Environment Canada Environnement Canada

Canada

National Laboratory for Environmental Testing

Quality Manual

August 2001

(NWRI Publication 99-304, Version 5.0)

NATIONAL WATER RESEARCH INSTITUTE

INSTITUT NATIONAL DE RECHERCHE SUR LES EAUX

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QUALITY MANUAL

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National Water Research Institute, Environment Canada

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Burlington, Ontario L7R 4A6
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August 2001

QUALITY MANUAL

NATIONAL LABORATORY FOR ENVIRONMENTAL TESTING

This Manual is issued under the authority of and approved by:

Dave Warry, Director

Concurred with:

Haig Agemian, Chief, IQM

Michael Comba, Section Head, OAL

Gino Sardella, Section Head, IAL

Trudy Searle, Administration Officer

Cynthia Young, Quality Assurance Officer
(Quality Manual Author and Controller)

Issue Date **December 3, 2001**
Version No. **5.0**

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PREFACE

The Quality Manual identifies the policies, procedures, and methodologies adopted by NLET to ensure that it consistently delivers the highest standard of service to its clients; to provide them with data that are scientifically defensible and of known and documented quality.

The policies and procedures cited in this Manual are binding on all affected personnel and conform to the requirements of the relevant national and international standards for laboratory competency adopted by Environment Canada and our accrediting agency the Canadian Standards Association (SCC); viz

- CAN-P-4D (ISO/IEC 17025) - General Requirements for the Competence of Calibration and Testing Laboratories.

This Manual, in addition to day-to-day use, will be used by NLET in its staff training programs and to meet requirements for laboratory accreditation.

1.0 LABORATORY PROFILE, MISSION AND ORGANISATION

1.1 Laboratory Profile

1.1.1 Identification

The National Laboratory for Environmental Testing (NLET) was established on April 1, 1983 with a mandate to operate as a reference laboratory within Environment Canada (EC). NLET provides a core laboratory capability offering a broad range of standard methods and customised analytical services in support of EC's monitoring and research programs. In addition, NLET produces certified reference materials and performance testing/evaluation samples and provides expert quality assurance advice to numerous laboratories within and outside Environment Canada. The offices and laboratories are located in Burlington, Ontario at the Canada Centre for Inland Waters. The address is:

National Laboratory for Environmental Testing
National Water Research Institute
Canada Centre for Inland Waters
867 Lakeshore Road, P.O. Box 5050
Burlington, Ontario L7R 4A6

1.1.2 Objectives

NLET contributes to the delivery of EC's science-based programs by providing a broad range of standard and customised analytical services and quality assurance products. NLET's mission is to support the laboratory science needs of ECS programs through responsive, cost-effective analytical and laboratory services that meet international standards of quality.

Analytical services are provided through two operational laboratories: Inorganic Analysis and Organic Analysis. The Laboratory offers scientific data, advice and information regarding the chemical analysis of surface, ground and precipitation waters, sediments, biological tissues, marine tissues and plants.

Scientific, consultative and laboratory support services, with a focus on quality assurance, are provided through the Information & Quality Management group.

1.1.3 Clients Served

NLET provides analytical laboratory science services and advice to the regional offices and to the research institutes of Environment Canada and, on occasion, to other federal departments. The Laboratory is a resource for leading-edge technology applied through a structured network/partnership collaboration with federal, university and private sector laboratories. In collaboration with the Standards Council of Canada (SCC) and the Canada Association for Environmental Analytical Laboratories (CAEAL) supports more than 200 accredited laboratories across Canada through the creation of 11,000 proficiency testing samples.

1.1.4 Workload and Staffing Level

The Laboratory processes approximately 20,000 samples annually. The breakdown by discipline (i.e. Section) together with assigned staff is as follows.

SECTION	NUMBER OF STAFF	NUMBER OF TESTS
Inorganic Chemistry	16	200,000
Organic Chemistry	14	148,000
Information & Quality Management	13	NA
Management and Administration	4	NA
TOTAL	47	348,000

1.1.5 Accreditation

NLET is accredited to Standard CAN-P-4D (ISO Guide 17025) by the Standards Council of Canada (SCC), in co-operation with the Canadian Association for Environmental Analytical Laboratories (CAEAL), for the specific tests listed in the scope of accreditation published by the SCC.

1.2 Quality Policy and Objectives

1.2.1 Rationale

NLET's Quality System supports the operations by focusing effort on the following areas so as to allow the Laboratory to meet its objectives. All activities planned and undertaken within NLET occur within one of these areas so as to ensure that the laboratory continues to produce competent results.

- People with Skills and Knowledge
- Environment with Facilities and Equipment
- Quality Control
- Procedures

1.2.2 Quality Policy

NLET, its management and staff are committed to:

- good professional practice and quality of service;
- the highest standards of analytical service to its clients;
- establishing and maintaining appropriate Quality Objectives;
- ensuring all laboratory personnel are familiar with and implement the quality documentation;
- laboratory conformance to CAN-P-4D.

1.2.3 Quality Objectives

- To ensure a quality system that is documented and incorporates adequate review, audit and internal quality control.
- To ensure personnel are adequately supervised and are proficient to carry out assigned

activities.

- To ensure test methods (and related work instructions) are validated and incorporate adequate quality control.
- To ensure all equipment, supplies and services are functioning properly and/or meet required specifications.
- To ensure that facilities are adequate to carry out the testing activity.
- To ensure that test results are supported by a traceable system of measurement and accorded uncertainties appropriate to requirements.
- To ensure sample management that incorporates adequate procedures for the security, receipt, identification, checking, routing, storage and disposal of all samples.
- To ensure data management that incorporates adequate procedures for the security, recording, calculation, validation, authorisation, transmittal, storage and disposal of all test data and related records.
- To ensure workload management that incorporates acceptable turnaround time and verification of resource availability prior to the acceptance of additional testing.

1.3 Laboratory Organisation and Management

1.3.1 Laboratory Organisation

NLET has two groups - Analytical Laboratories, further subdivided into Inorganic and Organic Analytical Labs and Information & Quality Management (IQM). The Section Head of each of the analytical labs and the chief of IQM report to the Director.

The Analytical Laboratories are divided into the following sections:
Inorganic Analytical Laboratory (IAL)

- Trace Metals Laboratory (TML)
- Major Ions & Nutrients Laboratory (MI&NL)

Organic Analytical Laboratory (OAL)

- Analytical Services
- Chemistry Services

The Information & Quality Management group consists of six components, in total, divided into two business lines. The first business line supplies support for all of NLET and consists of the following three components:

- Quality Assurance Office
- Computer Services
- Client Liaison Office

The second business line supports a broader client base supporting national programs and consists of the following three components:

- Proficiency Testing Products & Services
- Performance Evaluation Products & Services
- NCP Quality Management and Reference Materials

Appendix 1 provides an organisational chart for the laboratory. Appendix 2 provides an organisational chart showing NLET's position within the National Water Research Institute.

1.3.2 Laboratory Management

Technical Operations
Overall responsibility for Technical Operations in the laboratory is assigned to the Director. Responsibility for Technical Operations within each of the two laboratories resides with the respective Section Head.

Quality Assurance
Overall responsibility for Quality Assurance in the laboratory is assigned to the Quality Assurance Officer. This overall responsibility includes implementing a Quality System that is (i) understood, accepted and documented and (ii) incorporates adequate review, audit and internal quality control. Direct access to the most senior management (i.e. the Director) is maintained via membership on the NLET Management Team.

Responsibility for Quality Assurance within each of the individual Sections resides with the Section Head. This responsibility includes documentation of work instructions specific to the section and ensuring adequate training and supervision. It also includes, where appropriate, validation of test methods and application of adequate internal quality control.

Key Positions. The staff filling the key positions identified above are:

Director	Dave Warry
Chief, IQM	Haig Agemian
Section Head, OAL	Michael Comba
Section Head, IAL	Gino Sardella
Quality Assurance Officer	Cynthia Young
Branch Finance & Administrative Officer	Trudy Searle

All of the above staff comprise the NLET Management Team (NMT).

Summarised job descriptions for these positions appear in Appendix 3. Full job descriptions are available from the DO.

1.4 Conflict of Interest and Confidentiality

1.4.1 Laboratory Personnel

The responsibilities of all key personnel are defined in their job descriptions, so as to allow the easy identification of potential and perceived conflicts of interest. All personnel are issued Treasury Board's "Conflict of Interest and Post-Employment Code for the Public Service Confidentiality which obligates them to uphold policies governing conflict of interest and confidentiality of the laboratory. See Section 3.7.

1.4.2 Client Confidentiality

NLET shall hold in confidence all information acquired during the normal course of business from any other party, including clients. Laboratory personnel shall take all reasonable means to safeguard client information, including electronic storage and transmission and prevent the unauthorised disclosure of this information to third parties.

1.4.3 Conflict of Interest and Impartiality

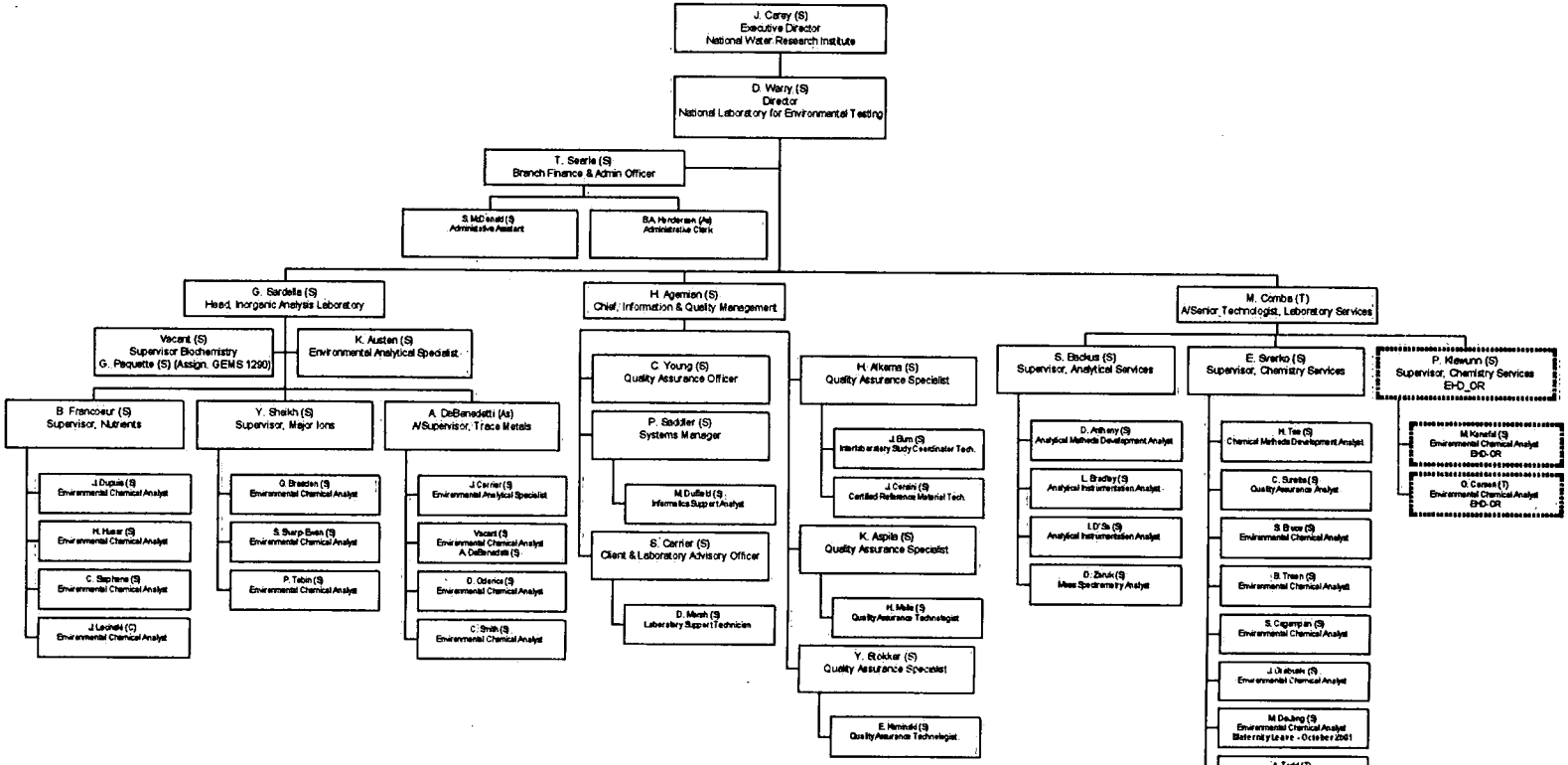
Any action that results in loss of confidence of the laboratory to produce competent, unbiased results will adversely affect the business of NLET. Any laboratory staff member encountering a situation which may be perceived as a conflict of interest is to declare that fact. This includes any situation in which any pressure is exercised by any other person to modify test results or otherwise reduce the impartiality of test results.

NLET must ensure management and staff are free from internal and external commercial, financial and other pressures that might adversely affect the quality of their work and avoid involvement in activities that compromise the confidence in the laboratory's competence, impartiality, judgement or operational integrity (see Public Service Reliability Checks policy).

1.5 Appendix 1. NLET Organisation Chart

See chart on next page

1.4 Appendix 1. NLET Organisation Chart

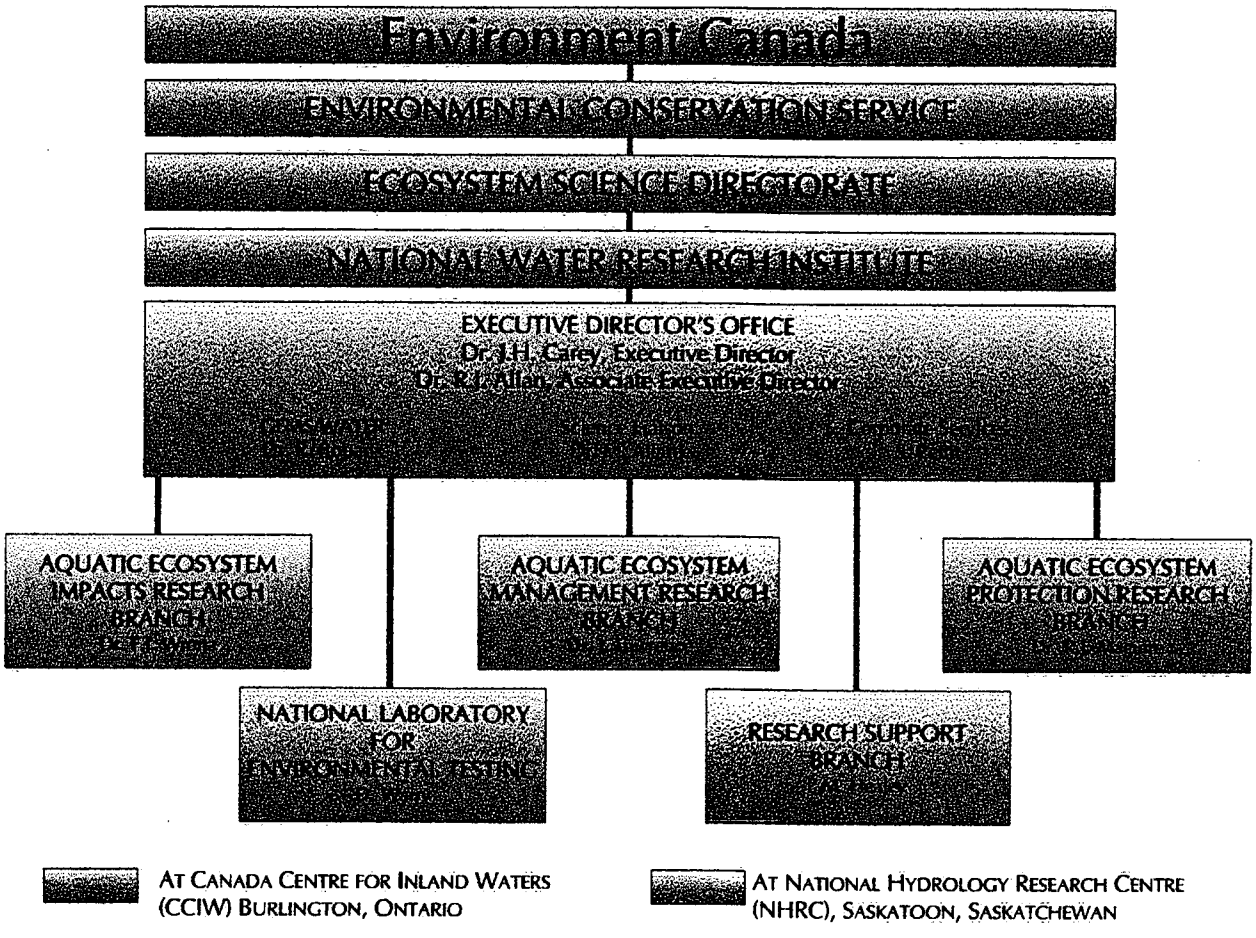


Legend

(S)	Substantive
(As)	Assignment
(V)	Vacant
(T)	Term
(P)	Proposed
(S)	Substantive
(As)	Assignment
(V)	Vacant
(T)	Term
(C)	Casual

1.6 Appendix 2. NWRI Organisation Chart

See chart on next page


Environment Canada
ENVIRONMENTAL CONSERVATION SERVICE
ECOSYSTEM SCIENCE DIRECTORATE
NATIONAL WATER RESEARCH INSTITUTE
EXECUTIVE DIRECTOR'S OFFICE
Dr. J.H. Carey, Executive Director
AQUATIC ECOSYSTEM IMPACTS RESEARCH BRANCH
AQUATIC ECOSYSTEM MANAGEMENT RESEARCH BRANCH
AQUATIC ECOSYSTEM PROTECTION RESEARCH BRANCH
NATIONAL LABORATORY FOR ENVIRONMENTAL TESTING
RESEARCH SUPPORT BRANCH
AT CANADA CENTRE FOR INLAND WATERS (CCIW) BURLINGTON, ONTARIO
AT NATIONAL HYDROLOGY RESEARCH CENTRE (NHRC), SASKATOON, SASKATCHEWAN

1.7 Appendix 3. Summarised Job Descriptions for Key Managers

DIRECTOR

Client Service Results
Management of an operational analytical laboratory providing accredited analytical chemistry services and associated scientific services to support goals and objectives of national environmental assessment and research programs of the department, involving monitoring, compliance, and emergency response.

