

VAEL Quality Systems Manual			Page 1 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

Vermont Agriculture and Environmental Laboratory

**163 Admin Drive
Randolph Center, Vermont 05061**

Quality Systems Manual

Revision 26

John Jaworski

Assistant Laboratory Director

802-585-4441

2021-04-05

David Crosby

QA Officer

802-272-8378

2021-04-05

VAEL Quality Systems Manual			Page 2 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

Table of Contents

1.0	Introduction.....	7
1.1	Objectives and Commitments of Management.....	7
1.2	Management’s Quality System Policy Statement.....	7
1.3	Employee Code of Ethics, Training, and Reporting of Unethical Behavior	7
1.3.1	Employee Code of Ethics and Laboratory Fraud	7
1.3.2	Ethics Training	8
1.3.3	Reporting of Unethical Behavior	8
1.3.4	Management Review of Data Integrity Procedures	8
2.0	Laboratory Organization and Responsibility	8
2.1	The Inorganic Chemistry Center.....	8
2.1.1	Metals	9
2.1.2	Nutrients	9
2.1.3	Wet Lab	9
2.2	The Organic Chemistry Department.....	9
2.2.1	Semi-Volatile Analyses.....	9
2.2.2	Volatile Analyses	9
2.3	The Biology Department.....	9
2.3.1	Central Dairy Laboratory	9
2.3.2	Animal Health Section	9
2.3.3	Micro and Molecular Biology Section.....	10
2.4	Laboratory Positions and Job Duties	10
2.4.1	Director.....	10
2.4.2	Assistant Director.....	11
2.4.3	Quality Assurance (QA) Officer	11
2.4.4	Supervisor.....	12
2.4.5	Sample Receiving.....	12
2.4.6	Chemist/Microbiologist I, II.....	12
2.4.7	VAEL Chemist/Microbiologist III, IV, V.....	12
2.4.8	Environmental Analyst (Seasonal Temporary).....	13
2.4.9	Special Duties.....	13
3.0	Sample Handling.....	15
3.1	Laboratory Contracting Policy.....	15

VAEL Quality Systems Manual			Page 3 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

3.2	Sample Collection.....	15
3.3	Sample Receiving/Rejection.....	15
3.4	Laboratory Information Management System (LIMS).....	15
3.5	Sub-Contracting.....	16
3.6	Legal Chain of Custody Procedures	16
4.0	Standard Operational/Administrative Procedures.....	16
4.1	Review/Revision.....	17
4.2	SOP Requests.....	17
4.3	Monitoring Procedures.....	18
4.4	Administrative SOPs.....	18
4.5	Purchasing of Services and Supplies	18
5.0	Data Production and Reporting.....	18
5.1	Data Recording and Editing.....	18
5.2	Data Reduction.....	19
5.3	Parser/Bench Sheet Review	19
5.4	Data Review, Validation and Approval.....	19
5.4.1	Primary Review.....	19
5.4.2	Secondary Data Review and Validation.....	19
5.4.3	Approval.....	20
5.5	Data Reporting.....	20
5.5.1	Results Report Format.....	20
5.5.2	Revised Reports.....	20
5.5.3	Remark Codes.....	20
6.0	Data Tracking and Storage.....	21
6.1	Paper Records	21
6.2	Electronic Records	22
7.0	Data Quality Control: Definitions and Procedures	23
7.1	Field Quality Control	23
7.2	Blind Samples	23
7.3	Laboratory Quality Control.....	23
7.3.1	Negative Control (Blanks)	23
7.3.2	Laboratory Control Samples (LCS)	24
7.3.3	Low-level Laboratory Control Samples (LCS Low, LCSL).....	24

VAEL Quality Systems Manual			Page 4 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

7.3.4	Quality Control Sample (QCS)	24
7.3.5	Analytical Duplicate (DUPE).....	24
7.3.6	Instrument Duplicates	24
7.3.7	Matrix Spikes (MSPK).....	25
7.3.8	Matrix Spike Duplicate (MSDP).....	25
7.3.9	Primary Calibration Standards	25
7.3.10	Initial/Independent Calibration Verification Standard (ICV).....	25
7.3.11	Continuing Calibration Verification Standard (CCV).....	25
7.3.12	Surrogates (SS).....	25
7.3.13	Internal Standards (IS).....	25
7.3.14	Tuning Solutions.....	26
7.3.15	Interference Check Solutions (ICS).....	26
7.4	Method Detection Limits (MDL).....	26
7.5	Limit of Quantitation (LOQ)	26
7.6	Reporting Limit (RL).....	26
7.7	Preparation Batch.....	26
7.8	Analytical Batch.....	26
7.9	Precision.....	26
7.10	Accuracy.....	27
7.11	Quality Control Acceptance Criteria	28
7.12	Reporting of Quality Control Data	28
8.0	Proficiency Testing	28
8.1	Water Pollution Study (WP Series for Non-Potable Waters)	28
8.2	MIC series for Potable and Non-Potable Waters (E. coli and Total Coliform).....	29
8.3	U.S. Geological Survey Analytical Evaluation Program for Non-Potable waters	29
8.4	National Air Toxics Trends Stations (NATTS) Air PT	29
8.5	Association of American Pesticide Control Officials (AAPCO) Check sample	29
8.6	Wisconsin Pesticide Residue (WPR) Sample	29
8.7	FDA- Center for Food Safety and Applied Nutrition Lab Proficiency Evaluation Test (CFSAN-LPET).....	30
8.8	USDA-APHIS-NVSL	30
8.9	Meat Inspection Program/Pet Foods- Food Safety Inspection Service (FSIS) Accredited Laboratory Program (ALP).....	30
8.10	Fertilizer-Magruder Check Sample Program	30

VAEL Quality Systems Manual			Page 5 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

8.11	Feeds and Commercial Pet Foods- AAFCO Program.....	31
9.0	System Audits	31
9.1	External Audits	31
9.2	Internal Audits	31
10.0	Demonstration of Capability.....	32
10.1	Method Validation.....	32
10.2	Initial Demonstration of Capability (IDOC)	32
10.3	Continuing Demonstration of Capability (CDOC).....	33
10.4	Analyst Files Containing Training Documentation.....	33
11.0	Maintenance.....	33
11.1	Instrument Logbooks.....	33
12.0	Preventative Actions	33
13.0	Non-conforming Work.....	34
14.0	Interruption of Service	34
15.0	Corrective Actions	34
16.0	Customer Feedback.....	35
17.0	Quality System Review.....	35
17.1	Quality Assurance Reports to Management.....	35
17.2	Annual Review of Quality System.....	36
17.3	Management Review	36
Appendix A: Laboratory Positions and Personnel.....		37
A.1	Summary Table.....	37
A.2	Vermont Agriculture and Environmental Laboratory Organizational Chart.....	38
Appendix B: Standard Operating Procedures.....		39
Appendix C: Sample Submission Forms.....		45
C.1	Sample Submission Plan	45
C.2	Client Registration Form:.....	46
C.3	Pet Food Sample Submission Form	47
Appendix D: Calibration Procedures.....		48
D.1	Support Equipment	48
D.2	Thermometers	48
D.3	Refrigeration / Freezer Units.....	48
D.4	Incubators/Water Baths/Ovens/Dry Incubator Blocks.....	48
D.5	Balances	48
D.6	Automated Pipettes and Dispensing Devices.....	49

VAEL Quality Systems Manual			Page 6 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

D.7 Computer Software 49

Appendix E: Internal Audit Template: 50

Appendix F: Corrective Action Investigation Report 51

Appendix G: Preventative Action Plan..... 52

Appendix H: SOP Annual Review Form..... 53

UNCONTROLLED COPY

VAEL Quality Systems Manual			Page 7 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

1.0 Introduction

This Quality System Manual documents or references documents that describe the Vermont Agriculture and Environmental Laboratory (VAEL) policies and procedures required by The NELAC Institute – TNI and the U.S. E.P.A. Region I Quality Assurance Office. The manual is reviewed by our TNI accrediting authority; the New Hampshire Environmental Laboratory Accreditation Program (NH ELAP) and US EPA Region 1.

The VAEL Biology Section performs dairy, animal health and microbiological testing. This section operates under a quality management system that meets specific US Food and Drug Administration (FDA) requirements. E. coli testing is performed in the Biology Section; its quality management system is described in this manual.

1.1 Objectives and Commitments of Management

The Vermont Agency of Agriculture, Food and Markets (VAAFMM) and the Vermont Agency of Natural Resources (ANR) rely on VAEL to provide high quality, scientific data, which is the basis for many program decisions. VAEL’s Governance Board consisting of VAAFMM and ANR representatives provide strategic guidance to VAEL.

1.2 Management’s Quality System Policy Statement

VAEL is committed to providing consistently high-quality data in a timely manner through the following objectives:

1. A qualified staff and fully equipped laboratory facility.
2. Successful participation in proficiency testing programs, including TNI, AOAC, USGS, NWRI, AAFCO, MAGRUDER, FDA, USDA-FSIS, USDA-APHIS-VS, AAPCO, WPR and NATTS.
3. A TNI-compliant quality management system
4. Management review and internal audits
5. Reporting results to clients within a 30 day or shorter timeframe.
6. Use of approved and documented test methods.
7. Informing clients when analytical data does not meet quality control requirements.
8. Use of a document control system to track version changes.

