of the contract unless authorized in writing by the Scientific Authority.

Phase Three: Post-Contract Period

1. The Scientific Authority shall have the right to take possession of all raw data and sample chromatogram which the contractor wishes to discard after the contract.

2. Report review - the final report must contain all data - including QA data.

APPENDIX 1

QUALITY CONTROL CLAUSES FOR ANALYTICAL CONTRACTS

The following clauses should be included in all analytical contracts issued by departmental project managers.

1. "A sound quality control program must be developed and documented by the contractor. All quality control data must be made available to the Scientific Authority and the project manager upon request."
2. "The proposed sample collection, handling, storage, preservation procedures and analytical methodologies must be documented and approved by the Scientific Authority before work is initiated."
3. "The contractor must participate in, and perform satisfactorily in, pertinent quality control round robins in a timely manner under the guidance of a Departmental Quality Assurance Laboratory designated by the project manager. Failure to comply with this requirement could result in partial withholding of funds and/or cancellation of the contract."
4. "Contract laboratories are encouraged to participate in appropriate external quality assessment on a continuous basis to establish their credibility."