Provides strategic and program specific scientific and technical advice to Departmental clients, senior management, other federal departments, provincial and foreign and international government agencies, and to firms engaged in similar activities.

Key Activities
Manages and directs the operation, and human, financial and physical resources of an operational analytical laboratory to support Departmental monitoring and research programs across Canada, including the development, adaptation and validation of project specific analytical laboratory methodologies and technologies.

Develops and approves all policies, directives and guidelines for the operational and scientific needs of the organisation.

Directs and approves the development, adaptation, and validation of all new technologies and scientific information created in the organisation.

Plans and coordinates collaborative initiatives with national and international agencies, and supports partnerships and joint strategies.

Provides scientific and technical advice to regional and national program managers of own Department, including policy advice.

Represents the Directorate and Department on regional, national and international committees and task forces.

Reviews and evaluates new knowledge and seeks out and approves all collaborations undertaken by the organisation with other partners in the relevant fields.

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CHIEF, IQM

Client Service Results
Management of intra-laboratory and inter-laboratory quality assurance components of a comprehensive national quality management program.

Management of laboratory information for a national client base with regard to analytical services available for effective decision making in ecosystem monitoring and research programs.

Management of mechanisms for selecting and implementing laboratory informatics technology that are harmonised nationally and internationally.

Scientific and technical advice to senior management, other federal departments, provincial and foreign government agencies, private sector laboratories and firms engaged in related activities.

Key Activities
Manages the operations and the human, financial and physical resources of the Information and Quality Management functions of a national laboratory in support of Departmental research and monitoring programs.

Develops policies, directives and guidelines on operational and scientific needs in the relevant fields.

Directs the development, adaptation and validation of new methodologies in information technology, and quality management products and services and the national client liaison function.

Manages business development, planning and auditing of the quality assurance and quality management programs for internal and external laboratory needs and develops national and international data quality objectives and standards.

Initiates, negotiates and maintains contracts and collaborative ventures with federal departments and private agencies in the relevant field.

Provides the lead in science liaison functions for the National Laboratory of Environmental Testing, provides input including policy advice to regional and national programs and represents the department on national and international committees.

Reviews and evaluates new knowledge and collaborates with other federal departments and private industries in the assessment of new technologies.

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HEAD, INORGANIC ANALYSIS LABORATORY

Client Service Results
Accredited analytical measurements of inorganic contaminants, specialised laboratory services, applied methods development, and analytical expertise that support various water related monitoring and research programs required by Environment Canada's five regional offices, two research centres and external partners.

Provide advice on inorganic chemistry methods, laboratory sampling protocols and quality control procedures to Departmental clients, other federal departments, provincial agencies, universities, and the private sector environmental laboratory industry in Canada.

Key Activities
Supervises and manages the operation of an Inorganic Analysis Laboratory (IAL).

Plans and administers the development, adaptation and validation of project specific analytical methodologies and technologies.

Plans and manages the financial and physical resources of the Inorganic Analysis Laboratory.

Establishes terms and conditions needed to provide and maintain laboratory service to all clients.

Directs and approves the implementation of the Quality Management System for IAL's component laboratories.

Provides advice to federal, academic and industry officials and scientists engaged in environmental monitoring and research.

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A/SR. TECHNOLOGIST, LABORATORY SERVICES (as per ORG CHART)
HEAD, ORGANIC LABORATORY (on WORK DESCRIPTION)

Client Service Results
Expert advice, accredited measurements of organic contaminants, specialised laboratory services, technical enhancements and methods development that support inter-jurisdictional water quality monitoring agreements, environmental assessments and water quality objectives as required by Environment Canada's five regional offices, two research centres and external partners.

Key Activities
Manages the day-to-day activities of the Organic Analysis Laboratory (OAL).

Administers the human and financial resources of OAL.

Plans and administers the development, adaptation and validation of project specific analytical methodologies and technologies.

Provides expert laboratory science and technology advice to federal, academic and industry officials engaged in environmental monitoring and research.

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QUALITY ASSURANCE OFFICER

Client Service Results

Lead, manage and coordinate a system of quality management for the National Laboratory for Environmental Testing (NLET) that ensures that all analytical results produced by the laboratory meet or exceed internationally recognised standards.

Provides expert guidance and advice to environmental testing private and public sector laboratories with regard to quality management systems.

Key Activities

Assesses, adapts and applies international quality standards to the operation of an analytical laboratory and ensures that all aspects of the laboratory operation comply these standards.

Develops, plans and audits all laboratory related quality assurance and quality control activities, as they apply to all aspects of the operation of an analytical laboratory.

Ensures that a formal and documented quality management system, appropriate to the operational needs of the laboratory, is in place and up to date.

Provides advice and recommendations with respect the operation and adaptation of laboratory quality management systems to a wide range of laboratory managers, scientists and clients.

Provides liaison between NLET and other agencies with respect to specialised, and internationally recognised quality assurance requirements.

Reviews and evaluates new knowledge in the relevant fields.

Represents the laboratory on national and international committees.

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BRANCH FINANCE & ADMINISTRATIVE OFFICER

Client Service Results

Business planning and financial, human resource and administrative services and advice to senior management and staff of the National Laboratory for Environmental Testing, NWRI.

Key Activities

Forecasts, controls and manages the Branch financial resources required to support the Branch Management and Administration Budget, for both discretionary and non-discretionary spending.

Provides advice and guidance on the development, implementation and delivery of policies and plans and reports for business plans, financial and administrative management (human resource and general administration). This includes the composition and preparation of agreements, reports, memoranda, and correspondence to departmental, national and international clients to respond to inquiries, obtain information and resolve problems.

Advises, plans, recommends and implements human resource management processes.

Supervises the staff of the unit.

2.0 QUALITY MANAGEMENT

2.1 Quality Objective

To ensure that a well structured and documented Quality Management System (QMS) is in place and that this system incorporates adequate review, audit and internal quality control. The purpose of the QMS is to ensure the services, products and advice offered by NLET meets the needs of our clients and requirements of the accrediting agency, SCC, as outlined in CAN-P-4D. The QMS is a structured management system of principles, objectives, policies, responsibilities and implementation plans at the organisational and project-specific levels. It provides the structure within which planning, implementation and performance assessment may occur.

2.2 Quality Definitions

2.2.1 Work Instructions

Instructions are used for the accomplishment of specific tasks associated with the operation of the quality system. They include published Methods, Standard Operating Procedures and other supporting work instructions such as Protocols necessary to ensure sample integrity, equipment operating instructions, quality control procedures and worksheets used in the conduct of laboratory testing. Test Methods and Protocols are documented in the SOP binders; and both are available in electronic version on the L drive.

2.2.2 Operational Procedures

Procedures related to the achievement of specific quality objectives. The operational procedures themselves designate who is responsible for seeing that the policy/procedure is carried out, what the related activities are, who carries out these activities, how, when and where these activities are carried out, what records are kept and what reports are issued. Operational Procedures are documented in the Quality Manual.

2.2.3 Non-conformity

The non fulfilment of specified requirements; viz

- failure of resources (i.e. personnel, equipment, facilities, work instructions, etc) to meet performance requirements or other specified requirements.
- failure of personnel to comply with documented work instructions or operational procedures.
- failure of test data to meet required standards due to:
  - failure (or suspected failure) to meet all conditions necessary to insure the integrity and representativeness of the sample (i.e. sample history deficiencies exist).
  - failure (or suspected failure) to comply with the test method or supporting work instructions.
  - failure (or suspected failure) in method performance as demonstrated by results provided by quality control samples.
  - inherent property of sample that compromises the testing (e.g. as verified by the method of standard additions).
  - relevant evidence provided by data validation (e.g. as a result of comparison with expected values, ranges or relationships).

2.2.4 Corrective Action

Actions carried out to eliminate the cause of a detected non-conformity and which include:
- investigating potential causes of the non-conformity;
- analysing all possible contributing factors to determine the root cause;
- initiating preventative action;
- applying controls to prevent re-occurrence, and;
- implementing and documenting changes resulting from corrective action.

2.2.5 Preventative Action

Actions carried out to eliminate the cause of a potential non-conformity and which include:
- investigating causes of the potential non-conformity;
- analysing all possible contributing factors to determine the root cause;
- initiating preventative action;
- applying controls to prevent occurrence, and;
- implementing and documenting changes resulting from preventative action.

2.3 Quality Documentation

2.3.1 Categories of Documentation

There are two categories and five hierarchical levels within the NLET system of quality documentation. The two categories consist of controlled documents and uncontrolled documents. The three hierarchical levels within the controlled category include: the *Quality Assurance Manual, Standard Operating Procedures,* and *Laboratory Protocols*. Forms are a separate controlled category of lesser importance. Within the uncontrolled category, the document hierarchy includes the *Manuals of Analytical Methods* and *Instrument QC Manuals*. Controlled documents are for use within NLET, although there may be copies made of some of these documents that, when distributed outside NLET, become uncontrolled documents and are designated as such.

Controlled documents include:

Quality Manual
The *Quality Manual* (QAM) describes the implementation of the NLET Quality Management System within the Laboratory. It specifies the activities required to achieve the quality goals established by NLET. It describes, in a systematic way, the measures that the Laboratory employs to implement the NLET QA program. The QM is updated on a regular basis by the QA Office and is approved by the Director, NLET.

Standard Operating Procedures
These documents describe all the written directions necessary to utilise laboratory testing procedures (i.e. methods) within NLET. They supplement and expand on the information contained in the *Manuals of Analytical Methods* and provide a working document where all details are specified. SOPs are updated on a regular basis by the Supervising Chemists and are approved by the appropriate Section Head. Updates are recorded in Appendix C attached to each SOP. Electronic copies are available in read-only format on the L drive (Quality Management System folder) of the LIMS in a subfolder titled "SOPs". Hardcopies are kept in SOP binders (blue) in a central area within each analytical Laboratory. SOPs are controlled documents, and the process for controlling the distribution and revision of these documents rests with the QA Office. See **Protocol 06-002 PROTOCOL FOR THE PROCESS OF UPDATING HARD AND ELECTRONIC COPIES OF THE STANDARD OPERATING PROCEDURES (SOPS)**.

Protocols

These documents specify the sets of definitive instructions which must be followed, without exception, by all staff, for those procedures that are standard across the Laboratory or across a series of analytical methods. These include procedures such as sample receiving, data management, preparation of standards and analyst proficiency records. Protocols are controlled documents, and control of these documents is maintained by the QA Office. The QA Officer ensures that all Protocols are current and shall maintain master copies. The index and the description of all Protocols are listed on the L-drive of the LIMS, as read-only files, accessible to all staff. Upon revision, the latest version is approved by the appropriate Section Head and updated on the L-drive by the QA Officer. An e-mail or memo is sent to all NLET staff to ensure the updated version is changed in their documentation. Responsibility for updating protocols rests with the Supervising Chemists, and these documents are approved by the Section Heads.

Forms

Some forms, that are in general use throughout the Laboratory, or used by the QA Office / Client Liaison Office / Computer Services Section / Administration Group, are maintained on the L drive and are controlled using version numbers and dates.

Uncontrolled documents include:

Manuals of Analytical Methods

The NLET *Manual of Analytical Methods* describes the general procedures that are followed to utilise every method employed in NLET. Documentation of individual methods is the responsibility of the Section Heads and the staff of each section, according to formats specified by
Protocol 06-003 PROTOCOL FOR THE PROCESS OF REVISING AND DOCUMENTING HARD AND ELECTRONIC COPIES OF ANALYTICAL METHODS.
Responsibility for the distribution of these documents lies with the Director's Office. The *Manual of Analytical Methods* is updated for public distribution about every 5 years. It is updated using the SOP available at the time of publication. *The Manual of Analytical Methods* is approved by the appropriate Section Head.

Instrument QC Manuals

Each Instrument QC Manual is kept in the operational Laboratory, close to the instrument to which it applies. It contains details of instrument identification, maintenance requirements, operation and calibration schedules, optimisation procedures and safety concerns. It also contains the manuals received from the manufacturer. Calibration procedures and all changes in instrument set-up are documented here. The Instrument QC Manuals are updated on a regular basis by laboratory staff, and are approved by the Supervising Chemists. The QA Office shall audit these manuals once a year.

2.3.2 Document Control

Document control is necessary to ensure that lab personnel have access to current policies and procedures at all times. Quality documents that are placed under a controlled distribution include, but are not limited to; the QM, SOPs and Protocols. Control is maintained using coloured paper for hardcopies. The QM is printed on yellow paper, SOPs on blue paper and Protocols on pink paper. Controlled copies of the QM are distributed to all staff (list maintained in QA Office) while uncontrolled copies are available for distribution on an 'as requested' basis (list also maintained). Electronic copies of SOPs and Protocols reside on the L drive (maintained by the Computer Section and backed up nightly) of the LIMS in read-only format and each contains a rider in the Header, on each page, that reads as follows: "*All copies of NLET Protocols/Standard Operating Procedures, residing outside of or produced other than by the Quality Assurance Office of the National Laboratory for Environmental Testing, shall be deemed unauthorised copies. Controlled copies are printed on coloured paper and do not carry this rider.*" This permits printing of these controlled documents but ensures that the controlled version is easily identifiable. Hardcopies of SOPS are held in blue

binders and reside in the laboratory where it applies; Controlled copies of Protocols are maintained in binders in the QA Office. Uncontrolled copies are placed in the associated SOP binders for reference (updated yearly). The master lists of the of SOPs and Protocols are kept by the QA Office. Upon revision, the latest version is approved by the appropriate authority and updated on the L-drive and an e-mail or memo is sent to all NLET staff to ensure the updated version is changed in their documentation.

Changes or Additions: Changes or additions, including hand-written amendments, to all documents (controlled or uncontrolled) may be initiated by any staff member of NLET, but they must follow the approval process before changes can be made. Changes or additions to controlled documentation undergo review and approval, as outlined below:

CONTROLLED DOCUMENTATION	APPROVAL AUTHORITY
Quality Manual	Director
Standard Operating Procedures	Section Head
Protocols	Section Head

UNCONTROLLED DOCUMENTATION	APPROVAL AUTHORITY
Manual of Analytical Methods	Section Head
Instrument QC Manuals	Supervising Chemist

The modification of controlled QA documents within NLET (those with coloured pages) takes place as follows:

A - If each page of a document has a version number:

- Any change must be approved by the appropriate authority, using Form 02-001 *Notice of New Version(s) - Controlled Document(s)* found in electronic format on the L drive under the folder titled "Forms".
- A white updated page(s) having the new version number (e.g.: from 1.0 to 1.1) on it is placed on top of the coloured page(s).
- A record of the change is documented in Appendix C at the end of the document.
- A copy of the change is submitted to the QA Office when initiated by the Section Head.
- Form QA 02-001 must be signed by the Section Head stipulating that:
  - the new version has been read and understood;
  - the old version has been replaced.

B - If the version number is indicated only on the front page of the document (i.e. Protocols), a full updated document is printed with the new version number, if practical. The old version is signed by the QA Officer and placed in the Obsolete Protocols binder.