VAEL’s quality assurance policy is maintained by employees at all levels. Adherence to this policy is documented through employee evaluations, QSM reviews, training sessions, and internal audits.

1.3 Employee Code of Ethics, Training, and Reporting of Unethical Behavior

1.3.1 Employee Code of Ethics and Laboratory Fraud

Laboratory fraud is the deliberate falsification of analytical or quality control data. Employee ethics have a profound effect on the integrity and quality of the work performed at the Laboratory. Policies regarding the handling, reporting and review of data are outlined below and are reflected in VAEL’s Standard Operating Procedures (SOPs). Improperly performed procedures are not tolerated. Unacceptable behavior includes falsifying data, improper data manipulations, inappropriate changes in concentrations of standards, misrepresenting quality control data, computer software or instrument clock manipulation, data file substitution, or concealment of known problems.

Laboratory employees are expected to conduct themselves in an honest and ethical manner while remaining free of commercial or financial pressure which could influence technical judgment.

VAEL Quality Systems Manual			Page 8 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

1.3.2 Ethics Training

The VT Agency of Administrations Human Resources Department provides all new full-time employees with State of Vermont Policies and Procedures. Each new employee must complete the HR New Employee Orientation (NEO) Program that includes policy on conflicts of interest. Records are maintained with Human Resources.

New Laboratory personnel complete a VAEL orientation program, which includes ethics and lab safety training, a tour of the VAEL facility, and review of the QSM, Chemical Hygiene Plan, Waste Management Plan, and relevant SOPs. Documentation is maintained in analyst training files.

Annual ethics refresher training is required for each employee. Training materials and an employee attendance sheet are retained by Management. Refresher training focuses on issues arising from activities such as hiring, training and supervising staff; handling, analysis and reporting of quality assurance data; legal responsibilities, potential punishments and penalties for improper, unethical and illegal actions. Annual training reinforces the Laboratory's QSM and SOP policies and procedures. Training may be conducted internally or by an outside source.

1.3.3 Reporting of Unethical Behavior

Employees are required to report any suspected unethical activities to the QA Officer and/or their Supervisor. Reporting can be either written or verbal. It then becomes management's responsibility to initiate an incident investigation, which may include reporting the incident to Agency Leadership or HR. Each person involved in the investigation must document the incident, reported information and actions taken.

All data integrity investigations are conducted in a confidential manner and documented. Clients are notified when the integrity of their data is compromised.

1.3.4 Management Review of Data Integrity Procedures

The QA Officer is responsible for annual QSM revisions. Technical Directors are responsible for ensuring the review and revision of SOPs. When a new revision of an SOP is issued, the SOP Revised By is updated to the person who revised the document. Revisions are reviewed and signed by SOP Revised By and the QA Officer.

2.0 Laboratory Organization and Responsibility

VAEL is an internal service organization charged with providing analytical support and services to ANR and VAAFM programs and non-Agency programs when capacity allows. VAEL is located within VAAFM and is administratively attached to the Secretary's Office. Frequently, VAEL's services are custom-tailored to meet user's individual needs and changing programmatic demands. Organizationally, the Laboratory is separated into an administrative center and three departments (biology, inorganic chemistry, and organic chemistry), with departments divided into the following specialty analytical sections or centers (also outlined in Figure 1):

2.1 The Inorganic Chemistry Center

This department has VAEL's highest sample throughput.

VAEL Quality Systems Manual		Page 9 of 53	
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

2.1.1 Metals

Analyzes for metals in a variety of matrices; supporting a number of programs and projects, including air quality, acid rain, landfill assessment, hazardous waste investigations, feed/fertilizer guarantees and lake sediment/fish studies. The center employs ICP/MS, ICP-OES, AA spectroscopy and a mercury cold vapor system as the methods of analysis.

2.1.2 Nutrients

Supports the efforts of field programs monitoring water quality impacts of urban, road and agricultural run-off and atmospheric deposition. Work may also include analysis of other non-water matrices. Analyses are performed by auto analyzers and ion chromatography.

2.1.3 Wet Lab

Conducts analyses for measuring physical properties of water quality samples including alkalinity, turbidity, chlorophyll content, COD, TSS, TDS, Conductivity, Total Organic Carbon, DO. This section also analyzes for protein, moisture, fat, fiber, salt, metals, micro-nutrients, macro-nutrients, nitrogen (fertilizer) and ash in feed, fertilizer, and meat samples.

2.2 The Organic Chemistry Department

Provides volatile and semi-volatile organic compound identification in water, solids, and air. Analyses are performed using gas chromatography, gas chromatography-mass spectroscopy, high performance liquid chromatography; liquid chromatography-mass spectroscopy, and liquid chromatography-quantitative time of flight mass spectroscopy (QTOF).

2.2.1 Semi-Volatile Analyses

Supports the VAAFPM Pesticide Monitoring, Pesticide Enforcement and Hemp programs. Analyses are performed using GCMS, HPLC, HPLCMSMS and QTOF.

2.2.2 Volatile Analyses

Supports the DEC Air Quality and Climate Division with air toxics testing on samples regularly collected at several Vermont sites. Analyses are performed using gas-chromatography-mass spectrometry and liquid chromatography.

2.3 The Biology Department

Is responsible for a range of testing procedures in support of the dairy industry and animal husbandry activities in the state. This department also has Molecular Biology and water microbiology testing laboratories.

2.3.1 Central Dairy Laboratory

Is responsible for analyzing raw and finished dairy products, in support of the VAAFPM's Food Safety program's oversight of Vermont's dairy industry to minimize the risk of unsafe products reaching consumers. The lab data is used to assess compliance with the FDA Grade A Pasteurized Milk Ordinance, which governs all aspects of the dairy industry through collaboration between Federal/State agencies and industry.

2.3.2 Animal Health Section

Provides analyses for the interstate, intrastate or international movement of animals. This section also

VAEL Quality Systems Manual		Page 10 of 53	
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

provides mastitis analysis, which helps to inform farmers and veterinarians of herd management issues.

2.3.3 Micro and Molecular Biology Section

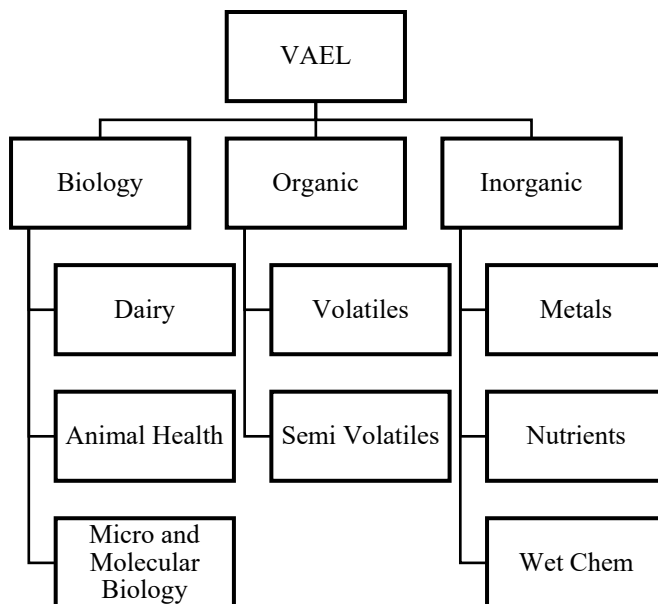
Provides for the analyses and detection of microbes and viruses. This section includes E. coli testing of non-drinking waters; DNA testing of ticks and mosquitos for the presence of insect borne diseases monitored by the VAAFMs Plant Industry and the VT Department of Health.

2.4 Laboratory Positions and Job Duties

The VAEL Management Team consists of a Laboratory Director, Assistant Director and Supervisors. The Director reports directly to the Vermont Agency of Agriculture, Food and Markets (VAAFMs) Secretary, who is appointed by the Governor.

VAEL scientists are assigned to a Department (Biology, Organics, or Inorganics) but are cross trained to assist in other sections when needed. Section Supervisors and Technical Directors are responsible for all aspects of analysis within their section: method development, quality control, training, technician supervision, equipment purchase recommendations, and workflow management. Seasonal Analysts assist in laboratory sections as workloads require. Laboratory personnel are listed in Appendix A.

Figure 1: VAEL Analytical Centers



2.4.1 Director

- Assures the Laboratory has personnel with the necessary education, training, technical knowledge, and experience for their assigned duties.
- Assures the Laboratory has appropriate equipment and supplies.

VAEL Quality Systems Manual			Page 11 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

- Assures the Laboratory has the capacity, facilities and resources to perform work.
- Acts as the liaison between the Laboratory and Laboratory users.
- Provides technical assistance to Laboratory users regarding the selection of appropriate analytical and/or sampling methods. May review Client QA Project Plans.
- Oversees the transformation of analytical data which may be necessary to meet program needs.
- Evaluates quality assurance data summaries provided by the QA Officer and determines when data quality is unacceptable.
- Manages all personnel employed by the Laboratory.
- Performs annual Management Review.
- Reviews and follows QSM protocols and procedures.
- May authorize data in absence of the QA Officer.