Review of controlled documents is an on-going process. To ensure that documentation remains current, each should be reviewed by the appropriate authority (see above table) at least every two years. Reissuing controlled documents (i.e. when the version number increases by a whole number) is at the discretion of the QA Officer, but shall occur at least once every 5 years.

Hand-written amendments are to be treated as temporary solutions and every effort should be made to reissue the document as quickly as practical.

Master List: The Quality Assurance Officer shall maintain a master list of all controlled documentation; this list shall identify all current revisions. This arrangement precludes the use of out-dated documents.

Distribution: The Quality Assurance Officer shall maintain a distribution list of all controlled documentation, and shall ensure that all persons identified on the distribution list receive updated documents and return or destroy all obsolete documents.

2.3.3 Departures from Quality Documentation

Departures from policies and procedures or methodologies documented in the Quality Manual, Standard Operating Procedures or Protocols may be permitted under exceptional circumstances. All such departures must receive prior written approval from the appropriate authority (see 2.3.2).

2.4 Quality System Training and Implementation

2.4.1 Laboratory Personnel Training

All laboratory personnel are required to understand and implement the NLET Quality System aspects that fall within their scope of responsibilities. Training on these aspects of their responsibilities is to be completed within 6 months of their engagement. Where appropriate, the Quality Assurance Officer is to conduct training for new personnel, or whenever quality system changes result in new or substantially modified quality procedures.

2.4.2 Records

Records of all quality system training, including formal and informal training and demonstration of understanding are initiated and reviewed by the Quality Assurance Officer and the appropriate Section Head. These records are maintained with other staff training records.

2.5 Audit and Review

2.5.1 Quality Audit

The Quality Assurance Officer will operate a Quality Audit Program by periodically carrying out systematic examinations (e.g. through observation, interviews and examination of records/documentation, etc.) to determine whether (i) policies, procedures and work instructions are implemented effectively and as documented and (ii) resources, policies and procedures are suitable to achieve the quality objectives.

All procedures cited in the Quality Manual together with compliance with work instructions will be subject to audit. Areas of activity that may be audited will include, but not be limited to:

- staff training and supervision
- equipment maintenance and calibration
- procurement of goods and services
- adequacy of laboratory facilities
- test method validation
- measurement traceability and uncertainty
- adequacy of work instructions
- document control
- audit and review
- internal quality control
- data management
- sample management

- workload management

The Quality Assurance Officer will develop and implement an annual audit plan that identifies both the auditors and the areas of activity to be audited. The auditors may be external to laboratory operations and whenever possible shall be independent of the activity to be audited.

Scheduled audits, in addition to any scheduled CAEAL or other accreditation audits, will occur on a frequency of at least twice annually. In addition, unscheduled audits may be initiated by the Quality Assurance Officer, at any time, after appropriate investigation. Such initiation may be in response to performance audit results, client feedback, requests from Section Heads, or any other circumstance which has caused doubt concerning either the quality of the laboratories tests or compliance with the provisions of the Quality Manual.

CAN-P-1510 (latest version), or other suitable check list, may be used when conducting an audit.

The steps to be followed in conducting a quality audit are:
- notify all concerned of the audit schedule.
- hold pre-audit meeting and verify arrangements
- conduct audit
- hold post audit meeting and convey (documented) findings.

The audit findings and any actions taken shall be documented and maintained on file by the Quality Assurance Officer. If remedial action is deemed necessary then the QA Officer generates, ensures completion and follow-up to form QA02-012 *Internal Audit - Remedial Action Form.*

Copies of relevant (summary) information shall be circulated by the Quality Assurance Officer to the NLET Management Team.

The Quality Assurance Officer, in co-operation with NMT, shall ensure that any corrective actions are discharged in the agreed to timescale and verify effectiveness.

2.5.2 Performance Audit

The Quality Assurance Officer will operate a Performance Audit Program which incorporates participation in proficiency testing supplemented by provision of check samples prepared by the Quality Assurance Section or other independent source external to the laboratory.

A summary of laboratory participation in proficiency testing programs, including the CAEAL program, appears in Appendix 4.

If a Performance Audit provides results which cause doubt concerning test method performance, the Quality Assurance Officer may, after appropriate investigation, initiate either a *Performance Testing - Remedial Action Form* (QA02-010) or a Quality Audit.

The results of Performance Audits and any actions taken shall be documented and maintained on file by the Quality Assurance Officer.

Copies of relevant (summary) information shall be circulated by the Quality Assurance Officer to NMT.

2.5.3 Client Feedback

Analytical Laboratories: All technical complaints originating from clients or other external sources shall be directed to the Client Liaison Office (CLO) in IQM. The CLO, in response to technical complaints, shall undertake an immediate investigation and within as short a time as possible

respond to the complainant with either an acceptable resolution or a proposed plan of action leading to an acceptable resolution. Acceptable resolution, where warranted, may include any combination of retest, third party testing, credit, or refund, as approved by the Project Chief, IQM. Alternately, acceptable resolution may include application of penalty provisions as specified in a contract. Subsequent to resolution, the CLO shall follow-up to ensure that everything has been resolved to the client's satisfaction.

If the investigation of a technical complaint causes doubt concerning Laboratory performance, then the QA Office is informed, and the Quality Assurance Officer may, after appropriate investigation, initiate either a corrective action or a Quality Audit.

The CLO shall maintain a record of all complaints and the actions taken. When appropriate, this information shall be circulated by the CLO to senior management, the QA Officer, and to the appropriate Section Head.

Proficiency Testing Products & Services: Client feedback for samples sent out for a CAEAL PT study is initiated by NLET using the Non-conformance Report Form. A copy of this form is enclosed with each set of samples sent to a participating CAEAL laboratory.

In the event of a non-conformance, completed copies of the form are forwarded to CAEAL and to NLET so that corrective action may be taken. The information on the form may either be faxed to CAEAL or NLET, or sent by e-mail, provided that all the required information listed on the form is contained in the body of the e-mail.

Responses to e-mails or faxes are handled with 24 hours of receipt and any corrective actions are put on file.

2.5.4 Quality System Review

Senior Management and the Quality Assurance Officer shall meet at least annually to evaluate the quality system so as to ensure its continuing suitability and effectiveness and to introduce any necessary changes or improvements. Such review shall include, but is not limited to:

- suitability of policies and procedures;
- reports from managerial and supervisory personnel;
- outcome of recent internal audits;
- corrective and preventive actions;
- assessments by external bodies;
- results of interlaboratory comparisons or proficiency tests;
- changes in the volume and type of the work;
- client feedback and pertinent discussion with clients;
- complaints, and;
- other relevant factors (e.g., quality control activities, resources and staff training).

All relevant records relating to quality audit, performance audits, client feedback and internal performance checks shall be available for the Review.

The results of the Review and any actions taken shall be documented and maintained on file by the Quality Assurance Officer.

Copies of the relevant (summary) information shall be circulated by the Quality Assurance Officer to NMT.

The Quality Assurance Officer, in co-operation with the NMT, shall ensure any actions are discharged in the agreed to time scale. Actions may include organisational changes, hiring additional staff, providing specialised training, updating or adding test methods or other work instructions, purchasing additional equipment, or modifying policies and (operational) procedures, etc.

2.5.5 Affect of Adverse Findings

Findings from any quality or performance audit that call into question the competence of test results will result in an investigation to determine which specific work may have been affected. If any test results have been affected, the clients of those tests results will be immediately notified by the Client Liaison Office.

2.6 Internal Quality Control

The Heads of the Inorganic Chemistry and Organic Chemistry Sections shall be responsible for implementing adequate internal quality control within their respective Sections. Internal quality control shall include the topics covered below.

2.6.1 Quality Control Samples

Quality Control Samples, as appropriate, shall be 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:

Type of QC Sample	Characteristic Monitored
Control Standard *	calibration accuracy/stability
Reference Sample**	method accuracy
Duplicate Samples	method precision
Analyte or Surrogate Spike	method recovery
Reagent Blank	blank response (calibration)
Method Blank	blank response (method)

* Control standards must be prepared independently of routine calibration standards.
** 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.

2.6.2 Level of Quality Control Effort

Each analytical method specifies the level of QC associated with it. In general, the QC Samples will typically be introduced into the analytical stream on a tray/batch basis and will normally comprise 20 - 30% of total sample through put. For example, a batch size of 15 - 20 could include QC Samples as follows:

- one control standard, if applicable;
- one reference sample;
- one analyte or surrogate spike, if applicable;
- one duplicate sample (or duplicate reference);
- one reagent blank, if applicable;
- one method blank, if applicable.

2.6.3 Control Charts, Control Limits and Nonconformity

Control Charts: Control charts are used to graphically monitor the ongoing performance of all methods with respect to specifically determined control limits for accuracy, precision, recovery, analytical stability, and contamination. Details of control charting practices are contained in Chapter One of all three volumes of the NLET *Manual of Analytical Methods*. The QC Module of ECOLIMS is the software that facilitates control charting. Control charts are produced by all analysts and monitored by the Supervising Chemists during data verification. Rules of analyst intervention have been established and are described in Appendix 6 of this section.

Control Limits: Control limits are either statistically or protocol defined, and, when exceeded, necessitate analyst intervention to determine the needed corrective action. Arbitrary defined limits are used in cases when statistically defined limits cannot be used, such as in the case where interim limits are required before a control chart has been created, in the case of too few events to define statistical significance, or, where statistical limits are not needed e.g. blank for ammonia analysis $\leq$3xMDL.

Nonconformity: Logs that document non-conformity in test method performance and the actions taken shall be maintained for each test. Maintenance of the logs shall be the responsibility of the analyst(s) assigned to the test.

2.6.4 Method Calibration (as opposed to Equipment Calibration)

All test methods, where applicable, shall provide detail of method calibration and shall incorporate, where appropriate, the features identified below:

- reagent blank used to establish calibration baseline;
- standards and samples have equivalent matrices at the point of measurement;
- adequate number of standards used to define calibration;
- low standard <10X detection limit, where applicable;
- appropriate curve fit applied;
- linearity, if applicable, established;
- control standard and reagent blank used to verify calibration accuracy/stability.

2.6.5 Method Quality Control

All test methods shall provide detail of method quality control and shall incorporate, as appropriate, the features identified below:

- the specific QC samples to be used (see 2.6.1)
- the control limits, or other specified limits that, when exceeded, trigger analyst intervention (see 2.6.3)
- the level of quality control effort (see 2.6.3)

NLET has adopted the policy that, if one measurement exceeds the +/- 3 σ control limits, the analysis must be repeated. If the next analysis exceeds the control limits, the analysis must be discontinued, and the problem must be identified and corrected. In each of these cases, it is also NLET policy that all non-conformances and remedial actions taken must be documented. The use of control limits as an approach to QC means that problems can be resolved only after they occur, rather than prevented from occurring.

Five analyst intervention rules have been developed to enable the analyst to intervene before a problem has occurred, but where it is apparent that it likely could occur. This approach is used when it is apparent that there is a statistical bias to the QC data, but before the analytical process is out of statistical control. This approach can only be adopted for the accuracy and precision portions of the analytical process, where reference (RF) and reference duplicate (RD) QC types are

employed. This technique allows the analyst to take remedial action before results are out of control. The five rules of analyst intervention are found in Appendix 6 of this section.

2.6.6 Glassware Cleaning

Glassware cleaning (i.e cleaning/sterilisation of all glassware and/or labware used for testing purposes) shall be carried out by designated staff within each section using procedures specified in the associated SOPs or Protocols.

Cleaning of sample containers shall be carried out using procedures specified in the Client Liaison Office publication: *Sample Collection Summary.*

2.7 Control of Non-conforming Work

2.7.1 Identification of Non-conformances

Staff shall report all detected non-conformities/suspected non-conformities to the appropriate Supervising Chemist/Section Head. In response the Chemist/Head may, as warranted:

- stop all further work until the non-conformity is corrected;
- carry out an investigation to confirm the non-conformity and determine root causes;
- initiate corrective action/preventative action, or;
- request the QA Officer to initiate an investigation or audit.

2.7.2 Reporting and Affect on Further Work

Non-conforming work must be reported to the client through the CLO via the Section Head. If the non-conformance is considered, upon investigation, to have affected prior work, the client of that prior work is also to be notified by the CLO.

Stoppages of work caused by discovery and identification of a non-conformance can only be rescinded by the Section Head. Such a decision to resume work, including justification for this decision, is to be documented and maintained in the client file. A copy is to be forwarded to the QA Officer.

Whenever investigation indicates that an identified non-conformance will continue to adversely affect the production of competent test results, corrective action is to be undertaken as soon as possible.

2.7.3 Cause Analysis

All non-conformances are to be investigated to determine root cause. This investigation is to be conducted by the QA Officer, wit the assistance from other personnel with the laboratories, as appropriate. The investigation is to be undertaken as soon as possible, and in the instance of stoppages of work, immediately.

Root causes of the non-conformance are to be communicated to the Section Heads and the Supervising Chemists.

2.7.4 Corrective/Preventative Action

Corrective actions and preventative actions may be initiated by designated staff including any Supervising Chemist. Where a corrective/preventative action has resulted from an investigation of

non-conforming work, the selection of the corrective action is the responsibility of the Section Head. The QA Officer is to be consulted.

Non-conformity/potential non-conformity and follow-up corrective action/preventative action shall be documented as specified in 8.3.3.

Any follow-up and monitoring work resulting from the corrective/preventative action, is to be initiated by the QA Officer. Members of the affected laboratory section or a QA Working Group may be called upon to assist. Corrective and preventative actions are to be reviewed during the next quality or performance audit to verify their effectiveness.

2.8 Appendix 4. Proficiency Testing Participation

See Table on next page

PROFICIENCY TESTING PARTICIPATION - NLET 2001/02

	STUDY / ORIGINATOR	DETERMINAND/ MATRIX	FREQUENCY	DURATION OF PARTICIPATION	CONTRIBUTION TO LAB CAPABILITY	COST
1.	CAEAL PE Studies, Canadian Association for Environmental Analytical Laboratories	Organochlorine Pesticides, Total PCBs, PAHs in water	4 samples, twice per year	since 1992	• requirement to maintain laboratory certification	$1,800
2.	CAEAL	PAHs in sediment	4 samples, twice per year	since 1992	• requirement to maintain laboratory certification	$600
3.	CAEAL	Hg in sediment (expanded this year to include 5 more Trace Metals)	4 samples, twice per year	since 1992	• requirement to maintain laboratory certification	$500
4.	CAEAL	Trace Metals, Nutrients, Physicals and Major Ions in water	4 samples, twice per year	since 1992	• requirement to maintain laboratory certification	$2,600
5.	FP QA Studies, Federal / Provincial Surface Waters, NLET (Canada)	Major Ions and Nutrients in acid rain and soft waters	10 samples, twice per year. Will cease participation in 2001.	since 1985	• evaluation of performance of the historical Acid Rain Laboratory • reduced requests for this analysis now but participation continues to support CRM production	Free
6.	FP QA Studies	Major Ions and Nutrients in surface waters	10 samples, twice per year	since 1985	• on-going performance evaluation of client analytical services	Free
7.	FP QA Studies	Trace Elements in surface waters	10 samples, twice per year	since 1985	• on-going performance evaluation of client analytical services	Free

8.	FP QA Studies	Total Phosphorus in surface waters	10 samples, twice per year	since 1985	• on-going performance evaluation of client analytical services	Free
9.	IMEP, International Measurement Evaluation Programme, joint project European Commission and NRC (Belgium)	Trace Elements in water	1 sample, every 2-3 years. Ceasing participation in 2001.	new in 1998	• comparison of laboratory performance against truly international standards, 201 participants from 35 countries	Free
10.	MOE, Ministry of Environment Performance Assessment Program (Canada)	PAHs in sediment	2 samples + 1 injection std.	new in 1998, one time request	• co-operative effort to characterise CRM for MOE	Free
11.	MOE	Toxaphene in standards and air extracts	to be determined	new in 2000	• participation at the request of client (D. Muir) to compare our toxaphene standards against other participants	Free
12.	NIST, National Institute of Standards and Technology (American)	Organochlorine Pesticides, Congener PCBs and Toxaphene in whale blubber	2 samples	new in 1999	• participation at the request of client who submits blubber samples (D. Muir)	Free
13.	NIVA, Norwegian Institute for Water Research	Major Ions and Nutrients in water	2 samples, yearly. Ceasing participation in 2001.	since 1998	• performance evaluation against international standards	Free
14.	CFIA, Canadian Food Inspection Agency, formerly DFO Mercury in Fish Study	Hg in biota	3 samples analysed in triplicate, four times per year. Will decrease participation	since 1994	• performance evaluation of client analytical services • decision made recently to reduce participation to once per year	Free

			to once per year.			
15.	CFIA, Fish Check Sample	Congener PCBs in biota	1 sample per year	new in 1998	• performance evaluation check of new PCB Congener method	Free
16.	NCPII-2, Northern Contaminants Program Interlaboratory Study	Trace Metals and Methlymercury in biota	4 samples, once per year	new in 1998	• performance evaluation of all laboratories involved in analysis for the NCP	Free
17.	NCPII-3	PCB Congeners and Organochlorines in biota	3 samples and 4 standards, every second year	new in 1999	• performance evaluation of all laboratories involved in analysis for the NCP	Free
18.	QUASIMEME Laboratory Performance Studies (Scotland)	Organochlorine Pesticides and Congener PCBs in biota	2 samples, twice per year	new in 1999	• participation at the request of client (D. Muir)	$1,200 paid by Muir
19.	QUASIMEME Laboratory Performance Studies (Scotland)	Toxaphene in biota	3 samples per year	since 1998	• participation at the request of client (D. Muir)	$1,200 paid by Muir
20.	IADN, Integrated Atmospheric Deposition Network	PCB Congeners in reference standard, precipitation samples fully extracted, half processed and raw	1 standard, 3 duplicates of samples	new in 2000	• participation at the request of client (EHD-OR)	Free (samples prepared by NLET)

2.9 Appendix 5. List of Certified Reference Materials

CERTIFIED REFERENCE MATERIALS IN USE IN MAJOR IONS AND NUTRIENTS LABORATORY

REFERENCE IDENTIFIER	SUPPLIER	STORAGE LOCATION
	WATER	
EPA#8	United States Environmental Protection Agency (USEPA)	L705
ULRG#4	United States Environmental Protection Agency (USEPA)	L705
CM95	National Water Research Institute (NWRI)	L705
SPEN-01	National Water Research Institute (NWRI)	L705
ULRG#3	United States Environmental Protection Agency (USEPA)	L705
ULRG#4	United States Environmental Protection Agency (USEPA)	L705
QCSPEX-NUT1	ATS Scientific	L705
QCSPEX-NUT2	ATS Scientific	L705
NUTREF	In-house	L705
Super-01	National Water Research Institute (NWRI)	L705
Beauport-95	National Water Research Institute (NWRI)	L705
QCS Mineral-1	U.S. Environmental Support Laboratory	L705
QCS Mineral-2	U.S. Environmental Support Laboratory	L705
ION-95	National Water Research Institute (NWRI)	L705
ION-96	National Water Research Institute (NWRI)	L705
TWC	Environmental Resource Associates	L705
QCSPEX-A1	ATS Scientific	L709
ION-94	National Water Research Institute (NWRI)	L711
GRM-02	National Water Research Institute (NWRI)	L711
GRM-07	National Water Research Institute (NWRI)	L711
HURON-03	National Water Research Institute (NWRI)	L711
ION-20	National Water Research Institute (NWRI)	L711
SUPER-02	National Water Research Institute (NWRI)	L711

2.9 Appendix 5. (continued)

CERTIFIED REFERENCE MATERIALS IN USE IN TRACE METALS LABORATORY

REFERENCE IDENTIFIER	SUPPLIER	STORAGE LOCATION
A	**WATER**	
SRM1643D	National Institute of Standards and Technology (NIST)	L747
SRM1641C	National Institute of Standards and Technology (NIST)	L747
SLRS-4	National Research Council of Canada (NRC)	L747
TM-21	National Water Research Institute (NWRI)	L740
TM-22	National Water Research Institute (NWRI)	L740
TMDA 51.2	National Water Research Institute (NWRI)	L740
TMDA 52.2	National Water Research Institute (NWRI)	L740
TMDA 53.2	National Water Research Institute (NWRI)	L740
B	**SEDIMENT**	
SRM2704	National Institute of Standards and Technology (NIST)	L747
MESS-2	National Research Council of Canada (NRC)	L747
BCSS-1	National Research Council of Canada (NRC)	L747
PACS-1	National Research Council of Canada (NRC)	L747
LKSD-3	CANMET (NRC)	L747
CTA-FFA-1	Polish Academy of Sciences	L747
C	**BIOTA**	
DOLT-2	National Research Council of Canada (NRC)	L747
DORM-1	National Research Council of Canada (NRC)	L747
TORT-2	National Research Council of Canada (NRC)	L747

2.9 Appendix 5. (continued)

CERTIFIED REFERENCE MATERIALS IN USE IN ORGANICS LABORATORY

REFERENCE IDENTIFIER	SUPPLIER	STORAGE LOCATION
S3429A	Accustandard	L765 (freezer)
S3429B	Accustandard	L765 (freezer)
EC305	National Water Research Institute (NWRI)	L765 (freezer)
EC248	National Water Research Institute (NWRI)	L765 (freezer)
EC250	National Water Research Institute (NWRI)	L765 (freezer)
1583	National Bureau of Standards	L765 (freezer)
CHM 842	Ultra Scientific	L765 (freezer)
CUS 3182	Ultra Scientific	L765 (freezer)
S6436	Accustandard	L765 (freezer)
Q0R03CA	QUASIMEME FRS Marine Lab	L765 (freezer)
EC110	National Water Research Institute (NWRI)	L765 (freezer)
1588a	National Bureau of Standards	L765 (freezer)
EC5	National Water Research Institute (NWRI)	L765 (freezer)
CLB1-A/B/C/D	National Research Council of Canada	L765 (freezer)
RPC-EPA-1	Ultra Scientific	L765 (freezer)
EDF2525(R-543)	Cambridge Isotope Laboratories	L-65 (freezer)
Q0R01CA	QUASIMEME FRS Marine Lab	L765 (freezer)
1945	NIST	L765 (freezer)
NCP II - 3	National Water Research Institute (NWRI)	L765 (freezer)
NCP II - 2 DORM-2	National Water Research Institute (NWRI)	L765 (freezer)
NCP II - 2 CRM 422	National Water Research Institute (NWRI)	L765 (freezer)
NCP II - 2 IAEA - 142	National Water Research Institute (NWRI)	L765 (freezer)
QC91-WB1	NIST	L765 (freezer)
C00 WB4	NIST	L765 (freezer)
EC416	National Water Research Institute (NWRI)	L765 (freezer)
EC418	National Water Research Institute (NWRI)	L765 (freezer)
LA-57795	Supelco (TCL Polynuclear Aromatic Mix)	L765 (freezer)
EC452	National Water Research Institute (NWRI)	L765 (freezer)
EC453	National Water Research Institute (NWRI)	L765 (freezer)
EC455	National Water Research Institute (NWRI)	L765 (freezer)
1647c	National Institute of Standards and Tech.	L765 (freezer)
EC1	National Water Research Institute (NWRI)	L765 (freezer)
EC7	National Water Research Institute (NWRI)	L765 (freezer)
EC5	National Water Research Institute (NWRI)	L765 (freezer)
CUS 3183	Ultra Scientific	L765 (freezer)
S6437	Accustandard	L765 (freezer)
EC420	National Water Research Institute (NWRI)	L765 (freezer)
EC516	National Water Research Institute (NWRI)	L765 (freezer)
EC517	National Water Research Institute (NWRI)	L765 (freezer)
CUS 3032	Ultra Scientific	L765 (freezer)
EC 5633C-0.1x	Accustandard (Custom Pesticide Mix)	L765 (freezer)

EC 5633B-0.1x	Accustandard (Custom Pesticide Mix)	L765 (freezer)
EC522	National Water Research Institute (NWRI)	L765 (freezer)
EC523	National Water Research Institute (NWRI)	L765 (freezer)
CUS 3033	Ultra Scientific	L765 (freezer)
EC 5633D-0.1x	Accustandard (Custom Pesticide Mix)	L765 (freezer)
EC701	National Water Research Institute (NWRI)	L765 (freezer)
S2984	Accustandard	L765 (freezer)
CUS 3031	Ultra Scientific	L765 (freezer)
EC 5633A-0.1x	Accustandard (Custom Pesticide Mix)	L765 (freezer)
EC606	National Water Research Institute (NWRI)	L-765 (freezer)
EC607	National Water Research Institute (NWRI)	L765 (freezer)

2.10 Appendix 6. Rules of Analyst Intervention

The five analyst intervention rules apply ONLY to the Reference (RF) and Reference Duplicate (RD) samples since these are homogeneous, remain stable, and contain substrate similar to the environmental samples.

2.8.1 Control Limits

If one RF or RD measurement in any tray (run) exceeds the control limits (±3*Sd*), another reference sample must be run. If the next analysis exceeds the control limits, the analysis must be discontinued, and the problem must be identified and corrected. In each of these cases, it is also NLET policy that all non-conformances and remedial actions taken must be documented.

2.8.2 Warning Limits

If two of three successive points exceed the warning limits (±2*Sd*), another reference sample must be analysed. If the next point is within the warning limits, the analysis can continue. Otherwise, discontinue the analysis, investigate the cause of the problem, and take corrective action. Document all non-conformances and corrective actions taken.

2.8.3 Standard Deviation Line

If four out of five successive points exceed 1 *Sd* limit, for the Shewhart Charts, another reference sample must be analysed. If the next point is on the opposite side of the centre line, or if it is on the same side of the centre line, but less than 1 *Sd* away from it, continue the analysis. If the point is on the same side of the centre line, and more than 1 *Sd* away from it, discontinue the analysis, investigate the cause of the problem, and take corrective action. Document all non-conformances and corrective actions taken.

2.8.4 Trend Monitoring

If four of five successive points are in decreasing or increasing order, analyse another reference sample. If the trend is broken, continue the analysis. Otherwise, discontinue the analysis, investigate the cause of the problem, and take corrective action. Document all non-conformances and corrective actions taken.

2.8.5 Centre Line

If six successive points are above or below the target value, analyse another reference sample. If the next point is on the opposite side of the target value, continue the analysis. If the next point is on the same side, discontinue the analysis, investigate the cause of the problem, and take corrective action. Document all non-conformances and corrective actions taken.

3.0 PERSONNEL

3.1 Quality Objective

To ensure personnel are adequately supervised and are proficient to carry out assigned activities.

3.2 Supervision

Dave Warry, Director of NLET, chairs the Management Team and is responsible for the Director's Office (DO).

Analytical services are provided through two operational laboratories: Inorganic Analysis and Organic Analysis. Scientific, consultative, and laboratory support services, with a focus on quality assurance, are provided through the Information and Quality Management (IQM) group.

The following individuals have supervisory responsibilities:

3.3.1 Inorganic Analytical Laboratory (IAL)

Section Head, IAL	**Gino Sardella**
Supervisor, Major Ions & Nutrients	**Bert Francoeur**
A/Supervisor, Trace Metal	**Anna Debenedetti**

3.3.2 Organic Analytical Laboratory (OAL)

Section Head, OAL	**Michael Comba**
Supervisor, Analytical Services	**Sean Backus**
Supervisor, Chemistry Services	**Ed Sverko**

3.3.3 The Information and Quality Management (IQM) group is divided into two sections. One group provides client, IT and quality management support for the entire laboratory. Those supervisory staff consist of:

Project Chief, IQM	**Haig Agemian**
Special Projects Officer	**Sharon Carrier**
Head, Computer Services	**Peter Saddler**

3.3.4 The Quality Management Products and Services group and consists of the following supervisors:

Project Chief, QMPS	**Haig Agemian**
Proficiency Testing Products & Services	**Keijo Aspila**
NCP Quality Management & Reference Materials	**Yvonne Stokker**
Performance Evaluation Products & Services	**Harry Alkema**

The duties and responsibilities for these positions, including required educational qualifications and experience, are contained in Job Descriptions and Statements of Qualifications, for each position, maintained on file in the DO and Human Resources Branch, NWRI.

3.3 Designated Alternates

Substitution arrangements for management and key supervisory positions follow:

POSITION REQUIRING SUBSTITUTION	CURRENT POSITION OF ALTERNATE	NAME OF ALTERNATE
Director	Project Chief Section Heads	On a rotational basis Haig Agemian Gino Sardella Michael Comba
Chief, IQM	Quality Assurance Officer Head, Computer Services Head, Performance Testing Head, NCP & Reference Materials Head, Performance Evaluation	On a rotational basis Cynthia Young Peter Saddler Keijo Aspila Yvonne Stokker Harry Alkema
Section Head, IAL	A/Supervisor, Trace Metals Supervisor, Major Ions & Nutrients	On a rotational basis Anna Debenedetti Bert Francoeur
Section Head, OAL	Supervisor, Analytical Services Supervisor, Chemistry Services	On a rotational basis Sean Backus Ed Sverko
Quality Assurance Officer	Project Chief	Haig Agemian
Head, Computer Services	Systems Technologist	Margaret Duffield
Special Projects Officer	Project Chief	Haig Agemian
Head, Performance Testing	Quality Assurance Technologist	Harold Malle
Head, NCP & Reference Materials	Quality Assurance Technologist	Ed Kaminski
Head, Performance Evaluation	Interlaboratory Study Coordinator Technologist	Joan Blum

3.4 Qualifications and Training

Minimum qualifications for Section Heads and Supervisors will normally be an appropriate degree and at least five years relevant experience. Minimum qualification for analysts will normally be an appropriate technical diploma and variable years experience depending on the complexity of the duties for the position being staffed.

New technical staff will, as a rule, be hired at the recruitment level (apprenticeship EG-03) and then have the opportunity to be promoted to the working level (EG-04) without competition. To do this, a set of competency criteria, covering technical skills, abilities and personal suitability, against which individuals will be evaluated, has been developed. This process is described in the document *"Selection Criteria for Non Competitive Reclassification of Apprenticeship Analytical Laboratory Technical Staff at NLET"*, dated August 22, 2001.

Every attempt will be made to recruit staff with the requisite qualifications. In those cases where there is a deficiency in qualifications the opportunity to upgrade qualifications shall be provided through in-house and/or external training.

The Quality Assurance Officer shall be responsible for the development and operation of an in-house training program that focuses on Quality Management including internal quality control practices. Upon hiring, every staff member is issued a controlled copy of the QM, and as described in Form 03-001, shall sign that they have read and become familiar with the QMS.

Supervisors shall be responsible for developing training plans for their staff. Such training plans shall take into account advances in technology and the associated need to upgrade staff skills and qualifications. Training requests and that taken are captured during the appraisal process using the Personal Training and Development Form.

Contracted personnel are held to the same requirements as NLET staff and therefore must be adequately supervised, competent and work in accordance with the quality system.

3.5 Analyst Proficiency

Prior to being assigned to carry out a specific routine test method the analyst shall be required to demonstrate acceptable proficiency. This demonstration will take the form described in **Protocol 10-002 PROTOCOL FOR THE ANALYST PROFICIENCY TEST**.

The analysts' Supervisor shall be responsible for ensuring that the analyst is proficient in the tests he/she is being asked to perform.

Each Section Head shall maintain a list of qualified analysts. This list shall include the analyst's name and position together with the tests for which the analyst is proficient. The list of analysts shall be maintained current and on file within each section. Copies of the Certificates of Proficiency shall be included in each SOP binder and another copy of each provided to the Quality Assurance Office.

3.6 Job Descriptions

All laboratory job descriptions shall be prepared and approved by the Supervisor.

Copies of all current job descriptions for all staff shall be maintained on file in the Director's Office with the original residing in Human Resources (HR), NWRI.

3.7 Confidentiality and Conflict of Interest Agreements

All staff employed by Environment Canada are issued a copy of the Treasury Board of Canada publication entitled "Conflict of Interest and Post-Employment Code for the Public Service" which includes an agreement, on the part of the employee, to hold in confidence all confidential information including proprietary rights. The agreement also requires employees to avoid situations which may allow others to perceive conflicts of interest, or to declare real and perceived conflicts of interest whenever avoidance is not possible via the Employee Certification Document and Confidential Report. Copies are held separately from personal files by the Director General, Human Resources of Environment Canada.

3.8 Personnel Records

Personnel records for all staff shall be maintained on file in the Human Resources Department. These records shall include: work descriptions; résumés; classification and personnel action forms; payroll information; letter of offer/deployment/transfer; appraisals; training records, occupational health & safety records; requests for and approved leave; hours of work (e.g. compressed, flex); awards, grievance and disciplinary materials. Copies of these are also held in the Director's Office files.

4.0 METHODOLOGY

4.1 Quality Objective

To ensure test methods (and related work instructions) are current, validated, incorporate adequate quality control and meet the needs of the client.

4.2 Methods

NLET published three volumes of analytical methods, for general use (clients and public), as follows:
Manual of Analytical Methods, Major Ions and Nutrients, Volume 1, 1994;
Manual of Analytical Methods, Trace Metals, Volume 2, 1994;
Manual of Analytical Methods, Organics, Volume 3, 1997.

Limited copies of each volume are still available for purchase. Updated versions will not be published but instead requests for copies of methods will be dealt with on an "as requested" basis. The associated SOP will be modified to delete excessive detail and will be copied to CD-ROM for distribution.