2.4.2 Assistant Director

- Assists in the organization and administration of VAEL programs and functions.
- Serves as point person in the absence of the Director.
- Reviews and tracks lab budget
- Assists in the development and implementation of appropriate measures to minimize occupational hazards and ensure workplace safety.
- Coordinates the purchasing of instruments and supplies for the laboratory.
- Reviews and follows QSM protocols and procedures.
- May authorize data in absence of the QA Officer.

2.4.3 Quality Assurance (QA) Officer

- Oversees the Lab quality control activities. Advises and trains staff in QA/QC, including QA/QC orientation for new and seasonal employees, QC data tracking.
- Reviews and approves client Sample Plans and relevant QAPPs.
- Issues and tracks Corrective Action Investigations. Identifies and advises actions to be taken when nonconforming work is identified.
- Reviews relevant standards (i.e., TNI, AAFCO, NATTS). Reviews/revises QSM to ensure compliance, annually.
- Coordinates and participates in external audits and assessments.
- Organizes, oversees, and may conduct annual bench audits for each analytical center. Initiates corrective action when necessary.
- Coordinates the scheduling, ordering, reporting, and tracking of proficiency test samples. Initiates corrective action when necessary.
- Reviews and approves all laboratory SOPs annually.
- Oversees the distribution, documentation, and archiving of Laboratory SOPs.
- Ensures that staff have demonstrated initial and ongoing proficiency in the activities they are performing. Maintains training, Initial Demonstration of Capability (IDOC) and Continuing Demonstration of Capability (CDOC) files.
- Verifies and maintains records on the accuracy and precision of laboratory equipment (automatic pipets, scales, thermometers)
- Oversees the Chain of Custody (COC) sample transfer into the Laboratory. Assures data handling and COC records are organized and accessible.
- Reviews and follows QSM protocols and procedures.

VAEL Quality Systems Manual			Page 12 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

2.4.4 Supervisor

- Responsible for the overall technical quality of the work performed in their section. Assuring the use of standard methods.
- Manages workflow in analytical section.
- Responsible for ensuring Laboratory employees are compliant with VAEL standards.
- Provides technical assistance to Laboratory staff regarding QA issues, method, and instrument selection.
- Reviews Laboratory SOPs. Ensures staff revise and update the documents as required.
- Oversees management of Laboratory contracts.
- Assures data quality reported by the Laboratory is documented.
- May participate in internal bench audits initiated by the QA Officer.
- Reviews and follows QSM protocols and procedures.

2.4.5 Sample Receiving

- Receives samples into LIMS per SOP 8.11
- Assists clients with Sample log-in questions. Identifies and corrects sample log-in errors, trains lab users on LIMS use.
- Confirms proper thermal and chemical sample preservation upon receipt.
- Monitors refrigerator temperatures in B11 and Sample Receiving
- Maintains supply of sample bottles.
- Manages sample pre-logs, distribution of bottles, labels, and field sheets for volunteer monitoring projects.
- Coordinates and communicates with the clients and responds to questions regarding log-in procedures.
- Organizes samples by test upon receipt.
- Reviews and follows QSM protocols and procedures.

2.4.6 Chemist/Microbiologist I, II

- Responsible for the technical quality of work performed.
- Complete Demonstration of Capability protocols for all procedures/methods prior to undertaking independent analysis.
- Works independently to analyze samples within hold and turn-around time.
- Responsible for generating data packages containing all information needed to reproduce a result. Maintenance of both paper and electronic copies (when applicable) of data for methods performed. Performs self-review of data packages to ensure it meets quality objectives.
- Communicates any technical or quality issues to the QA Officer and Technical Director
- Remains current on equipment and methods used in sample analysis within their analytical center.
- May participate in interlaboratory performance evaluation studies.
- Reviews and follows QSM protocols and procedures.

2.4.7 VAEL Chemist/Microbiologist III, IV, V

- All Chemist/Microbiologist II duties and responsibilities
- Reviews (validates) data packages generated by other analysts for completeness. Verifies

VAEL Quality Systems Manual			Page 13 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

- required quality control samples were analyzed at correct frequency and meet acceptance criteria.
- Provides equipment and technology recommendations needed to efficiently operate and maintain uninterrupted operation of his/her analytical duties.
 - Capable of resolving technical problems encountered in sample analysis.
 - Responsible for ordering needed consumables supplies.
 - Responsible for equipment maintenance and maintenance contract oversight and acts as a liaison with service engineers to troubleshoot equipment problems.
 - Generates and maintains current, easy-to-use SOPs which include referenced method requirements.
 - Maintains quality assurance documentation on procedures, equipment, reagents, and standards.
 - Initiates corrective action when appropriate.
 - Participates in Interlaboratory Performance Evaluation studies.
 - Assures all data generated are properly reviewed and meet internal acceptance criteria or are properly flagged.
 - May perform special duties to serve entire lab, see section 2.4.9 Special Duties.
 - Reviews and follows QSM protocols and procedures.

2.4.8 Environmental Analyst (Seasonal Temporary)

- Works under the direction of a staff chemist/microbiologist.
- Follow method SOPs and QA/QC requirements.
- Informs their immediate supervisor when precision and accuracy values are beyond established warning and control limits or other issues are encountered.
- Maintains records for tests performed.
- Is responsible for providing clean glassware and sample containers.
- Other duties as required
- Reviews and follows QSM protocols and procedures.

2.4.9 Special Duties

In addition to fulfilling the job duties, staff may be given additional special duties. These roles may include:

2.4.9.1 Lab Evaluation Officer (LEO)

- As part of FDA's Laboratory Evaluation Program, conduct on-site surveys at independent milk laboratories.
- Surveys include Laboratory records review, facilities and equipment inspection and analyst demonstration of approved procedures in order to determine compliance with the FDA 2400 forms for approval or accreditation under NCIMS Laboratory Approval Program.
- Administer Appendix N Proficiency Sample Program
- Maintain FDA LEO Certification

VAEL Quality Systems Manual			Page 14 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

2.4.9.2 Safety Officer

- Maintains and implements a Laboratory Chemical Hygiene/Safety Plan and Safety Data Sheets.
- Responsible for hosting annual safety training and ensuring all staff participate.
- Orients all new Laboratory employees and users to Laboratory Safety Plan.
- Oversees the maintenance of safety systems within the building.
- Responsible for hazardous waste management; storage and disposal.
- Conducts Safety Audits to ensure OSHA compliance

2.4.9.3 LIMS Administrator

- Maintains the daily operation of the Laboratory Information Management System (LIMS), which may include training of users / staff, updating database with client information, programs, assist lab users / staff with any LIMS issues and work to get them corrected.
- Coordinates with ADS and LIMS vendor to troubleshoot issues.
- Applies vendor-supplied revisions and validates system after patches are applied.
- Develops and maintains parsers to allow electronic instrument data transfer.
- Creates reports and forms.
- Modifies LIMS to meet TNI requirements and staff and client needs.
- Maintains electronic standard/reagent inventory program.

2.4.9.4 Technical Director

- Any Scientist III or higher
- Remains current on methods and equipment in their analytical center.
- Provides technical guidance to personnel performing analyses.
- Oversees instrument preventative maintenance service.
- Communicates equipment and technical support needs to the Laboratory Supervisor.
- Assists in the hiring and supervision of seasonal help
- Responsible for the work quality performed in assigned analytical center
- Works with supervisor and other Technical Directors to cross-train lab staff from other laboratory sections.
- Works to resolve technical problems encountered in sample analysis.
- Generates and maintains current SOPs within their work area.
- Works with staff in their analytical centers to complete and document demonstration of capability protocols.
- Maintains quality assurance documents and maintenance logs for equipment, reagents, and standards.
- Initiates corrective action when appropriate.
- Participates in proficiency tests.
- Assures data are properly reviewed and validated.
- Reviews and follows QSM procedures and protocols.
- Assures all electronic files are backed-up on a scheduled basis and back-ups are properly documented and stored. Assures that instrument hard drives are adequate for instrument

VAEL Quality Systems Manual			Page 15 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

needs. All data is removed according to the lab's records retention policy.

- Approve results in the absence of the QA Officer-

2.4.9.5 Web Master

- Maintains web page content.

3.0 Sample Handling

3.1 Laboratory Contracting Policy

Clients must provide a Sample Submission Plan (SSP, Appendix C) to the Laboratory on an annual basis. SSPs are reviewed by the Lab Management (QA Officer, Supervisor and/or Director) who confirms; the lab can meet the client's needs and has the capacity to accept the samples. Sample Submission Plan information includes:

1. Program personnel and contact information.
2. Tests requested.
3. Sampling schedule and project duration
4. Required turn-around times, if different than standard 30 days
5. Sample delivery method (in-person, courier, other)
6. Any additional data quality requirements

All sample submission plan revisions (request for new, additional, or different tests) must be approved by VAEL management.

The Laboratory's TNI accreditation status is posted on VAEL's web site and on the wall in Sample Receiving (Room 142). VAEL notifies clients in writing if its TNI status changes during the life of the contract or if the contract needs to be amended after work has commenced.

3.2 Sample Collection

Samples are collected by AAFM or ANR field personnel, contracted site investigators, and community volunteers. The required containers, preservation and holding times for the parameters analyzed at the Laboratory are found in WinLIMS and on the VAEL website.