Electronic copies of methods are available on the L: drive in the Quality Management System folder under Methods. These are "read only" documents available to NLET staff for reference.

4.3 Standard Operating Procedures

SOPs comprise the test methods that are used routinely in the laboratory and are written to contain great detail so to be useful as training documents. Appendix 7 contains a copy of the SOP template. An index of current SOPs is found on the L drive. It contains SOP numbers, title, revision number and date of issue. The SOP numbers relate to each laboratory section in the following manner:
MI&NL - 01-1xxx
TML - 02-2xxx
OAL - 03-3xxx
QMPS - 04-4xxx

Electronic copies, "read only", are available to NLET staff on the L: drive in the Quality Management System folder under SOPs.

4.4 Supporting Work Instructions - Protocols

Work instructions, other than test methods, that are used in the conduct of laboratory testing shall be identified as Protocols. Test methods may cross reference supporting work instructions, as required.

Examples of Protocols include:

- 04-001 PROTOCOL FOR SAMPLE MANAGEMENT WITHIN THE LOGISTICS LABORATORY i.e. procedures for sample reception and initialisation

- 05-010 PREPARATION OF ACID HERBICIDES (AHs) STANDARDS i.e. procedures to follow in the preparation of standards for use in Acid Herbicide analysis in OAL

4.5 Validation, Review and Authorisation

The adoption of routine test methods and related procedures, including revisions to existing methodology, will undergo the following validation, review and authorisation processes.

4.5.1 Validation

The Section Head will ensure that the appropriate methodology has been selected and that all necessary method development and method validation requirements are carried out and documented in accordance with
Protocol 06-001 PROTOCOL FOR THE VALIDATION OF NEW OR MODIFIED ANALYTICAL METHODS.

Method validation is the process of establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting predetermined specifications and quality attributes. At NLET, method validation ensures that performance requirements for accuracy, recovery, precision, specificity (contamination), detection limits, calibration and linearity are met.

All method validation data and other relevant data collected during the method development process shall be maintained on file, under the control of the Section Head. Hardcopies shall be maintained with the appropriate method SOP, in a designated area of each Laboratory Section. Electronic validation data, where available, resides on the "L" drive of the LIMS under the "Quality Management System" folder in the "Validation Data" subfolder.

4.4.2 Review

The Section Heads will review and the QA Officer will control all test methods and related procedures.

In the case of test methods the Section Heads and QA Officer will verify that:
- internal quality control, and specifically method calibration and method quality control, are adequate;
- all calculations used to translate original test data into a final result are correct;
- all relevant ancillary procedures are included or referenced, and;
- the test method is validated based on performance history and/or documented validation data;
- the test method is validated based on the latest international, regional or national standards;
- the test method is reviewed and updated every 5 years.

4.4.3 Authorisation and Method Selection

Test methods and related procedures, subsequent to review by the Quality Assurance Officer, are authorised by the respective Section Head or Project Chief.

When methods are used that are not covered by standard methods, client approval must be obtained, specifications of client requirements must be met, the purpose of the test identified and the method must be validated before use.

Non-client specified methods are authorised by the Section Heads upon documented acceptance by the client of the method, which are with published reference methods or laboratory-developed methods that have been validated. Such validation to follow 4.4.1 above.

Whenever laboratory staff feel that the client has specified an inappropriate method, this fact will be documented and transmitted to the client by the Section Head via the CLO. Copies of this correspondence are to be retained on the appropriate client file.

4.6 Non-routine Test Methods

The use of non-routine Test Methods shall be approved by the appropriate Section Head. Non-routine methods shall be documented and this documentation shall include technical justification for their use or for departure from accepted, routine test methods. Test methods developed within the laboratory shall be planned, with appropriate documentation, and shall be assigned to qualified personnel.

Non-routine methods may be used for client testing, only on the approval of the client. Such approval is to be documented in the appropriate client file (CLO). Section Heads are to ensure that the selected method meets client specifications.

All such methods should be used for only a limited application. Alternately, they must undergo the test method validation, review and authorisation process in order to become classified as routine. Refer to
Protocol 01-003 PROTOCOL FOR THE EVALUATION AND ACCEPTANCE OF ANALYTICAL METHOD DEVELOPMENT UNDER THE NEW PRODUCTS AND SERVICES ACTIVITY ELEMENT.

4.7 Test Method Format

The format used for documenting routine test methods, SOPs, should include the following elements, as appropriate (see template in Appendix 7)

Number, Title, Version Number, Date Authorised, ECOLIMS Codes.

Background. Includes historical, scientific and practical information that might be of interest to analysts or clients.

1. Scope and Application. Includes parameters to be determined, concentration ranges, if applicable, and types of materials to which method can be applied.

2. Summary of Method. Synopsis of theory/principle of the method and short description of steps involved in the procedure.

3. Interferences. Includes those interferences that may significantly affect the results.

4. Safety. Includes a description of the safety hazards associated with the method and any protective gear which may be required by the analyst.

5. Apparatus, Equipment and Materials. Includes the identification of instrumentation, labware or glassware used, together with any descriptive information including diagrams. Any instrument performance characteristics or ambient conditions that need to be monitored should be identified. Includes any special materials or supplies used.

6. Reagents and Consumable Materials. Includes solvents, media, reagents, stock solutions, calibration standards, quality control samples, reference materials etc. A listing of reagents and clear instructions on their preparation are given. Information on the quality of reagents to be used, their acceptable shelf life and details of any special storage requirements are given.

7. Sample Collection, Preservation and Handling. Includes identification of quantity of sample required for testing together with requirements for sample collection, chemical preservation, containers, packaging, holding times, storage conditions and sample pre-treatment (i.e. removal of unwanted material, homogenisation and sub-sampling).

8. Sample Receiving. Includes details pertaining to sample submission, retrieval and responses to non-conformances with samples.

9. Quality Assurance/Quality Control. Includes the analyst certification process, instrument performance, MDLs, measurement uncertainty, QC Aliquot types to control accuracy, precision and recovery via control charting and corrective action. Criteria for analyst intervention is described.

10. Preparation and Procedure. Details all successive steps in the procedure including sample preparation, instrument set-up, calibration, operation, maintenance, troubleshooting and shutdown.

11. Data Reduction and Calculations. Includes all formulae and calculations, software operation, download to LIMS, decimal trimming and verification

12. Method Performance. Includes validation data for determination of MDLs, accuracy, precision, recovery and measurement uncertainty.

13. Reporting of Data. Includes data reporting procedures, data management, units, significant figures and record keeping.

14. Comments. Includes miscellaneous information.

References.

4.8 Appendix 7. SOP Template

Number: SOP 0X-XXXX

Title: SOP FOR THE ANALYSIS OF

Version Number: **Date Authorised:**

Background:

Procedure:

1. Scope and Application
2. Summary of Method
3. Interferences
4. Safety
5. Apparatus, Equipment and Materials
6. Reagents and Consumable Materials
7. Sample Collection, Preservation and Handling
8. Sample Receiving
9. Quality Assurance/Quality Control (QA/QC)
10. Preparation and Procedure
11. Data Reduction and Calculations
12. Method Performance
13. Data Management
14. Comments

References:

APPENDIX A: Table 0X-XXXX:1: Method Codes, Detection Limits and Verification Data
APPENDIX B: Diagrams and Illustrations
APPENDIX C: Record of Revisions

5.0 SERVICES, EQUIPMENT, AND SUPPLIES

5.1 Quality Objective

To ensure all equipment, supplies and services are functioning properly and/or meet required specifications.

5.2 Procurement

The Project Chief and/or appropriate Section Head shall be responsible for preparing and approving specifications for all purchased services, equipment, and supplies used in laboratory testing. Supplies will include reagents, glassware, spare parts etc. and services will include sub-contracted testing as well as equipment servicing.

Suppliers of calibration services or sub-contracted testing must be accredited to ISO Guide 17025.

The individual(s) approving the specifications for goods and services shall, where appropriate, carry out an assessment of suppliers. Approved suppliers shall: (i) provide goods and services that are of adequate quality to sustain confidence in the laboratory's tests, or (ii) in the case of sub-contracted testing, provide services that meet standards of competence equivalent to those in place at the National Laboratory for Environmental Testing. Approved suppliers, those with standing offer status, are listed on the Public Works, Government Services web site at http://soi.pwgsc.gc.ca.

The Section Head shall maintain a Purchase Order Binder that identifies all purchased goods by:

- purchase order number;
- description including grade/batch number, species/lot number, model/serial number, etc.;
- vendor name;
- date of receipt;
- disposition of order and reason, i.e., accepted or rejected;
- assigned inventory number, if applicable.

Prior to acceptance, all purchased goods shall be checked by: (i) verifying appropriate correspondence between the purchase order and packing slip, and (ii) verifying, when applicable, conformance to any prescribed specifications. Such checking shall normally be carried out by the individual(s) initiating the purchase order.

5.3 Inventory Control

The Section Head shall maintain an appropriate inventory of reagents and other consumables used on an ongoing basis. Reagents or other supplies kept in the laboratory stores, refrigerators, freezers or cylinder storage areas shall be rotated on a first in/first out - last in/last out basis. Expiry dates shall be monitored and reagents or other supplies shall be retested or discarded once the expiry date has passed.

Material Management shall assign an inventory number (EDR = Equipment Distribution Record) and affix an EDR label to all purchased equipment. The EDR number shall be recorded in both the Capital Equipment Inventory and in the appropriate *Instrument QC Manual*. The EDR numbers are maintained by Materiel Management within NWRI.

5.4 Equipment Maintenance

The *Instrument QC Manuals* shall be maintained for all major equipment used in instrumental analyses. The manuals will specify:

- supplier, model, serial number;
- significant equipment modifications;
- date commissioned;
- repair and maintenance history;
- calibration history; and
- performance history.

The analysts assigned to the specific tests utilising the equipment shall be responsible for maintaining these manuals.

Instrument QC Manuals (yellow binders) and the manufacturer's Instrument Operating Manuals shall be kept at a known central location, near the instrument. Instrument maintenance and calibration shall be carried out using procedures specified in the Instrument Operating Manual.

The following instruments have a maintenance agreement:

DESCRIPTION	SUPPLIER	MODEL NUMBER	SERIAL NUMBER	EDR	LOCATION
ICP - Optical Spectrometer	On Site Ltd. Burlington, ON	ARL-3580-OES	1462	252864	L742
ICP - Optical Spectrometer	On Site Ltd. Burlington, ON	TJA-IRIS (13283300)	1329	B02691	L742
ICP - Optical Spectrometer	On Site Ltd. Burlington, ON	VGE-PQ2+	944	B02221	L738

5.5 Handling of Equipment

Equipment documentation shall include procedures for the safe handling, transport, storage, use and maintenance. Control charts or other method of determining and documenting appropriate correction factors is to be included in this documentation.

Equipment that has been subjected to adverse handling, overloading or gives suspect results, or is shown to be defective or outside specified limits is to be taken out of service. This equipment is to be isolated to prevent use for testing. It is to be clearly marked as "out of service" and examined at the next available opportunity for potential effect of departure from specified limits. Should examination determine that the equipment contributed to the production of non-conforming results, the procedure under Section 2.7 - Control of Non-conforming Work shall be followed.

Equipment that has been outside the direct control of the laboratory shall be checked and validated before its re-entry into service.

All equipment is to be safeguarded from adjustments that would invalidate results.

5.6 Inventory of Equipment

NLET equipment inventory lists, for each laboratory section, are maintained on the L drive in the Capital Equipment folder. For the analytical laboratories, they are further divided into major capital equipment, >$25K, and minor capital equipment, >$5K but <$25K. The lists are revised annually.

5.7 Computing Systems

Computing systems include both hardware and software components. Computing systems used in the acquisition, manipulation, storage, retrieval and transmission of data and test results are validated in accordance with the requirements detailed below for each type of computing system. As well, procedures must be in place for protection of data that includes transmission. See **Protocol 14-005** for details.

5.7.1 Commercial Systems

Commercial systems include pre-packaged hardware and software components which have been combined in accordance with manufacturer specifications. These computer systems are validated in accordance with manufacturer instructions. Documentation on such validation is retained in laboratory computing system records.

5.7.2 Custom Systems

Custom systems are those systems where one of the components (hardware or software) is designed to meet specific requirements and is not normally provided by any manufacturer as part of a commercial system, or one of the components (hardware or software) has been significantly modified from a commercial system in order to meet local requirements. Two such systems are in use in NLET. The fist is our LIMS, ECOLIMS, and the second type are assorted Excel macros that are custom designed, in-house, for specific applications.

Design requirements for custom systems are documented and the design is checked against design requirements for adequacy up to full system installation. These checks are documented to show continuing conformance of design to requirements.

Once installed, the performance of custom systems is measured against other proven methods for data acquisition, data manipulation, data storage, data calculation, and for the production, retrieval and transmission of test results. Such measurement is documented and the system must be demonstrated to conform to requirements before its use is authorised within the laboratory. Implementation approval is documented and rests, in the case of ECOLIMS, with the Project Chief, IQM and, in the case of macros, with the appropriate Section Head.

6.0 FACILITIES

6.1 Quality Objective

To ensure that facilities are adequate to carry out the testing activity.

6.2 Required Environmental Conditions

The following environmental conditions are monitored and controlled by the Building and Property Service group of CCIW. When tolerances are exceeded they are contracted to address such problems. When results are jeopardised by the environmental conditions, then the tests are terminated and not restarted until conditions again meet necessary criteria.

6.2.1 Air Supply

The laboratories are currently served by a dual air duct system with thermostat controls in each laboratory. The air supply is controlled to maintain a range of 30 to 50% humidity with the set points at 35% in the winter and 50% in the summer. The main air supply units have pre-filters and final filters that are 85% efficient.

The laboratory air systems are supplied with 100% outside air. The air supply to each laboratory is based on a variable volume system. The laboratories are controlled to maintain a slight negative pressure relative to the corridors. The face velocities of the fumehoods are monitored and auxiliary room exhaust is used when necessary to maintain pressure difference.

6.2.2 Fumehoods

Fumehoods, throughout the complex, are tested annually by a representative from Health Canada at the request of the Health, Safety and Fire Officer, Lindsay Harrower (L146B, # 4767). The criteria that must be met is outlined in Treasury Board's Manual, under Occupational Health and Safety, Appendix A. A copy of this appendix and the Fume Hood Face Velocity Survey form is on file in the QA Office.

6.2.3 Lights

The laboratories are lighted by means of T8 fluorescent lights with electronic ballast. They are controlled by a wall switch in each laboratory.

The Building and Property Services (BPS) keep and updates a maintenance program for the CCIW complex. The Head of BPS is located in room L109 and the telephone number is (905) 336-4988.

6.3 Housekeeping

Analysts are responsible for maintaining assigned work areas in a safe, clean and orderly manner.

Special services, as described below, are required from the janitorial contractor to ensure no contamination occurs in the laboratories.

6.3.1 Janitorial Requirements

ROOM NUMBER	DESCRIPTION	IDENTIFIER	REQUIREMENTS
L703 L705 L707/708 L711	Laboratories	Reagent preparation Nutrients analysis Major Ions analysis Major Ions & Biocides analysis	No wax No phosphate No ammonia
L721/L725/L727	Laboratories	GC/MS	No wax
L760/L761/L765	Laboratories	GLVX/Extraction/ Organic Standards Repository	No wax
L766/L768/L771/L774	Laboratories	Extraction/Coldroom/ Organic Analysis	No wax
L774A	Laboratory	CRM/RM preparation	No phosphate No ammonia
L439, L454, Penthouse	Laboratories	PT/CRM/RM preparation NCP QA/QC	No admittance to janitorial staff
L201	Walk-in Cooler	CRM/RM preparation	No admittance to janitorial staff

6.4 Power and Water Supplies

6.4.1 Power Supply

There is an emergency standby diesel generator, that serves the facility in the case of a power outage. Only selected equipment is served by emergency power due to generation limits.

Equipment serviced in this way includes:
- exit and emergency lighting;
- horn and CO_2 system from chemical room, L757;
- walk-in freezer and cooler in W236;
- freezers in the corridor at north end of the complex;
- walk-in coolers, L771, W149, W151 and W105;
- GC/MSDs, L721.

A voltage stabiliser, or its equivalent, is used with most laboratory instruments as protection against power surges.

6.4.2 Water Supply

ASTM Type I reagent water is used throughout the laboratories unless otherwise specified.

The CCIW complex is served by a central reverse osmosis (RO) water supply system that is serviced on a quarterly basis by Culligan. The RO water is contained in a 1,000 gallon tin-lined tank. Further refinement of this water, if required, is carried out in each laboratory.

To produce Type I water in the Inorganic Analytical Laboratories, the product of reverse osmosis is passed through a commercial polisher, which consists of a mixed bed ion exchanger and a 0.2 micrometer membrane filter. The electrical resistivity of the polished water is monitored on an as-used basis and utilised only if the reading is greater than 16.7 megohm-cm. Records of these readings are kept and cartridge change schedules are documented in the associated Instrument Quality Control Binder for each water system.

The Organic Analytical Laboratory, to reach a final organics free end product, first produces their own RO water from tap water using a Millipore ELIX 10 RO system (located in L760). This RO water is then further refined employing a MilliQ Gradient system, which consists of a deionization carbon filtration and final polishing through a Millipak 40 final filter. The electrical resistivity of the polished water is monitored on an as-used basis and utilised only if the reading is greater than 18 megohm-cm. Both reading and cartridge change schedules are recorded in the Instrument QC Manual.

The IQM PT/PE Products & Services components incorporate one of three different systems depending on need. The water in the Penthouse lab is fed directly from the complex's RO system with no further treatment. Where adequate for use, the product of reverse osmosis is passed through a commercial polisher, which consists of a mixed bed ion exchanger and a 0.2 micrometer membrane filter (L201 and L439). In L454, the RO water undergoes ion exchange and carbon filtration but no membrane filter is used due to the large quantities of water processed.

6.5 Special Laboratory Areas

The computer room (L702) remains locked at all times. The Head, Computer Services; the Systems Technologist; and the Chief, IQM, have access.

The Logistics Laboratory (W236), where the sample walk-in freezer and cooler are housed, is located at all times except when the Laboratory Support Technician is in attendance. Sample walk-in coolers L105, L149 and L151 are kept locked except when in use.

The Organic Standards Laboratory (L765), GC/MSD Laboratory (L721), GC Laboratory (L725), GC/MS Laboratory (L721), PE Production Laboratory (L201), PT Production Laboratory (L454) and the QA Office (L751A) are also locked at all times. Two staff members, the OAL Section Head and the Supervisors, have access to the Standards Laboratory and Instrumental Laboratories. The QA Officer and the Chief, IQM, have access to the QA Office.

The Administrative Offices and all other laboratories, including the 7th floor walk-in cooler, are locked outside working hours by building security.

PT and CRM preparation activities are separated from the Analytical Laboratory facilities as they exist on different floors. In the Analytical Section, the water and sediment/ biota samples have completely separate analytical facilities in the laboratories to minimise the potential for contamination during the analytical process.

6.6 Security

6.6.1 Personnel Passes

It is essential that all personnel be able to produce proper identification if and when such proof is requested by authorised security personnel.

(a) Full-time Continuing employees possess a Government of Canada, Environment Canada photo identification card (blue/grey);
(b) Term (over six months) employees possess a Government of Canada, EC, temporary photo identification card (pink);
(c) Contract, Term (under six months), Agency, Casual, Volunteer, Visiting Scientists etc. possess an Environment Canada temporary identification card (green);
(d) Temporary personnel (up to three weeks) will be issued a temporary pass (white).
(e) Applications for I.D. cards and parking permits can be made at the Main Security Desk.
(f) All passes are surrendered to the CCIW Security Officer on termination of service.
(g) The loss of any ID card must be reported to the Security Officer as soon as possible. The loss is then reported to Headquarters and the RCMP.

6.6.2 Off Hour Entry

After normal working hours, and on weekends and holidays, all persons are required to sign in and out on the Entry Control Record. Only holders of CCIW building passes, Government of Canada ID cards, or persons named on a valid Temporary Pass will be admitted.

6.6.3 Visitors

All visitors to the Laboratory must enter by way of the main entrance and be signed in by the commissionaire on duty, upon approval of the unit or person to be visited. To expedite arrangements pertaining to visitors, the Security Office should be notified before they arrive.

6.6.4 Children on Site

Except for school tours, Open Houses and other similar events, dependent children will not be allowed into any area of the laboratories without approval of the Director, NLET. The parent is also required to sign both a Waiver and Release and an Indemnity Declaration form.

6.7 Safety

The Canada Labour Code and Canadian Occupational Safety & Health Regulations are legislation intended to protect the safety and health of all federal government workers. Recently, the Canada Labour Code was amended to give the employer many new duties and liabilities, enhance the powers and responsibilities of occupational safety and health committees and ensure that all employees are aware of their responsibilities and their rights under this code. NLET supervisors are required, and other staff are encouraged, to learn how these changes will affect them.

Safety is a primary consideration in NLET's laboratory environment. An NLET policy is being developed to reflect this concern. All staff must be aware of all hazards, utilise safety clothing/equipment and take every precaution to ensure healthy and safe working conditions are maintained. Specific instructions and precautions are described in each Standard Operating Procedure.

A review of the building safety rules is an essential part of the staff orientation process so it is required that all new staff read the latest version of the Canada Centre for Inland Waters (CCIW) *Laboratory Safety Manual* (July 1992) and view the Laboratory Safety video available from the CCIW library. It is recommended that these be reviewed from time to time as part of the ongoing safety program.

Under WHMIS legislation, the employer is responsible for implementing, updating, and informing all employees about controlled products. Thus, the WHMIS Education Program must be part of the employees indoctrination and must ensure that workers can apply the information to safeguard their own health and safety. Staff orientation includes the viewing of the WHMIS video available from the DO.

6.7.1 Fire and Emergency Evacuation Procedure

The following steps comprise the evacuation procedure for the 7th floor:
Chief Floor Fire Emergency Officer (CFFEO) or his/her alternate proceeds to the assembly point **L702A** and waits for communication from Chief Building Fire Emergency Officer (CBEFO).
All Deputy Floor Fire Emergency Officers (DFFEOS) and Floor Monitors proceed to the assembly point L702A. This step is necessary to establish a count of all the inspection teams and to assign additional duties in case of any team member/s being away from the respective work areas. Note: in situations where CFFEO or his/her alternate is away, the first DFFEO arriving at the assembly point will automatically assume control and direct the evacuation of the floor assigning someone to look after his/her designated inspection area.

- All designated DFFEOS and floor monitors proceed to their designated areas. If there are any disabled or injured individual/s in the area, inform CFFEO by calling 4932 (L702A) for assistance, if required.
- CFFEO arranges for two monitors. The monitors and the disabled or injured individual/s proceed to the assembly point (L702A).
- Each floor fire team proceeds with the sweep of its designated floor quadrant. Note: sweeps to be conducted by "pairs" of team members, if possible. Designated teams obtain the keys for the service cores (located in L714 and L743) and ensure that personnel working there evacuate immediately. The designated inspection teams are required to unlock the door and look inside. This step is necessary to ensure that there is no injured or unconscious employee trapped in the service core. After completion of the sweep, each team proceeds to the assembly point and reports to the CFFEO.
- CFFEO reports floor status and status of disabled to CBFEO by calling the main security desk at 4555. Note: report to include which stairwell is being used to evacuate disabled/ injured individuals.
- CFFEO may assign additional monitors to assist the disabled as required.

Following notification of CBFEO all floor teams proceed with evacuation of the floor. The two designated teams evacuate via Northeast and Northwest stairwells, if safe to do so, otherwise use the stairwell across from the assembly point to evacuate and station themselves at the designated entrances to ensure no unauthorised person/s re-enter the building and all evacuated personnel remain well clear of the building.

IMPORTANT: Each DFFEO and Floor Monitor is responsible for arranging his/her alternate if they are going to be away on vacation or any other business and for informing the CFFEO accordingly.

The above mentioned steps should not be considered as applicable in all cases as some or all may require modification depending upon the situation that exists at the time of emergency.

Staff orientation includes reading the CCIW *Fire and Emergency Procedures Manual* available from the Director's Office.

6.7.2 Seventh Floor Fire And Emergency Evacuation Designation Of Area For Inspection

Chief Floor Fire Emergency Officer (CFFEO) Yousuf Sheikh
Henry Husar (alternate)

INSPECTION TEAM	ALTERNATE	LABORATORIES AND OFFICES TO BE INSPECTED
Northwest Quadrant		
Keith Austen	Gino Sardella	L736, L738, L740, L742, L745, L747, L750, L752, Penthouse Lab, L754 (Men's Washroom), L755 (Service Core), L756, L757 (Chemical Storeroom).
Trudy Searle	Jacques Carrier	L737, L739, L739A, L741, L741A, L743, L744, L746, L746A, L748, L749, L751, L751A.
Southwest Quadrant		
Henry Husar	Jacques Dupuis	L701, L702, L702A, L704, L706, L706A, L709, L710, L712.
George Braedon	Bert Francoeur	L703, L705, L707, L708, L711, L711A.
Northeast Quadrant		
Shelley Bruce	Donna Zaruk	L753 (Women's Washroom), L760, L761, L765, L766, L768, L771, L774.
Sharon Carrier	Ivy D'Sa	L759, L759A, L762, L763, L764, L764A.
Southeast Quadrant		
Don Anthony	Todd Kish	L721, L725, L727, L730, L734 (Women's Washroom), L735 (Printer Room), L735A (Copy Room).
Violetta Richardson	Serge L'Italien	L713, L713A, L714, L714A, L715, L716 (Service Core), L717, L717A, L718, L720, L722, L723, L726, L728, L728A, L731, L732, L732A, L733 (Men's Washroom).
Fourth Floor		
Ed Kaminski	Yvonne Stokker	All labs and offices with rest of team.

6.7.3 Entrances to Be Guarded Until The Building Has Been Safely Inspected

INSPECTION TEAM	ALTERNATE	ENTRANCES TO BE GUARDED
Evacuation Area C		
Keith Austen	Gino Sardella	Entrance to evacuation area C (next to bicycle stand)
Trudy Searle	Jacques Carrier	Entrance to evacuation area C (next to bicycle stand)
Evacuation Area E		
Shelley Bruce	Donna Zaruk	Entrance to evacuation area E (next to cafeteria service entrance)
Sharon Carrier	Ivy D'Sa	Entrance to evacuation area E (next to cafeteria service entrance)

6.8 Plans of the CCIW Complex

6.8.1 Floor Plan, 7th Floor

Appendix 8 shows a floor plan for NLET, 7th floor only.

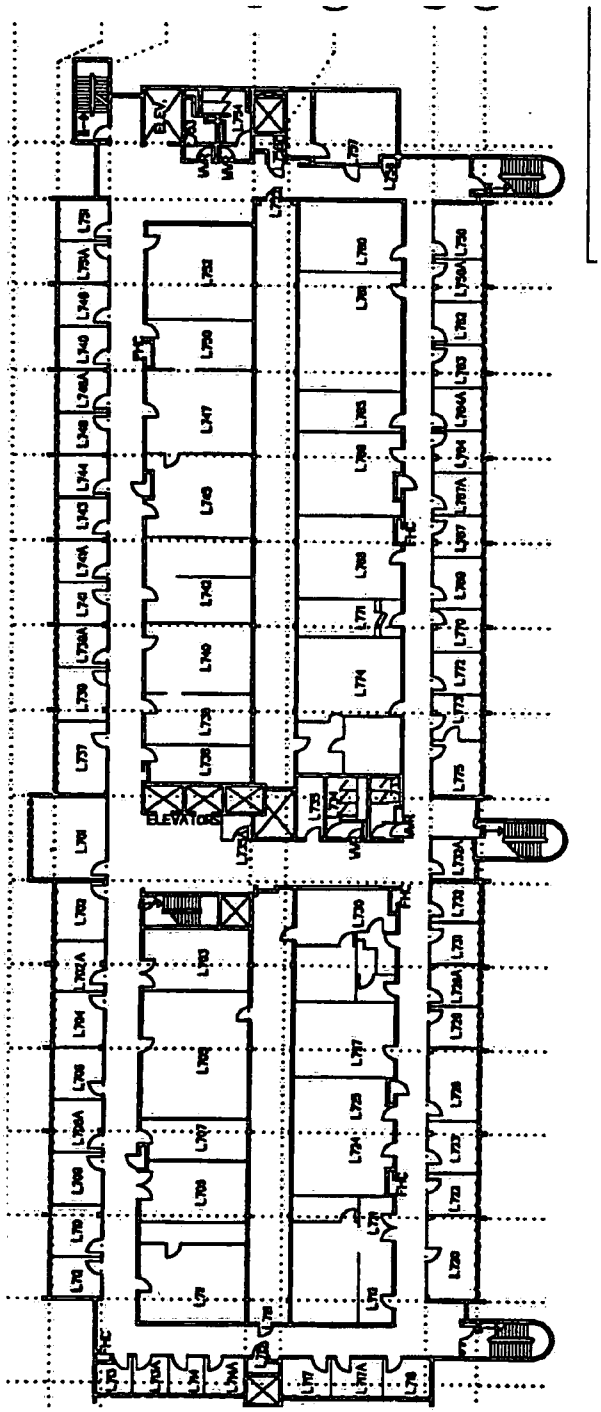
6.8.2 Floor Plan, 2nd Floor

Appendix 9 shows the location of the Logistics Laboratory (sample receiving) within the NWRI Ecotoxicology Laboratory Facility on the 2nd floor.

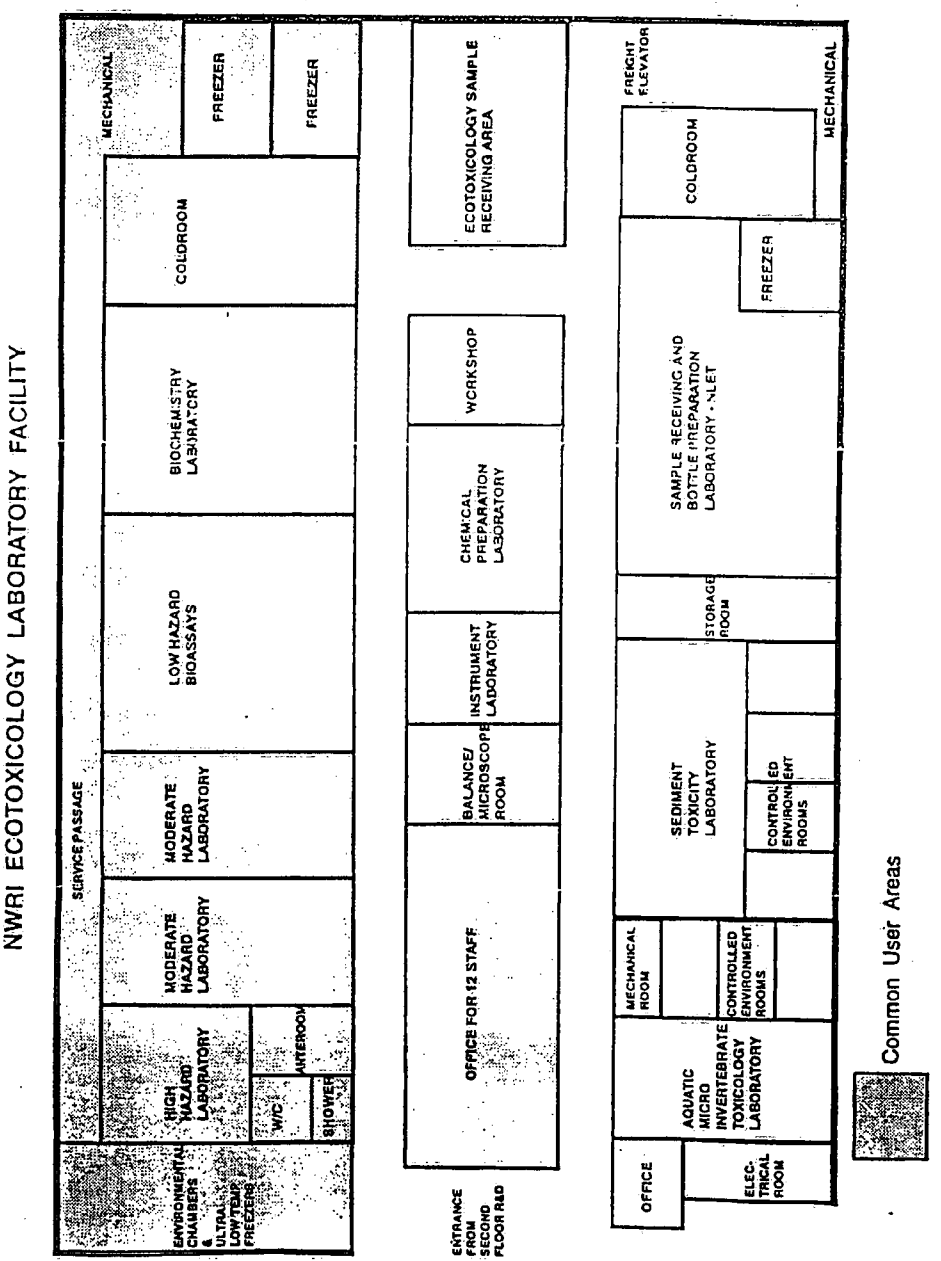
6.8.3 Site Map

Appendix 10 shows a site map for emergency evacuation assembly areas.