3.3 Sample Receiving/Rejection

VAEL Sample Receiving staff accept/reject samples, according to the Sample Receiving SOP 8.11. In brief, sample receiving staff check all samples for proper labeling, volume, container, and preservation. All samples are logged into the Laboratory's Information Management System (LIMS). VAEL has the right to reject samples when they fail to meet the Sample Receiving SOP requirements.

3.4 Laboratory Information Management System (LIMS)

The LIMS performs the following functions:

- Sample management and tracking
- Chemical Inventory and tracking
- Sample/Reagent label generation, including bar coding.
- Data management tracking (data entry, comments/remark codes, validation, approval)
- Quality control data tracking
- Electronic data transfer/acceptance
- Billing and customer information

VAEL Quality Systems Manual			Page 16 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

- Data reporting (electronic and paper)

The LIMS application and database are hosted on a cloud server and backed up via an automatic schedule daily through SherWeb, located in Virginia, USA. Backups are monitored and checked for errors, and restoration procedures tests are scheduled and performed regularly. LIMS data are stored indefinitely, while backup copy retention time is seven (7) days. Server Maintenance is scheduled monthly; security patches on servers are kept current. The LIMS security roles are defined and managed by the LIMS administrator(s) and protected by username and password. The server is protected by standard firewall and encryption, accessible by the WinLIMS vendor (QSI) only.

3.5 Sub-Contracting

VAEL does not sub-contract client samples to third-party laboratories. When clients have submitted samples and VAEL is unable to perform the test(s) due to instrument or staffing issues, clients will be notified immediately and be given the option of removing their samples from the laboratory at their own expense.

3.6 Legal Chain of Custody Procedures

Legal chain of custody (COC) procedures ensure the necessary documentation for litigation and enforcement. Details of date/time of pick-up and delivery and by whom samples are handled during the collection and analysis of samples must be included. Communication with the laboratory must take place prior to COC samples being received by the laboratory.

4.0 Standard Operational/Administrative Procedures

Methods used at VAEL have been published in international, regional, or national standards, or by reputable technical organizations, relevant scientific texts or journals, or as specified by the equipment manufacturer. Laboratory-developed methods or methods adopted and validated by the laboratory may also be used, when appropriate.

VAEL maintains standard operating procedures (SOPs) that accurately reflect all phases of analytical methods with reference to the source method. Information in SOPs includes:

- 1 Identification of test method
- 2 Applicable matrix or matrices
- 3 Method detection limit (MDL) / Limit of quantitation (LOQ)
- 4 Scope and application, including components to be analyzed
- 5 Summary of the test method
- 6 Definitions
- 7 Interferences
- 8 Safety
- 9 Equipment and supplies
- 10 Reagents and standards
- 11 Sample collection, preservation, shipment, and storage
- 12 Quality control
- 13 Calibration and standardization
- 14 Procedure
- 15 Calculations
- 16 Method performance
- 17 Pollution prevention

VAEL Quality Systems Manual			Page 17 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

18	Data assessment and acceptance criteria for quality control measures
19	Corrective actions for out of control data
20	Contingencies for handling out of control or unacceptable data.
21	Waste management
22	References
23	Any tables, diagrams, flowcharts, and validation data
24	Additional notes
25	SOP revision summary table
26	Staff sign off page.

SOP Master Copies are maintained in Room 138, where all staff can view them. A controlled copy of each SOP is maintained in the laboratory where the method is performed for easy reference.

4.1 Review/Revision

Review: Each SOP has a cover page listing the title, author/revised by, reviewer/approver and effective date of the revision. SOPs for current methods are reviewed annually. Method review may take many forms:

Ongoing Changes: During the year, analysts may need to make changes to an SOP. Proposed changes are reviewed with the QA Officer and may result in hand-written changes to the Master Copy of the SOP or a revisioning of the method. Hand-written changes are made in ink, including the analyst's initials and the date of change on the "master copy" of the SOP. These changes are approved by the QA Officer and Technical Director. All analysts performing the analysis or validating data produced by that method also initial and date these changes. Controlled copies are re-issued once the approved change(s) has been made in the Master Copy.

A draft copy of each SOP is available for comment on the Vael SharePoint (Quality Assurance → SOPs → Draft SOPs). This draft is used to document questions, comments, or suggestions for improvement, but do not take immediate effect. The draft copy is locked for editing, use the comments feature to suggest changes, so the analyst suggesting changes is documented, if there is need for further follow-up.

Annual Review/Updates: SOPs are reviewed annually using the SOP Review Worksheet (Appendix H). Technical Director's assign SOPs to specific analysts for review, rotating through analysts each year. Once updates are approved, signed, and dated by the QA Officer, then the SOP Review Log is updated.

The SOP document is locked and saved:

- In the "[https://vermontgov.SharePoint.com/teams/AGR-VAEL/QA/SOPs/Current SOP Uncontrolled/](https://vermontgov.SharePoint.com/teams/AGR-VAEL/QA/SOPs/Current%20SOP%20Uncontrolled/)" directory with the watermark "uncontrolled". This version may be accessed and printed freely for analyst review. Uncontrolled copies may not be present at the bench.
- in the "[https://vermontgov.SharePoint.com/teams/AGR-VAEL/QA/SOPs/SOP Manual/](https://vermontgov.SharePoint.com/teams/AGR-VAEL/QA/SOPs/SOP%20Manual/)" folder, with access restricted to Vael management.

Revision: An SOP is revised when there is a change in the method used to generate data.

4.2 SOP Requests

When an SOP is requested, an uncontrolled copy is distributed.

VAEL Quality Systems Manual			Page 18 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

4.3 Monitoring Procedures

Several activities are monitored at VAEL. Documentation of these monitoring activities are found in:

- Reagent and standard preparation notebooks
- Instrument maintenance and service records
- Refrigeration/incubator monitoring records
- Pipette calibration records
- Analytical balance records

4.4 Administrative SOPs

VAEL has Administrative SOPs to describe lab-wide policies and procedures, including Sample Receiving Procedures, Manual Peak Integration, etc. Administrative SOPs are listed in Appendix B.

4.5 Purchasing of Services and Supplies

VAEL uses state-approved vendor contracts for laboratory supplies and services. A list of vendors is maintained by VAEL management. Careful consideration of lab and quality requirements is made for all purchases. Instrument/ equipment maintenance and service that cannot be performed by the staff will be completed by an instrument service engineer.

5.0 Data Production and Reporting

All VAEL-generated analytical data are recorded, reviewed, reported, and archived per Laboratory protocols described in this section and in Laboratory SOPs. Analytical centers have slightly different data reduction, validation and reporting protocols which depends on how data is generated and transferred into the LIMS and specific method requirements.

5.1 Data Recording and Editing

Traceability requires lab employees document and retain all pertinent information related to a measurement. Calibration, calibration verification, and analysis records must be detailed and traceable to the standards used. All results, information and calculations used to generate a result must be documented.

All written records in notebooks and on bench sheets need to be legible and recorded in permanent ink. Sharpies or other markers are not used. Corrections are made by drawing a single line through the incorrect entry, initialed and dated with the date the correction was made (best practice is to use year-month-day). Writing over an incorrect entry or the use of white-out, correction tape or erasers is not acceptable. Provide a reason for the correction, if not obvious. Forms must provide enough space to allow for legible corrections to be made, initialed, dated and a reason for the correction documented. Do not remove pages from notebooks. All records must be signed or initialed and the reason clearly indicated such as “prepared by”, “reviewed by” or “validated by”.

When an analyst prefers to type entries and add them to a lab notebook or log, the entry must be entered in sequence with the latest entry, not taped in the middle of prior entries. The typed entry should be trimmed to fit within the page so that it can be taped onto the page on all sides. The author must initial and date the entry with permanent ink, avoid writing on the tape itself, since ink will quickly wear off the tape.

VAEL Quality Systems Manual			Page 19 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

5.2 Data Reduction

Data reduction is the process of transforming raw data into reportable results. The Laboratory's goal is to minimize the number of transformation steps needed. Fewer transcription and calculation errors occur when parsers, spreadsheets and bench sheets are used in automated data processing and importation into LIMS. All parsers, spreadsheets and bench sheets are validated for correctness and accuracy prior to approval and implementation.

Laboratory SOPs include equations, or equation references, used to calculate results. Manually calculated data is verified by a second analyst. All calculations and information used to recalculate results are documented.

5.3 Parser/Bench Sheet Review

For many tests, raw data undergoes further calculations to generate reportable results. Parsers are validated each time of use, during the primary data review. Prior to any calculation format being approved for use, it is validated for accuracy and correctness. Revisions and subsequent validations of parsers, bench sheets and validation sheets are tracked electronically by revision # and date (year-month-day). Bench sheets and validation sheets contain revision # and date for easy identification. Only the latest version is used within the laboratory.

5.4 Data Review, Validation and Approval

5.4.1 Primary Review

The analyst generating data is responsible for its correctness and completeness. It is the analyst's responsibility to perform a primary review on their own work verifying:

- The instrument was calibrated and performing within method specifications.
- The appropriate type and quantity of method-specified quality control samples was analyzed.
- The QC results met pre-established control limits.
- Each type of calculation is correct.
- Data were remark coded appropriately, when applicable
- A Data Package was assembled containing a validation cover sheet and all relevant raw data.
- Data uploaded into WinLIMS matches results reported in the data package.