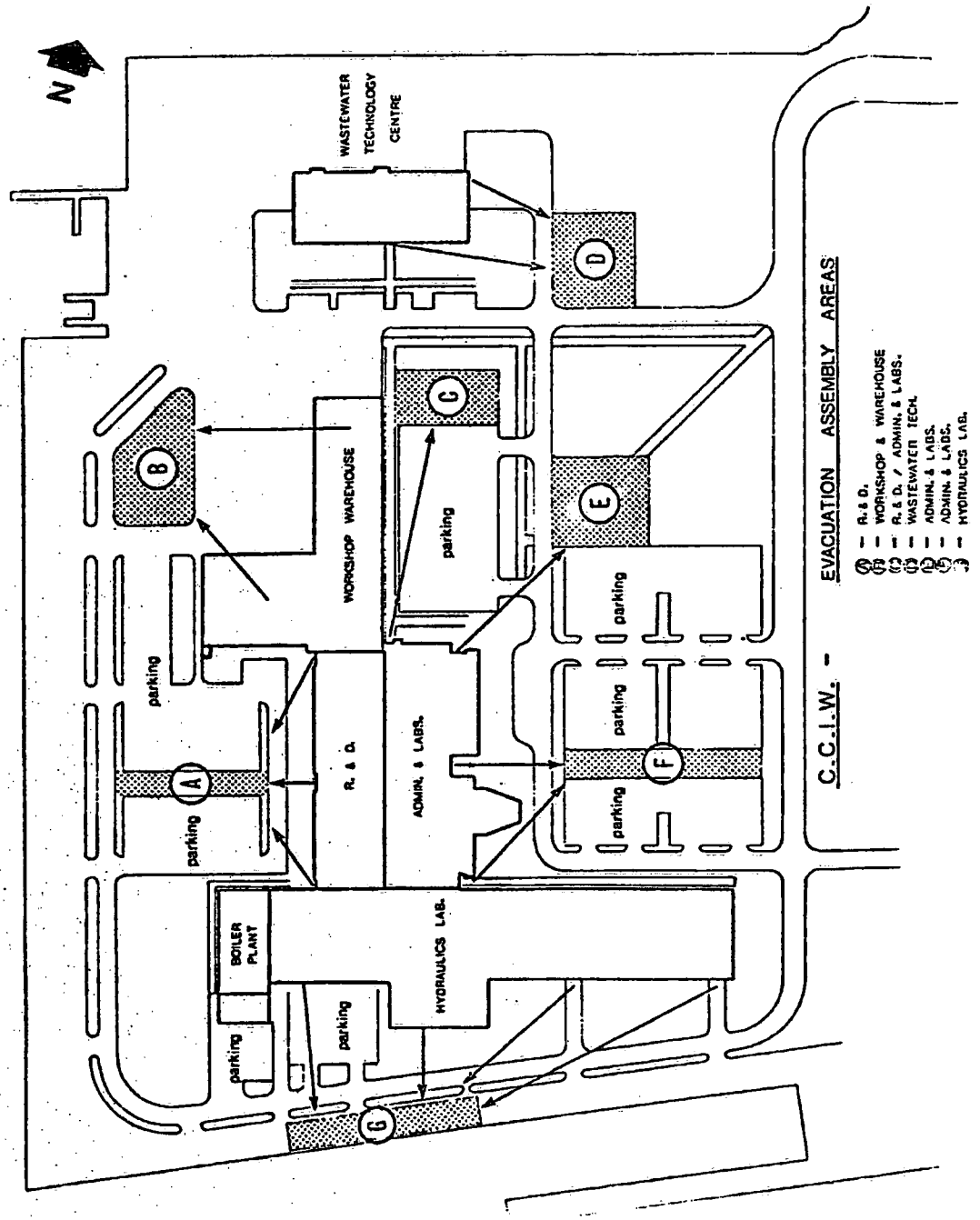
6.8.1 Appendix 8. FLOOR PLAN, 7th FLOOR



6.8.2 Appendix 9. FLOOR PLAN, SAMPLE RECEIVING AND BOTTLE PREPARTION LABORATORY ON THE 2nd FLOOR



6.8.3 Appendix 10. SITE MAP



7.0 SAMPLE MANAGEMENT

7.1 Quality Objective

To ensure sample management, within the Analytical Laboratories, that incorporates adequate procedures for the security, receipt, identification, checking, routing, storage and disposal of all samples. The procedures employed by the Proficiency Testing Products & Services section are detailed in the SOPs.

7.2 Field Supplies

Most clients own their sample bottles and shipping containers. To ensure uniformity among these containers, recommended sizes and types are included in
CLO Publication *NLET Sample Collection Summary*,
sent as part of the client package at the beginning of each fiscal year. The package also includes: an NLET *Schedule of Services*, a supply of *Request for Analytical Support Forms* and copies of the ECOLIMS *Miscellaneous Sample Submission Form*.

Clients should contact the Client Liaison Office at (905) 336-6261 to obtain field supplies from the Laboratory. These supplies include, but are not limited to:

- filters or other consumables used in sample collection;
- chemical preservatives;
- field kits;
- shipping instructions;
- laboratory Submission Forms.

NLET provides a sample container cleaning service for some of their Regional Clients. The sample containers are washed and, before being shipped to clients, 5 per cent are randomly selected for quality control checks according to
Protocol 12-002 SAMPLE CONTAINER WASHING PROTOCOL.

The Laboratory Support Technician shall maintain an inventory of the containers shipped, and/or on hand, to ensure that an adequate supply of containers is available to each Regional Office.

7.3 Sample Reception and Routing

Samples submitted to the Laboratory for analysis are received and logged in by the Laboratory Support Technician, or by another properly trained staff member. The activities relating to sample reception, log-in, internal tracking and routing are fully described in
Protocol 04-001 PROTOCOL FOR SAMPLE MANAGEMENT WITHIN THE LOGISTICS LABORATORY.

7.4 Sample Storage, Release and Disposal

7.4.1 Holding Times

Holding time is defined as the maximum allowable time a sample can be stored prior to stabilisation or analysis after sample collection according to method or client requirements. Holding times are

monitored and flagged automatically by ECOLIMS. If the Holding Time is exceeded a flag is displayed to the right of the result on the final report. Results are flagged with the letter "C" if the client exceeded the Holding Time and with an "L" if the lab did so. Holding Time discrepancies may also be recorded during sample initialisation on the *Sample Anomaly Report* (Form QA07-001) and the client contacted for instructions. It is the responsibility of each Supervising Chemist to assure that analysts make every effort to meet Holding Times. The documented Holding Times for analyses are found in
CLO Publication *Sample Collection Summary*.

The stability of organic residues in water samples varies depending upon residue structure and the water type. The Holding Time for these samples is only 7 days so NLET recommends the addition of solvent (dichloromethane) to stabilise residues and reduce the rate of decay. This procedure is described in
Protocol 06-010 PROTOCOL FOR THE STABILISATION OF WATER SAMPLES SUBMITTED FOR ORGANIC RESIDUE ANALYSIS.

7.4.2 Storage

Samples are stored in a manner which satisfies requirements for safety, maintenance of sample integrity, and ease of retrieval. After samples have been removed from the second floor storage area, they are brought to the seventh floor. The same storage requirements apply until the samples have been analysed and approved for release.

Samples are stored to minimise the potential for contamination from outside sources. Low-level and high-level samples, when known, are stored separately, to minimise the potential for cross-contamination. Samples and standards are stored in separate refrigerators or freezers. Storage areas for volatile organic solvents are kept separate from the samples and are vented to the outside.

Placing of samples in the proper storage environment is the responsibility of the analysts picking up the samples. Section Heads and/or Supervising Chemists are notified if there are any samples which must be analysed immediately.

Water Sample Containers

Trace metal containers, except for the Arsenic, Selenium and Antimony containers, are kept at room temperature in their laboratory area. The Arsenic, Selenium and Antimony containers are kept at 4° C. The laboratory area is locked after working hours. Nutrient, major ion, and organic sample containers are kept in the cold room, W236. When brought up for analysis, major ion container containers are stored at room temperature in the laboratory, for a maximum of seven days before completion of the analyses. Containers for nutrient and organic analysis are stored at 4° C in the cold room, L771. The cold room is locked after working hours.

Biota and Sediment Sample Containers

All containers for trace metal sediment samples are kept at -20 ° C, in a freezer, in L747 and trace metal biota samples are kept in a lockable freezer, in the north west hallway. Containers of organic samples are kept at -20 ° C, in a freezer, in L771. Organic extracts are stored at -20 ° C in a freezer in W236 for up to one year. Laboratory L747 and cold room W236 are locked after working hours.

7.4.3 Release of Samples

All water sample containers are released three weeks after the final report is issued according to **Protocol 04-002 PROTOCOL FOR THE RELEASE OR DISPOSAL OF SAMPLES,**

unless otherwise specified. The chemist reporting the data is responsible for the disposal of the sample containers.

7.4.4 Disposal of Samples

Water samples are flushed down the sink or disposed of according to the CCIW Safety Manual.

The Logistic Laboratory is informed, by the Building and Property Management, of the date the garbage bins are collected from the premises. The Laboratory Support Technician disposes of the sediment and biota samples the day prior to collection.

Disposal of samples, in each of the laboratory sections, is described in greater detail in **Protocol 04-002 PROTOCOL FOR THE RELEASE OR DISPOSAL OF SAMPLES**.

7.5 Chain of Custody

NLET does not, at present, analyse samples used for enforcement purposes so a chain of custody is not currently required. However, a sample tracking system, outlined in Section 7.3, is in place.

8.0 DATA MANAGEMENT

8.1 Quality Objective

To ensure data management that incorporates adequate procedures for the security, recording, calculation, validation, authorisation, transmittal, storage and disposal of all test data and related records.

8.2 Sampling Information

See 7.3 for a description of the sampling and other information that is recorded at the time of sample reception.

8.3 Test Data

8.3.1 Original Test Data

All original test data including QC data shall be recorded in a permanent form (e.g. note book, work sheet, instrument print out or magnetic media) at the time observations are made. Any changes to original records are to be authorised by initials and shall be made so that the original is not obscured.

The following information shall accompany the test data:

- name of analyst
- sample ID
- test method ID
- date of test
- equipment I.D, where applicable

The test data are entered into the ECOLIMS database by means of the program TRAY. When a user enters and updates the data from the TRAY file to the ECOLIMS database, all of the above information is included.

Data can be retrieved by:

- Project number;
- Schema and/or;
- Sample number.

A template of the tray pattern used to record test data for each analytical method is contained in the SOP for that method. A hard copy of the raw data and the analyst's worksheets, including the Quality Control Report for the current fiscal year, is kept on file in the laboratory area where the test is performed.

8.3.2 Absent Test Data

Test data may be absent if any of the following conditions exist:

- damaged sample
- insufficient sample
- sample history deficiency, and
- laboratory accident

Non-numerical codes are assigned to the reports when any of the above conditions exist. Flags can be assigned during sample reception or sample analysis.

The following non-numeric codes are used in the Laboratory to deal with absent test data:

BR	Broken	LC	Laboratory Contamination
DE	Depleted	NA	Non Applicable
DS	Destroyed	NR	Not Received
FC	Field Contamination	SI	Suspected Interference
IS	Insufficient Sample	EX	Externally Reported

The specifications for determining when and how test data are to be flagged are described in **Protocol 14-006 NON-NUMERIC CODES USED BY THE ECOLIMS DATABASE**.

8.3.3 Non-conforming Test Data

Test data will be considered to be non-conforming if any of the following conditions exist.

- failure (or suspected failure) to meet all conditions necessary to insure the integrity and representativeness of the sample (i.e. sample history deficiencies exist)
- failure (or suspected failure) to comply with the test method or supporting work instructions.
- failure (or suspected failure) in method performance as demonstrated by results provided by quality control samples
- inherent property of sample that compromises the testing (e.g. as verified by the method of standard additions), and
- relevant evidence provided by data validation (e.g. as a result of comparison with expected values, ranges or relationships)

Documentation of all non-conformances that occur during the analytical process is a requirement. This is accomplished using various forms and audit trail sheets as best meets the needs of each of the Laboratory sections. Non-conformances must be brought to the attention of the Supervising Chemist and any actions taken (even if No Action is the outcome) must be authorised. A signature /initials and date are sufficient proof of authorisation.

When test data are accompanied by a significant non-conformance, the data are reported to the client with a narrative describing the nature of the non-conformance. A log of non-conformances will be kept and reported to management as part of the annual review of the QA system.

8.3.4 Revised Test Reports

When a revised test report must be issued, the Section Head or Supervising Chemist is required to first "Unaccept" the affected samples in ECOLIMS. An audit trail of this action is recorded by the LIMS, that includes the date, name of the user performing the task and any comments included. The new data are entered, either by changing the value or adding a new value. When the value is modified, ECOLIMS logs this action. When a recheck value is added, an "R" flag appears beside the new number, thereby maintaining both the new and original data in the database, though only the recheck value will appear in the revised report. The Section Head issues a memo to the client, to accompany the revised report, referencing the original report by date and sample set and identifying the new report as supplemental. Note that revised test reports must also meet the requirements of CAN-P-4D.

8.4 Data Validation

The appropriate Section Head shall ensure 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.

8.5 Specifications for Reported Results

8.5.1 Flagged Results

Flags (and explanatory comments) will appear on the test reports if there is no result or if the data is otherwise qualified (see 8.3.2 and 8.3.4).

8.5.2 Significant Figures

The number of significant figures of any analytical result shall be consistent with the number of significant figures in the data base used to generate the result. Significant figures are normally set at three and the decimal points will not exceed the number of decimal points specified in the validated MDL. This correspondence is checked and controlled for each result through the Laboratory LIMS system.

8.5.3 Low Level Data

Unless otherwise specified, test data which are below the established detection limit (DL) shall be reported as < DL (e.g. <0.01mg/L).

All test data are automatically checked through the computer system for values being reported that are lower than Method Detection Limits (MDL). No numeric values less than the validated MDL are reported, unless a Project Specific MDL is established and
Form QA08-002 ***Letter of Agreement for Provision of <MDL Values***
has been completed. Under these circumstances, values less than the validated MDL can be prepared and reported by manual procedures.

8.6 Test Reports

8.6.1 Format and Content

Test reports shall contain adequate information, as appropriate:

- name and address of laboratory;
- name and address of client;
- unique sample I.D.;
- type of sample;
- location of sampling;
- time of sampling;
- date test carried out;
- test method used;
- test result, or;
- flagged test result;
- test recovery, if requested;

- test confidence limits and/or measurement uncertainty associated with each result, if applicable;
- name of sub-contractor;
- name of person authorising report,
- date test report issued; and;
- confirmation that the results meet the requirements of CAN-P-4D.

8.6.2 Authorisation

Analytical results shall be checked by the analyst(s) and then verified by the appropriate Supervising Chemist and/or Section Head. Once authorised, results are accepted into the ECOLIMS database, and a paper copy of the final report is generated. This report is signed for release to the client by the appropriate Supervising Chemist or Section Head. A copy of the signed cover sheet is provided to the CLO for filing.

Where data are not captured by ECOLIMS, final reports (special) may be issued as Excel spreadsheets. These reports require the same authorisation as those created using ECOLIMS. A signed cover sheet must accompany the data. Copies of these reports are filed by the CLO.

Occasionally, preliminary results are released, as a special request, for clients. These reports must be clearly identified as "preliminary" and the name of the Supervising Chemist or Section Head authorising the transmission of the data should be evident. Preliminary results are always followed-up by the issuance of a final report as quickly as possible.

8.6.3 Transmission

Properly authorised final reports are sent on a weekly basis to clients. A copy of the letterhead is filed as proof of delivery. Regional clients receive a hard copy of the final analytical results. Those results are also available electronically through ECOLIMS.

Special final reports may first be transmitted by fax or e-mail though are always followed-up with a hardcopy version. Preliminary reports may be sent in any format; fax, e-mail or paper copy depending on the client request.

At all times, client confidentiality must be assured.

8.7 Storage and Disposal of Records

8.7.1 Storage

It shall be the responsibility of the Section Heads to ensure that all records used to generate a result are stored in a secure manner and are easily retrievable. Hard copies of these records are kept in the analytical area for the current fiscal year. After one year, they are removed from the Laboratory area and stored in the NLET storage area on the first floor of the CCIW complex, for a period of five years. Final results are also archived in the ECOLIMS database for a period of five years.

8.7.2 Disposal

All records will be disposed of after a period of five years unless otherwise specified by legal or other written agreements with clients. See Appendix 11 for specifics.