Data packages are then available for secondary review by a different analyst.

5.4.2 Secondary Data Review and Validation

The validator (different analyst, Scientist III or higher) performs a secondary review of the data package. Validation is performed by qualified staff. A data package undergoes the same data review as the primary review (See 5.4.1). When the validator identifies errors in the data package, it is the validator's responsibility to provide written comments (including validator's initials and date) on the validation cover sheet. The data package is then returned to the analyst generating the results for correction. After the necessary changes, the analyst returns the package back to the validator for another review to assure all resulting corrections have been properly documented. When a validator feels data should not be reported due to quality issues, it is their responsibility to notify the analytical center technical director.

VAEL Quality Systems Manual			Page 20 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

Once raw data has passed the secondary review and the validator is satisfied the WinLIMS results accurately reflect the information in the data package, the validator performs the WinLIMS validation function, validating the reviewed sample results. An analyst cannot validate their own work.

5.4.3 Approval

WinLIMS validated data are available for approval. Approval is performed by either the Laboratory Director, QA Officer, Supervisors, or designees prior to reporting results. Data are reviewed verifying:

- Data Completeness: Dates & Times of sample collection, receipt, analysis, validation and the names of individual responsible for each step in the process.
- Chemical relationships within the sample (TP>DP, TN>NOX)
- Results are properly remark coded, when applicable

Once these criteria are met, the approver approves the WinLIMS worklist, which is test specific. At this point, the client may download these approved results as an Excel/.csv file. When all worklists associated with an order are approved, the order itself is reviewed, approved and an official PDF report of the results is automatically emailed to the client by WinLIMS.

5.5 Data Reporting

Results are only released to those who have WinLIMS access (those named in the client registration form for that project). All data inquiries outside of the Client Registration form requires written permission (e-mail is acceptable) from the Program Manager. All records are held secure and confidential.

5.5.1 Results Report Format

Approved data are available to laboratory users as a PDF report and as a spreadsheet from WinLIMS. Final reports are only issued after order approval.

5.5.2 Revised Reports

When an error is found on an approved report, the Laboratory QA Officer un-approves and invalidates the erroneous data. Once changes are made by the original analyst, the data goes through the validation and approval process again. After the data is approved, a revised report is issued. The client is then notified and sent a revised report by email. A Corrective Action Investigation is initiated to identify the cause of the error, and to implement procedures to prevent future occurrences.

5.5.3 Remark Codes

Remark codes are used to describe conditions that may have influenced test results, including observations at sample submission (received codes), during analysis, data validation and approval. Codes are also used to qualify quality control data (QC Codes). All report formats used to report results include a column with remark codes. VAEL Remark codes are listed and described below. In some cases, a sample or order comment may be used to further explain irregularity. Multiple codes may be used on one result.

Remark Code	Description: Codes applied to Sample Results
A	Laboratory accident, sample not processed

VAEL Quality Systems Manual			Page 21 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

B	Blank corrected result
E	Estimated value
H	Hold time exceeded
I	Matrix interference
J	Result is greater than the method detection limit, less than the limit of quantitation
N	Sample not processed
R	Filter residue < 2.5 mg
Z	Result less than the method detection limit
U	Not Detected
Received Code	Description: Codes applied at time of Sample Receipt
C	No collection time given
P	Sample preservation inappropriate
S	Samples submerged
W	Outside temperature range
G	Sample submission inappropriate
QC Codes	Description: Codes applied to QC Results
K	Sample concentration greater than 4 times the matrix spike
M	Parent/duplicate less than the limit of quantitation
F	Fails Criteria

6.0 Data Tracking and Storage

The VAEL data tracking and record keeping system allows for the reconstruction of all activities required to produce an analytical result. All records are stored under appropriate conditions and are readily retrievable. Backup and access policies for electronic files are in place. Records are legible, held secure and in confidence for a minimum of 5 years, after which records are destroyed in accordance with the State of Vermont's record retention policies and procedures.

6.1 Paper Records

Raw data for calibrations, quality control measures, worksheets, instrument response records and vendor-supplied standard certification paperwork are archived at the Laboratory for 5 years after data is reported to clients. Once the minimum retention period is met, original paper and electronic records may be destroyed.

Laboratory notebooks and instrument maintenance logs are retained for five years after last entry. Destruction requires the Laboratory Supervisor's approval. Information contained in notebooks includes sample processing steps, extraction and digestion records, instrument maintenance and routine checks, data reduction and transformation steps, standard and reagent receipt, and preparations (if bench logs are not used).

Inactive SOPs revisions and QSMs are archived. These documents may be destroyed 5 years after the archival date.

VAEL Quality Systems Manual			Page 22 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

Records for all procedures and policies pertaining to sample handling and receiving are retained for a minimum of 5 years. Records of any deviations from policies are also retained either on bench sheets, in the LIMS or in both locations. Paper copies of Legal Chain of Custody logs are permanently retained.

6.2 Electronic Records

Electronic logs and bench sheets are stored as paper and/or electronic copies. Raw electronic instrument/data files are stored on the State of Vermont S-drive. S-drive files are automatically backed up by ADS at 12-hour intervals. Each backup is retained for 14 days, with the oldest back-up being removed. S-drive accesses requires SOV employee credentials approved by the VAEL Director and the Vermont Agency of Digital Services (ADS).

Other electronic files and records (SOPs, QSMs, CAIs etc.) are stored on the State of Vermont, VAEL SharePoint site, stored in a Microsoft Cloud. SharePoint files are automatically backed up by ADS at 12-hour intervals. Each back-up is retained for 14 days with the oldest back-up being removed. SharePoint has file recovery features if files are inadvertently deleted or over-written. Access to the SharePoint requires SOV employee credentials approved by the VAEL Director.

The LIMS data resides on a remote server hosted by the LIMS vendor. Data in the LIMS are maintained until the LIMS is superseded or until the software is obsolete.

Records Storage Locations and Retention Times

Record Type	Media Type	Storage Location	Retention Time
Archived SOPs	Electronic Paper	SharePoint, B11	5 years after archive
Vendor-supplied Certificate of Analysis	Electronic Paper	SharePoint, WinLIMS, Laboratory of use	5 years after expired
Notebooks	Electronic Paper	SharePoint Laboratory of use	5 years after replaced
Instrument Raw Data	Electronic Paper, current year Paper, archived	S-drive Laboratory of use B11	5 years after data are reported, or until software is obsolete or information is no longer readable
Result Data Packages	Paper, current year Paper, archived	Laboratory of use B11	5 years after data are reported
LIMS Data	Electronic	Cloud	until superseded or obsolete
Sample Collection/Field Forms	Electronic Paper, current year	WinLIMS Sample Receiving	5 years after data are reported
Standard/Reagent Logs	Electronic	WinLIMS	5 years after data are reported
PT Performance	Electronic Paper	SharePoint QA Officer Files	5 years after results are reported
Chain of Custody Forms and Data packages	Electronic Paper Paper	SharePoint Lab of Use (up to year 5) Vermont State Archives	Permanently retained. 5 years after results are reported. Permanently retained

VAEL Quality Systems Manual			Page 23 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

7.0 Data Quality Control: Definitions and Procedures

Quality control procedures are necessary to develop information to evaluate the quality of VAEL's analytical data. Quality control (QC) terms are defined and explained below. This section is intended to be a guide for laboratory users, and specific projects. Methods may require additional or more frequent analysis of QC samples due to difficult sample matrices, project requirements, critical measurements, or enforcement actions.

Analytical precision and accuracy are measured during analysis by including reference standards and laboratory-generated quality control samples, which include analytical duplicates, matrix and surrogate spikes, and matrix spike duplicate samples. When quality assurance acceptance limits for laboratory data are method- or TNI-specified, the stricter criteria are adopted. When a method does not specify limits, they are established using historical laboratory data.

When possible, measurements are traceable to a national or international standard of measurement. Reference standards and materials used at the lab or by equipment calibration services are traceable to a national or international standard.

7.1 Field Quality Control

The results of quality control samples taken in the field reflect the precision and accuracy of the entire process, from sample collection through analyses. Field quality control samples are logged into the LIMS with a unique sample ID number. Field duplicates are collected for the VAEL TP/DP method to evaluate method precision because Analytical Duplicates (Sec 7.3.5) cannot be analyzed by this method.

7.2 Blind Samples

The composition and/or origin of blind samples is known to the submitter but not to the analyst. Blind samples can be a duplicate sample, blank, proficiency sample, or an inter-lab comparison sample.

7.3 Laboratory Quality Control

Quality control samples are used to verify calibrations, identify reporting limitations, or assist in identifying instrument, method, or sample interferences. Quality Control Sample Tracking is done through the LIMS. Data acceptance criteria are found in each method's SOP and in LIMS.

7.3.1 Negative Control (Blanks)

A sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value and is sometimes used to adjust analytical results. Blanks include:

7.3.1.1 Initial Calibration Blanks (ICB)

Initial Calibration Blanks are aqueous solutions prepared and diluted with the same volume of chemical reagents and solvents used in the preparation of the primary calibration standards. They may be used to give a null instrument response reading when running a calibration curve or to establish instrument background. The ICB does not assess for contamination during the preparation and processing steps.

VAEL Quality Systems Manual			Page 24 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

7.3.1.2 Continuing Calibration Blank (CCB)

Continuing Calibration Blank is the ICB solution reanalyzed at a regular interval throughout an analytical run to assess baseline drift.

7.3.1.3 Method Blank (MBLK)

Method Blank (Laboratory Reagent Blank, Procedural Blank), is a sample of a matrix similar to the batch of associated samples (when available) that is free from the analytes of interest and is processed simultaneously with and under the same conditions as samples through all steps of the analytical procedures, and in which no target analytes or interferences are present at concentrations that impact the analytical results for sample analyses. Analysis of a method blank verifies that interferences from contaminants in solvent, reagents, glassware, and other sample processing devices are quantified.

7.3.1.4 Filter Blank (FBLK)

Filter blanks are filtered laboratory reagent water analyzed as a sample when sample filtration is necessary. Analysis of a filter blank is used to monitor background contamination introduced by filtration.

7.3.2 Laboratory Control Samples (LCS)

Laboratory Control Samples (LCS, Blank Spike, Laboratory Fortified Blanks) are prepared by adding known quantities of method analyte(s) to a volume of reagent water and is carried through entire prep, analysis and reporting of results. The LCS is processed exactly like samples within the analytical batch. The concentration is typically mid-range of the calibration (LCSM). LCS results are used to evaluate the total analytical process.

In multi-parameter methods, the number of components to be spiked and the acceptance criteria is specified by the referenced test method or other regulatory requirement. When acceptance criteria are not specified, the SOPs describe these requirements.

7.3.3 Low-level Laboratory Control Samples (LCS Low, LCSL)

LCSLs are prepared at or below the method LOQ and processed like an LCS. Results are used to evaluate method performance near the reporting limit. For methods requiring a digestion, one LCSL is prepared with each prep batch. For methods that do not require digestion, an LCSL is analyzed and evaluated quarterly to verify the LOQ.

7.3.4 Quality Control Sample (QCS)

Quality Control Sample (Certified Reference Material CRM, Standard Reference Material SRM) can be either an uncontaminated sample matrix, (i.e., fish, soil, ash) spiked with known and certified amounts of analytes or a contaminated sample matrix. The QCS is used to establish intra-laboratory or analyst-specific precision and bias or to assess the performance of the measurement system.

7.3.5 Analytical Duplicate (DUPE)

Analytical Sample Duplicate (Duplicate, Lab Duplicates) are two aliquots taken from the same sample container, that are processed and analyzed separately. Results are used to measure analytical precision from sample preparation through analysis for a given matrix.

7.3.6 Instrument Duplicates

Instrument Duplicates are two aliquots of the same extract or digestate and analyzed in duplicate.

VAEL Quality Systems Manual			Page 25 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

Results are used to measure instrument precision only. For some methods, the average value of instrument duplicates may be reported. However, method precision may not be calculated using instrument duplicates for methods requiring pre-digestion, extraction, or any other sample preparation steps.

7.3.7 Matrix Spikes (MSPK)

Matrix Spikes (MS, MSPK, Laboratory Fortified Sample Matrix) are prepared by adding a predetermined quantity of analyte(s) stock solution to a sample prior to sample extraction/digestion and analysis. A portion of the un-spiked parent sample and the spiked sample are analyzed. A percent recovery provides a measure of accuracy for a method in matrix.

7.3.8 Matrix Spike Duplicate (MSDP)

Matrix spike duplicates are used to estimate method precision for analytes frequently found below the LOQ. A second aliquot of the sample is treated like the original matrix spike sample. The relative percent difference (RPD) of the matrix spike and the matrix spike duplicate is calculated and used to assess analytical precision. Final laboratory reports indicate when RPD values are calculated from matrix spike duplicates.

7.3.9 Primary Calibration Standards

Primary Calibration Standards (Primary Standard, Calibration Standard) are prepared from dilutions of a NIST-traceable stock standard solution or from in-house reagent grade materials. The standards are used to calibrate the instrument response with respect to analyte concentration.

7.3.10 Initial/Independent Calibration Verification Standard (ICV)

Initial/Independent Calibration Verification Standard (ICV, Second Source Standard, Quality Control Check Sample) is a certified reference standard from a different source than the primary calibration standard, when possible. ICVs are processed the same as the primary calibration standard and are an independent check on the primary standard used to calibrate the instrument.

7.3.11 Continuing Calibration Verification Standard (CCV)

Continuing Calibration Verification Standard (CCV, Calibration Check Standards, Same Source Standard, Calibration Check Compounds, Calibration Verification Check (CVC), or Continuing Calibration Check Standards (CCC)) is a primary calibration standard(s) that is analyzed with test samples to verify continued calibration of the analytical system.

7.3.12 Surrogates (SS)

Surrogates are compounds not commonly found in samples, but have similar chemical structures, extraction and/or chromatography properties. These compounds are added to all blanks, calibration and check standards, samples (including duplicate and laboratory control samples) prior to analysis. Recoveries are calculated for each surrogate. Surrogate compounds and their acceptable recovery ranges are specified in analytical methods and SOPs. The Laboratory tracks surrogate recovery results. Historical data is used to monitor systems and establish warning limits that are narrower than method specified control limits. Recovery data is reported with every sample result.

7.3.13 Internal Standards (IS)

Internal Standards (IS) are used to correct for matrix interference in some methods. When used, known

VAEL Quality Systems Manual			Page 26 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

amounts of standard(s) is added to every unknown sample and QC sample prior to analysis.

7.3.14 Tuning Solutions

Tuning Solutions are used to verify that the resolution and mass calibration of the instrument are within required specifications prior to calibration and sample analysis (GC/MS) and to set instrument operating parameters (ICP/MS and GC/MS).

7.3.15 Interference Check Solutions (ICS)

Interference Check Solutions (ICS) contain known concentrations of interfering elements. They are analyzed prior to samples to demonstrate that correction equations are adequate (ICP/MS).

7.4 Method Detection Limits (MDL)

The Method Detection Limit (MDL) is the minimum concentration of a substance that can be measured and reported with 99% confidence, that the analyte concentration is greater than zero. It is determined from repeated analysis of low-level samples for a given matrix containing the analyte at a known concentration. MDLs are determined at method-specified frequency for those analytes and matrices that require them in accordance with EPA 821-R-16-006; "Definition and Procedure for the Determination of the Method Detection Limit, Revision 2" (December 2016).

7.5 Limit of Quantitation (LOQ)

The Limit of Quantitation (LOQ) is the lowest level that can be reliably achieved during routine laboratory operating conditions. It is set at the lowest calibration standard of a method, when applicable.

7.6 Reporting Limit (RL)

The reporting limit (RL) is the minimum value reported as a detection. The RL must be greater than or equal to the limit of quantitation (LOQ).

7.7 Preparation Batch

A preparation batch is composed of one to twenty samples of the same matrix that are prepared together with the same processes, personnel, and reagent(s). The maximum time between the start of processing of the first and last sample in a preparation batch is 24 hours. Each preparation batch must have associated QC data.

7.8 Analytical Batch

An analytical batch is defined as a group of samples (extracts, digestates or samples) that are analyzed together with the same processes, personnel, and reagents and having a defined set of quality control samples. Several preparation batches can be analyzed together in an analytical batch.

7.9 Precision

Precision is a measure of how well duplicate measurements reproduce and are calculated from laboratory duplicates, instrument duplicates, duplicate analysis of a Laboratory Control Sample (LCS) or matrix spike duplicates (MSD). Relative percent difference (RPD) is the current measure of precision for most analytes and is calculated as follows:

$$RPD = \frac{|C_1 - C_2|}{m} \times 100\%$$

VAEL Quality Systems Manual		Page 27 of 53	
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

Where:

RPD = relative percent difference

C₁ = larger of the two observed values

C₂ = smaller of the two observed values

m = mean of two observed values

When calculating from three or more replicates, relative standard deviation (RSD) is used:

$$RSD = \frac{s}{m} \times 100\%$$

Where:

RSD = relative standard deviation

s = standard deviation

m = mean of replicate analyses

Standard deviation is defined as:

$$s = \frac{\sqrt{\sum_{i=1}^n (y_i - m)^2}}{n - 1}$$

Where:

s = standard deviation

y_i = measured value of the replicate

m = mean of replicate measurements

n = number of replicates

7.10 Accuracy

Accuracy is a measure of how near a result is to the true value. It is expressed as a percent bias or percent recovery. Method accuracy is determined from the analysis of an LCS, continuing calibration verification, or quality control check samples.

Matrix effects are assessed by evaluating matrix spike results. The amount of analyte recovered after a sample has been spiked and processed reflects matrix effects upon the accuracy of the method for the sample.

Percent recovery is calculated using the following equation:

$$\%R = \frac{S - U}{C_{sa}} \times 100\%$$

Where:

%R = percent recovery

S = measured concentration in spiked aliquot

U = measured concentration in un-spiked aliquot

C_{sa} = actual concentration of spike added

The above calculation does not take spike volume into consideration. Lab protocol requires that a <5% volume change occurs when a spike is added negating the need to volume correct.