8.8 Access to Records

Unless access to specific records is specified by contract or mandated by audit, all client or other requests for access to records must be directed to the Quality Assurance Officer.

Access to a clients own specific records will not be unreasonably denied. Requests by a third party must be accompanied by written consent from the client.

Records that may be made available, on request to the Quality Assurance Officer, shall be limited to:

- staff curriculum vitae;
- records of analyst proficiency;
- equipment maintenance logs;
- reagent preparation logs;
- records of non-conformance;
- data validation records;
- original test data;
- logs or records relating to primary measurement (i.e. weight, volume, temperature);
- logs or records relating to water quality (i.e. reagent water, dilution water), and;
- performance audit or quality audit results.

Under no circumstances, except as dictated by a Court of Law, shall records be removed from the laboratory. Requirements for ensuring client confidentiality shall be observed when making records available.

8.9 **Appendix 11.** Records Disposal Schedule

ADMINISTRATION	
Policy	5 years, A*-2, D**-3
Routine	2 years
Greetings	1 year
cc	6 months
Magazines, subscriptions	1 year
Legal, Parliamentary, etc.	see Public Service manual
Reports	Public Archives
BUILDINGS & PROPERTIES	
Policy	5 years, A-2, D-3
Routine	2 years
EQUIPMENT & SUPPLIES	
Policy	5 years, A-2, D-3
Routine	2 years
FINANCE	
Policy	6 years, A-2, D-4
Routine	2 years
Agreements, Arrangements	Public Archives
PERSONNEL	
Policy	5 years, A-2, D-3
Routine	2 years
Advertising of Job Openings	1 year (HR has originals)
Health & Safety	see CCIW manual
Reports & Statistics	3 years
Incentive Awards funded by the Institute	6 years, A-2, D-4

Note: *A = Active
**D = Dormant (usually stored in cages in the warehouse)

9.0 WORKLOAD MANAGEMENT

9.1 Quality Objective

To ensure workload management that incorporates consideration and verification of resource availability prior to acceptance of testing work, acceptable turnaround time, and verification of these factors prior to the modification of accepted testing work.

9.2 Contract Review

The Director, NLET, delegates authority for the review and acceptance of contracts involving testing work to the Client & Laboratory Advisory Officer (CLO), in consultation with the Section Heads, for testing that falls solely within the capability of their section laboratory. The NMT sets general guidelines as to how much work may be accepted from each client and of what type. Testing work outside of traditional client credits is documented via Memorandums of Understanding.

All requests for testing work are forwarded to the appropriate Section Head for initial review. Reviews of proposed work shall include availability of qualified personnel, laboratory facilities, testing equipment and appropriateness of testing methods. Specific testing requirements are to be defined, documented and understood prior to acceptance of any testing work.

Records of Contract Review

Records of contract review will be maintained in appropriate files within the Client Liaison Office. Such files will include all relevant discussion with the client on the work to be undertaken, any sub-contracting considerations, any departures from accepted test methods, acceptance of methods to be used and any changes which may subsequently alter the work or the test results.

Deviations from Contracts or Amendments to Contracts

The client is to be notified if any deviations from contracts established for testing work. Records of such notifications is to be maintained in the appropriate regional binder. Amendments to contracts may be undertaken only after the ramifications of such amendment have been reviewed in the same manner as the initial contract review given above.

9.3 Service to the Client

NLET encourages its clients to participate in all phases of work undertaken on their behalf by the laboratory. Laboratory personnel are encouraged to invite clients to view ongoing work, with such limitations as are imposed by the need to maintain the confidentiality of work in progress for other clients. Laboratory work instructions are to include procedures for the receipt of clients and for the extra steps required to maintain confidential the work undertaken for other clients during the time of a visit.

NLET provides an avenue for client feedback, through communication, in any form, with the Client Liaison Office, and actively solicits such. Yearly surveys are conducted via inclusion in the client packages that are mailed prior to the start of each fiscal year.

9.4 Turnaround

Unless written arrangements are made with the Client Liaison Office (CLO), the elapsed time between sample receipt at the laboratory and test report authorisation, shall not exceed eight weeks in the Inorganic Analytical Laboratory and sixteen weeks in the Organic Analytical Laboratory. Status reports, summarising the current situation in each Laboratory section with regard to samples on hand, samples completed, and projected backlog, shall be prepared by the Client & Laboratory Advisory Officer and forwarded quarterly to the Management Team.

The Section Heads shall schedule staff and take whatever measures are deemed necessary, in order to meet turnaround requirements. If it is apparent that specified turnaround times will not be met, the CLO shall so advise the client and negotiate compensation. A non-conformance report will accompany all results exceeding holding times.

9.5 Workload Control

Before the beginning of each fiscal year, an information package is sent from CLO to all clients. This package contains:

- *NLET Schedule of Services*, which outlines the analyses available and their costs;
- *Request for Analytical Support Forms*, which enables clients to provide their estimated workload for the approaching fiscal year on a monthly basis;
- *ENVIRODAT/Miscellaneous Sample Submission Forms*, which are the forms that must accompany each batch of samples sent to the Laboratory;
- *Sample Collection Summary* document, which provides the Project Leader with the information needed to store, preserve and ship samples from the field location to the Laboratory.

Prior to acceptance, all requests and tenders for testing services, above the planned amount allotted to each Project Leader will be reviewed, to determine whether the requirements for testing are clearly defined and the necessary resources are available. The Management Module of ECOLIMS is utilised to make supply/demand projections. If demands exceed the projected ability to deliver results within specified time frames, clients are notified and sample projections are revised.

9.6 Sub-contracting

NLET may, from time to time, enter into agreements with private laboratories to conduct analysis at the NLET facility on behalf of clients. These arrangements are made on a project-specific basis, and such arrangements are negotiated by CLO on behalf of NLET with the interested parties. Client approval must be obtained and agreements reached this way are confirmed in writing before any action is taken.

If these arrangements are made with a private laboratory such that the work is to be conducted off-site, then, the contracted laboratory must be accredited and a Quality Assurance Plan must accompany any such agreement, unless it is expressly rejected through written agreement with the Project Leader. The purpose of this is to ensure that results obtained through a third party are comparable with those obtained at NLET. The reporting of subcontracted results must meet the same criteria as those produced in-house.

10.0 MEASUREMENT TRACEABILITY AND UNCERTAINTY

10.1 Quality Objective

To ensure that test results are supported by a traceable system of measurement and accorded uncertainties appropriate to requirements.

At this time, NLET has not officially addressed the issue of Uncertainty so that portion of the manual has been left in template form.

10.2 Traceability of Measurement

All measurements made within the laboratory are traceable to a national standard or other intrinsic standard. Measurement instruments and certified reference materials are traceable to a national measurement laboratory such as the National Research Council (NRC - Canada) or the National Institute of Standards and Technology (NIST - US) or intrinsic chemical or physical units or related to such standards through an unbroken chain of physical or chemical comparisons and whose uncertainty of measurements have been quantified.

The laboratory adheres to the requirements of the SCC Policy on the Acceptability of Calibration Sources used by Accredited Testing Laboratories (SCC Document D 92.8)

10.2.1 Equipment Performance Requirements Determine Calibration Intervals and Effort

The performance requirements of all instruments have been determined, (including uncertainty requirements), to establish the appropriate frequency and level of calibration required for each. Calibration intervals (and uncertainty requirements 0 for all measurement equipment are retained in the equipment files. Changes to calibration interval (or uncertainties) required from calibration service providers may be instituted if equipment performance or test method/result uncertainty requirements are changed. Such changes are recorded.

Certificates for calibrated masses, volumetric glassware and thermometers shall be maintained on file by the appropriate Section Head.

10.2.2 Physical Measurement Traceability:

The laboratory calibration program includes all instruments which provide physical measurement results. All instruments are related to stated references, usually national or international standards, through an unbroken chain of comparisons(, all having stated uncertainties).

Gravimetric Measurement Balances, used in any procedure which affects the results of testing, shall be included in the laboratory calibration program. At present, all balances are calibrated by an ISO 17025 accredited service provider at an interval of every 18 months. Verification checks shall be carried out on a daily or as-used basis.

Instrument Quality Control Manuals, yellow binders or Duotangs, shall be maintained that record balance location, model, manufacturer and serial number together with dates, analyst's name, calibration certificates and results of daily verification checks. These binders are kept in close proximity to the associated balance or in a nearby cupboard. The Supervising Chemist is

responsible for maintaining them, each analyst is responsible for filling in relevant details and the QA Officer is responsible for annual surveillance to ensure compliance.

Volumetric Measurement Class A glassware shall be used, as appropriate, and the delivery volumes of auto pipettes and dilutors shall be checked.

Procedures for checking delivery volumes are contained in the associated Instrument QC Manuals.

Instrument Quality Control Manuals, yellow binders, shall be maintained which record the results of volumetric checks together with dates, analyst's name and equipment ID.

In OAL two binders exist: one in L765 covering syringes used in the Standard Repository Laboratory; the other is stored in L761 and holds documentation for the all remaining OAL syringes in use. In TML, the binder is located in the cupboard in L750 and in the MI&NL, the two binders reside in L705.

Temperature Measurement Thermometers used in any procedure that affects the results of testing, shall be included in the laboratory calibration program. This includes those thermometers used to establish quality control for samples stored at specific temperatures. Verification checks shall be carried out on a pre-determined basis

One digital thermometer is sent out for calibration by NRC (ISO 17025 accredited) every two years. This reference is then used directly to check equipment or is used to check other thermometers on a regular basis that are used in verification checks. The Instrument QC Manual for the calibrated digital thermometer is maintained by the QA Officer and resides in the QA Office. It holds the calibration certificates together with dates, analyst's name and thermocouple when borrowed for use.

The Instrument QC Manuals for temperature controlled equipment contains the details for temperature checks, control limits, action to be taken when limits are exceeded and verification against the calibrated thermometer.

10.2.3 Chemical Measurement Traceability

The value of chemical standards in the laboratory are related to stated references, usually national or international standards, through an unbroken chain of comparisons. Traceability is the continuing basis to document the traceability chain (and quantify its associated measurement uncertainties).

10.2.3.1 Reagent Water and Dilution Water

Reagent Water: The reagent water supply shall meet the requirement of each analytical method. In general, this is achieved through maintaining records of: Resistivity > 16.7 megohm-cm.

Records shall be maintained which record the conductivity and/or resistivity of reagent water on a daily or on an as-used basis. In the case of the Nutrients Laboratory, reagent water is checked against MilliQ and reverse osmosis (R.O.) distilled water. The replenishment of any consumables, i.e. resin associated with the reagent water supply, shall also be documented.

The locations of the *Instrument QC Manuals* for water systems and the name of the person responsible for maintaining each follow:

SECTION	LOCATION	PERSON RESPONSIBLE
IAL	L-705	B. Francoeur
	L-707	B. Francoeur
	L-708	B. Francoeur
	L-711	B. Francoeur
	L-747	A. Debenedetti
OAL	L-760	E. Sverko

10.2.3.2 Reagents, including calibration standards

All reagents, including calibration standards, shall meet appropriate requirements for performance and/or accuracy by ensuring:

- reagents of certified purity are used
- reagent water of appropriate purity is used
- gravimetric measurements are traceable in accordance with the SCC Policy on the Acceptability of Calibration Sources
- volumetric measurements are traceable (e.g. Class A glassware used)

Records shall be maintained which record:

- supplier, grade, batch no.
- dates of preparation or verification
- measurement of weights, volumes, time intervals, temperatures and pressures and related calculations
- relevant processes (e.g. pH adjustment, sterilisation)
- verification results
- discard date
- analyst's name

All reagents, including standards, shall be properly labelled. The label shall identify the material, concentration, date prepared and expiry date.

Maintenance of records, proper labelling of reagents (including certified reference materials), storage under appropriate conditions, and disposal prior to expiry date shall be the responsibility of the analyst(s) assigned to the tests.

10.2.4 Reference Materials

The laboratory uses only Certified Reference Materials which are accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes traceability to an accurate realisation of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

Procedures for using reference materials to verify calibration and/or method performance appear in the SOPs.

All reference material certificates shall be maintained on file by the appropriate Section Head.

A current inventory of certified (and other) reference materials used for Method Quality Control purposes appears in Appendix 5. The inventory provides the reference material description and storage location.

10.3 Measurement Uncertainty

All quantitative measurements made in the laboratory are attributed an associated uncertainty of measurement. This value is a determination of the confidence that the client may place in the derived value, and the size of that confidence region.

The uncertainty associated with any result is entirely dependent on the procedure, which includes the method, the equipment, the sample, and the personnel use the method to acquire test data. All of these factors contribute to the uncertainty of the test result.

The establishment of the parameters, calculations, and determination of uncertainties associated with any test method/procedure are the responsibility of the Testing Division. Section Heads within the testing division may make use of proficiency testing and quality control data to generate standard uncertainties associated with groups of test results or test methods.

The determination of uncertainties to be used in testing and analysis shall form part of the approved method for all methods used in the laboratory.

END OF MANUAL

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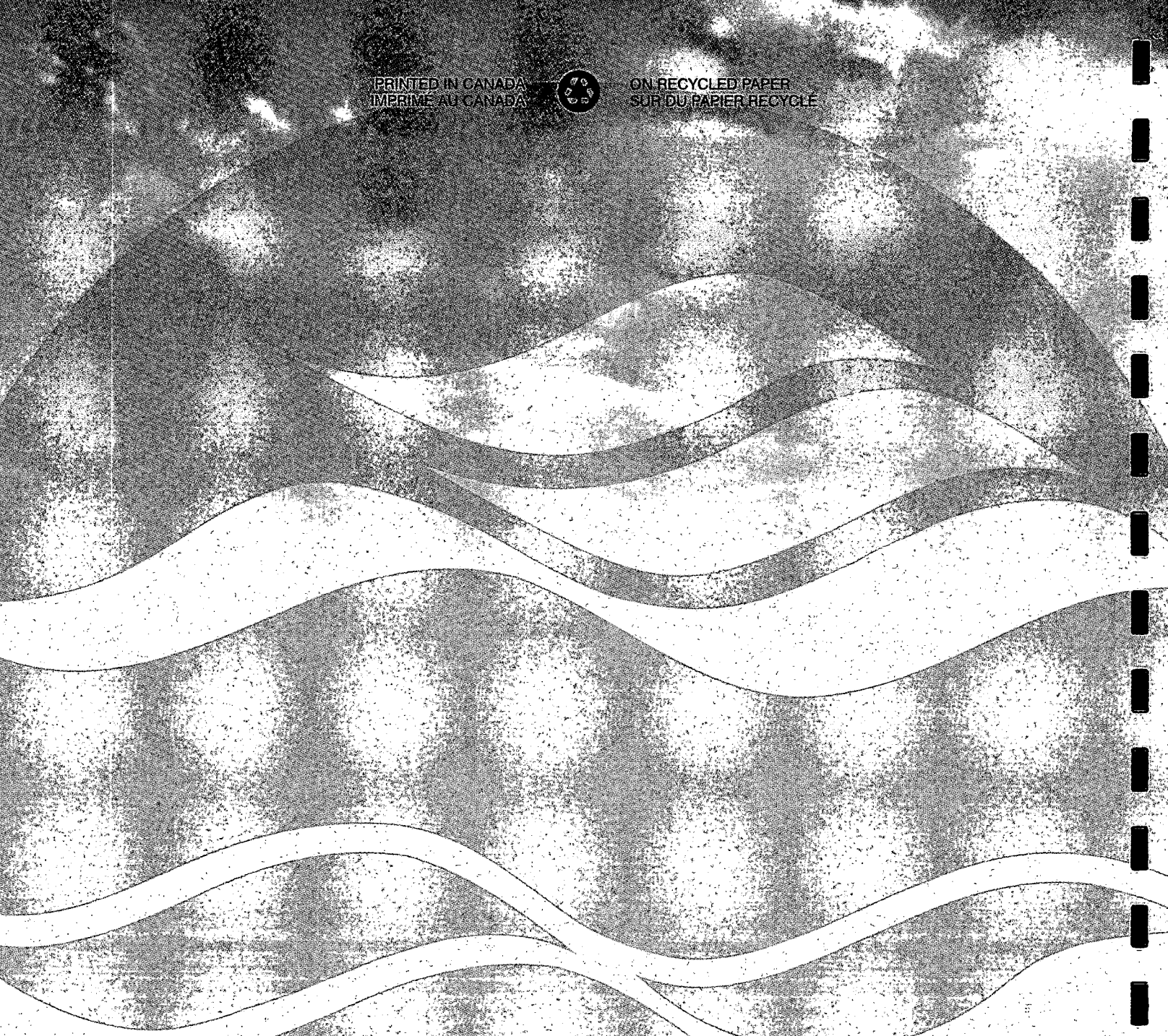

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