Percent bias is another measure of accuracy and is calculated using the following equation:

VAEL Quality Systems Manual		Page 28 of 53	
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

$$\%B = \frac{O-T}{T} \times 100\%$$

Where: %B = percent bias
 O = measured concentration of reference material
 T = actual concentration of reference material

7.11 Quality Control Acceptance Criteria

Quality control acceptance criteria are established by the method or by reviewing historical data for each method/matrix. The acceptance limits must meet method-specified criteria and may be narrower. Quality Control acceptance criteria are summarized in their corresponding SOPs by parameter and matrix. Limits for multi- parameter tests may be set the same for all parameters, in which case, the limit is reflective of most parameters. Control charts using 20 data points (when possible) are used to review established acceptance limits annually (some methods do not produce 20 QC samples annually). When >1% of QC samples fall outside the current limits, the method is evaluated for gross failures and corrective actions may be initiated. In the absence of gross method failures, the control limits may be expanded but still must meet method-specified acceptance criteria. When <1% of QC samples fall outside the current limits, the limits are not changed.

7.12 Reporting of Quality Control Data

Laboratory analysts run the appropriate quality control types at the SOP specified frequency. Relative Percent Difference or Percent Recovery are calculated externally and brought into LIMS. Order specific QC data (analytical dups, surrogates and matrix spikes and matrix spike duplicates) are available on the “NELAC Level II” report. When Control Limits are exceeded, QC data is remark coded. A sample result qualifier or a comment is added, when the failed QC result indicates a sample result(s) may be compromised.

8.0 Proficiency Testing

Proficiency Testing (PT) programs evaluate laboratory performance on specific tests or measurements. Successful PT program participation is a requirement for many VAEL accreditations. PT samples are handled in the same way as samples; no special treatment is allowed. When analyzing a PT, the same staff, methods, procedures, reporting protocol and equipment are used. Manually reported results are reviewed to ensure accuracy.

PT results are reviewed by the Laboratory QA Officer and distributed to the Laboratory Supervisor, participating laboratory staff and to laboratory users upon request. A Corrective Action Investigation is initiated by the QA Officer when the lab’s PT results are unacceptable.

8.1 Water Pollution Study (WP Series for Non-Potable Waters)

Semi-annual evaluation. NELAC accreditation status is dependent on successful analysis of these samples. Results are reported to the accrediting authority (NH ELAP). Analysis of WP samples is rotated through trained analysts for each method.

- Trace Metals (aluminum, antimony, arsenic, barium, beryllium, cadmium, chromium, cobalt, copper, iron, lead, mercury, manganese, molybdenum, nickel, selenium, vanadium, zinc, silver, strontium, thallium, uranium)
- Minerals (spec. cond., total dissolved solids, total hardness (calculation), calcium,

VAEL Quality Systems Manual			Page 29 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

- magnesium, total alkalinity, chloride, sulfate, sodium, potassium, fluoride)
- Nutrients (ammonia as nitrogen, nitrate as nitrogen, total Kjeldahl-nitrogen (calculation), total phosphorus, total nitrate, and nitrite)
- Aggregate Organic Constituents (total organic carbon, COD)
- Miscellaneous Parameters (total suspended solids, turbidity, nitrite, silica)

8.2 MIC series for Potable and Non-Potable Waters (E. coli and Total Coliform)

Semi-annual evaluation. NELAC accreditation status is dependent on successful analysis of these samples. Results are reported to the accrediting authority (NH ELAP). Analysis of MIC samples is rotated through trained analysts for each method.

- Total Coliform
- E. coli

8.3 U.S. Geological Survey Analytical Evaluation Program for Non-Potable waters

Semi-annual evaluation, round robin. Analysis is rotated through trained analysts for each method.

- Nutrients (nitrate/nitrite as nitrogen, phosphorus, ammonia, nitrate, total nitrogen, silica).
- Trace Constituents (aluminum, antimony, arsenic, barium, beryllium, cadmium, calcium, chromium, cobalt, copper, iron, lead, magnesium, manganese, molybdenum, nickel, potassium, sodium, selenium, strontium, silica, silver, thallium, vanadium, uranium, zinc)
- Major Constituents (chloride, sulfate, specific conductance, silica, alkalinity, pH, total phosphorus, calcium, potassium, magnesium, sodium)
- Precipitation (conductivity, pH, sulfate, calcium, magnesium, potassium, sodium, total phosphorus)
- Mercury

8.4 National Air Toxics Trends Stations (NATTS) Air PT

Through the VT DEC Air Quality & Climate Division, VAEL participates in the NATTS performance test for analytical methods conducted at VAEL. The PT is administered by the EPA's NATTS contractor (Battelle) with results reported through the Battelle web portal.

- Metals – Teflon air filters (8 analytes) – 2x annually
- TO-15 Volatile organic compounds – air (14 compounds) – 2x annually
- TO-11 Carbonyl compounds- air (4 compounds) – 2x annually

8.5 Association of American Pesticide Control Officials (AAPCO) Check sample

The Organic section participates in the Association of American Pesticide Control Officials (AAPCO) check sample program. This is a program to test proficiency analyzing pesticide formulation products. Four to six active ingredients are tested annually covering a wide range of active ingredients and product types. The lab uses existing methods or develops new methods when needed. Analysis of PT samples are rotated through all trained analysts. A comprehensive statistical report using inter-laboratory results is generated. The laboratory evaluates results for performance evaluation.

8.6 Wisconsin Pesticide Residue (WPR) Sample

The Organic section participates in the Wisconsin Pesticide Residue Check Sample Program. This

VAEL Quality Systems Manual			Page 30 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

program tests proficiency extracting and analyzing residue level pesticide samples. Samples are sent two times a year. A soil sample is sent in the spring and a vegetation sample in the fall. Each test consists of 4 samples: one sample for each of 4 different categories. Analysis of PT samples are rotated through all trained analysts. A comprehensive statistical report using inter-laboratory results is generated. The laboratory evaluates results for performance evaluation.

8.7 FDA- Center for Food Safety and Applied Nutrition Lab Proficiency Evaluation Test (CFSAN-LPET)

The Dairy Laboratory participates in the Raw Milk and Finished Milk CFSAN Proficiency Sample Programs in the Fall and Spring. Proficiency Samples are tested annually for the following methods: Petrifilm Aerobic Count, Dairy Coliform, Alkaline Phosphatase, Antibiotic Residue (Charm SL, Charm SL Sulfa Drugs, Charm SL Tetracycline, Delvotest 5 pack, IDEXX Snap), Electronic Somatic Cell count and Direct Somatic Cell count. PT results are entered into FDA FOODSHIELD Database. PT data are compiled from all state and federal dairy testing laboratories. Individual test results must be within statistical limits. Analysts reporting more than 2 sample results outside of statistical limits have their certification status downgraded for the affected method.

8.8 USDA-APHIS-NVSL

The Animal Health Lab participates in USDA Sample Proficiency Test Programs for Equine Infectious Anemia (EIA) and Brucellosis. The Laboratory receives a single set of EIA proficiency samples. One analyst sets the samples up on AGID and all analysts read the PT samples. Then the Laboratory submits a single set of results for scoring. The Brucellosis Program requires individual participation with each analyst receiving a different test panel of samples to be analyzed on the Buffered Antigen Plate Agglutination, Card, Standard Plate and Rivanol test methods. Results are scored based on known sample sera concentrations. Analyst scoring less than 90%, are required to perform another PT panel for the failed method. A second failure results in the loss of certification for the affected method.

8.9 Meat Inspection Program/Pet Foods- Food Safety Inspection Service (FSIS) Accredited Laboratory Program (ALP)

FSIS ALP check samples are analyzed bi-monthly for Fat, Moisture, and Salt. Laboratory results are scored individually using CUSUM statistics. The laboratory is notified when results exceed acceptance criteria limits and is no longer permitted to participate in the check sample program for the failed parameter. However, the laboratory may continue the bi-monthly samples for the other accredited tests. To regain re-instatement for the failed test parameter, the Laboratory is required to complete CAI, and request and pass a 14 concurrent sample set for the method.

Occasionally a review of records or on-site audit will occur by the ALP staff. Record reviews involve sending current SOPs to ALP for review against the ALP Chemistry Laboratory Guidebook (CLG).

8.10 Fertilizer-Magruder Check Sample Program

These fertilizer samples contain varying levels of the primary nutrients (N, P, & K) as well as secondary (Ca, Mg & S) and many micro-nutrients. Contaminants of interest, including trace metals (As, Cd, Cr, Co, Hg, Pb, & Se) are often included in the evaluation. Samples are analyzed according to our laboratory methods. A comprehensive statistical report using inter-laboratory results is generated. The laboratory evaluates results for performance evaluation.

VAEL Quality Systems Manual			Page 31 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

8.11 Feeds and Commercial Pet Foods- AAFCO Program

The Animal Feed Control Official's PT Program uses samples of commercial feed, covering a wide variety of feeds and supplements. They are analyzed for crude protein, crude fat, crude fiber, moisture, ash, calcium, sodium, phosphorus, and a variety of micronutrients. Samples are analyzed according to laboratory methods. A comprehensive statistical report using inter-laboratory results is generated. The laboratory evaluates results for performance evaluation.

9.0 System Audits

A system audit is an evaluation of facilities, equipment, personnel, training, procedures, record-keeping, data validation, data management, and reporting aspects of a system to determine whether activities are being conducted as planned and will effectively achieve quality objectives. System audits can be conducted by external auditing authorities (external audit) or in-house (internal audit).

9.1 External Audits

VAEL's accrediting bodies, include:

- New Hampshire Environmental Laboratory Accreditation Program-NH ELAP, a TNI accrediting authority, which conducts an on-site system assessment every two years (usually in May).
- New York Environmental Laboratory Accreditation Program-NY ELAP, a TNI accrediting authority, provides secondary accreditation on some NH ELAP accredited methods, allowing VAEL to accept samples from NY Waters. No on-site assessments are performed but NY ELAP does perform a bench review VAEL procedures and policies.
- Battelle, under contract to EPA, continues to perform technical systems audits of air methods, including: Metals, Carbonyls (TO-11) and Volatiles in air (TO-15).
- FDA-CFSAN-LPET perform audits of the dairy section (Biology).
- USDA-APHIS-VS audit for the Vermont Equine Infectious Anemia testing program.
- USDA-FSIS audits food chemistry methods used for the meat inspection program.
- External audits are also periodically conducted by the USGS and the USEPA Region 1 Office of Research and Development, Ecosystem Research Division. 16.80

9.2 Internal Audits

Internal Audits are a tool to:

- 1) verify analyst compliance with the laboratory's quality policies.
- 2) address any ongoing quality issues.
- 3) highlight technical, equipment or management support needed within the analytical center being audited.

It is the QA Officer's responsibility to plan and organize annual internal audits within each of the laboratory's analytical centers. Internal audits are conducted using the Internal Audit form (Appendix E) by Technical Directors or VAEL Scientists, level IV or higher. When possible, the auditor's roles and responsibilities make them independent, but knowledgeable of, the activity being audited. Internal audits cover all elements of the laboratory's management system, including quality system operations, data reporting, sample receiving and analytical methods.

VAEL Quality Systems Manual			Page 32 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

10.0 Demonstration of Capability

10.1 Method Validation

New Method– New methods are validated before they are made available to clients. Validation documentation includes:

- a) Evidence that analyst(s) participated in vendor-provided training courses when new technology is employed.
- b) Development and approval of an SOP
- c) an MDL determination
- d) LOQ verification
- e) LDR determination, if applicable

New Instrument, Existing Method - When a new instrument replaces/supplements an existing instrument, it is validated by:

- a) Review and revision of SOP, if applicable
- b) an MDL determination
- c) CDOC for every analyst performing the method.

Changes to Equipment Beyond Routine Maintenance - When an instrument requires parts replacement beyond routine maintenance, a method verification is performed that includes:

- a) Verification of MDL
- b) Verification of LOQ
- c) Blank verification
- d) LDR determination if applicable

10.2 Initial Demonstration of Capability (IDOC)

An IDOC is performed by an analyst prior to using any method any time there is a significant method change or the method has not been performed in a 12-month period. Requirements vary depending on the complexity of the equipment or procedure to be performed, but at a minimum the analyst must:

- Read, understand, and agree to follow SOP, sign signature page on SOP.
- Review reference methods (if applicable)
- Observe an analyst performing at least one analysis procedure completely (more complex procedures may require several observation trainings).
- Prepare and analyze a batch of laboratory control samples while the trainer observes. This includes the method specified batch QC in addition to four (4) control samples. If an LCSL is not part of the batch QC, but is possible to run, one is also included. Control samples are named IDOC1 and IDOC2, create a duplicate for each of these. All 4 control samples must be within method recovery limits and the relative percent difference between each pair must be within method limits. Document control limits as analyte comments in WinLIMS. All results must meet method acceptance criteria.
- Prepare as above on a separate day and independent from the trainer. Control samples are named IDOC3 and IDOC4. All results must meet method acceptance criteria.

For NELAC- accredited microbiology methods, the IDOC consists of successful analysis of four samples fortified with a known quantity of target organism(s) with results meeting acceptance criteria.

VAEL Quality Systems Manual		Page 33 of 53	
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

10.3 Continuing Demonstration of Capability (CDOC)

VAEL analysts (including those performing NELAC-accredited microbiology methods) must demonstrate continued proficiency annually for all tests they are reporting. Accepted materials for documentation are stored in the analyst's training file and shall consist of one of the following.

- Acceptable performance of blind or PT sample.
- Another Initial DOC
- At least 4 consecutive laboratory control samples with acceptable levels of precision and accuracy (LCS or ICV).
- Authentic samples with results statistically indistinguishable from those obtained by another trained analyst.
- A documented review of QC samples performed by the analyst, ensuring that 95% or more of all QC samples run in that year are within acceptable limits.

10.4 Analyst Files Containing Training Documentation

The QA Officer maintains an electronic and/or paper file for each analyst including documentation they have completed necessary training to perform assigned methods. These files include:

- New Staff Orientation
- IDOC Documentation
- Annual QSM Review
- CDOC Documentation

11.0 Maintenance

Preventative maintenance (PM) is performed on equipment to maintain optimal performance and minimize instrument down-time/ analytical services interruptions. Routine PM is performed by qualified Laboratory personnel. Annual PM on some instruments is performed by a qualified analytical instrument repair/maintenance service engineer. Logbooks are kept for each instrument to document an inventory of critical replacement parts, instrument problems, repairs, and routine maintenance. Some equipment is maintained under maintenance insurance (REMI).

11.1 Instrument Logbooks

Physical and operational instrument changes, including any equipment maintenance, damage, malfunction, modification, or repairs made is recorded in instrument logbooks. Specifically, these logbooks document all maintenance and upgrades including replaced parts, as well as setting changes made for trouble-shooting purposes. Logbooks are accessible to all instrument operators. Entries are legible, written in clear language including date, author's initials, and include a general heading describing the type of entry.

Instrument Logs are reviewed during internal audits.

12.0 Preventative Actions

Laboratory staff are encouraged to identify opportunities for improvement and when resources are needed. A Preventative Action Form (Appendix G) is used to document needed improvements and potential sources of non-conformance either technical or related to the quality system in general. Forms are submitted to the Laboratory Supervisor and QA Officer. When approved, preventative actions and follow-up are documented to measure its success after implementation. Analysts are not

VAEL Quality Systems Manual			Page 34 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

allowed to make significant changes to procedures unless through the approval process involving the Laboratory Supervisor and Quality Assurance Officer.

13.0 Non-conforming Work

If at any time, it is determined an irregularity in the analytical process has compromised the Laboratory's ability to generate quality, defensible data, the analyst will notify the Laboratory Supervisor. The Laboratory Supervisor will work with the analyst(s) and the QA Officer to evaluate the extent and nature of the compromised data. The QA Officer will then notify clients in writing within 5 working days of the non-conformance discovery. This procedure applies to situations in which the Laboratory has determined the significance of the irregularity justifies recalling work which has already been released or has decided it will not report results. This policy does not apply to situations in which a data flag or sample note can be used to qualify the data. Corrective actions must be initiated promptly to remedy the situation.

14.0 Interruption of Service

When an instrument or analytical process is unable to generate quality, defensible data, the analyst notifies the Laboratory Supervisor and QA Officer. The QA Officer and Supervisor will evaluate whether an interruption of service is necessary. If so, the QA Officer will notify clients immediately. Clients will have the option to remove their samples and submit them to another lab. Samples for the affected tests will not be accepted until the issues have been remedied and service has been reinstated.

15.0 Corrective Actions

Corrective actions are initiated by identification of a problem through a system or performance audit, data review, management review or laboratory user's or staff member's request. The process is generally initiated by the QA Officer or Laboratory Supervisor and is documented on a Corrective Action Investigation Form (Appendix F). The assigned analyst has the ultimate responsibility of evaluating the effectiveness of the corrective actions. When a corrective action is ineffective, it the analyst's responsibility to notify the Lab Supervisor. Laboratory management will verify corrective action effectiveness by either performing a follow-up data review, submitting a proficiency sample, or performing other internal audit activities. The steps in the corrective action process are:

- Identify and define the problem
- Assign responsibility for investigating the problem
- Determine the cause of the problem
- Determine the corrective actions needed to remedy the problem
- Implement corrective action
- Establish effectiveness of the corrective action
- Verify effectiveness of corrective action (by laboratory management)

Corrective action may also be initiated by an analyst during or after analysis of samples. Laboratory personnel are aware corrective actions may be necessary if:

- Unacceptable or uncharacteristic instrument conditions, calibration or continuing calibration data is generated
- QC data are outside precision or accuracy warning or control limits

VAEL Quality Systems Manual			Page 35 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

- Peak shapes and or baselines are unacceptable
- Blank(s) contain target analytes above acceptable levels
- A surrogate recovery falls outside the expected range

Investigation of problems revealed by routine analysis of laboratory QC samples are the responsibility of the analyst generating the data or the Technical Director of the analytical center reviewing the data.

When the corrective actions have not resolved the irregularity, it is the analyst's responsibility to notify the Laboratory Supervisor/QA Officer, who will then assess the data and determine if the data are to be released and how it will be qualified. This process is likely to require contact with the client(s) and written instructions on how to proceed. Client interactions are documented and filed.

Corrective action investigations should be completed within 10 working days of issuance. The QA Officer and Laboratory Supervisor's review should be completed within 10 working days of receipt. When an analyst is asked to provide additional information or would like to respond to the reviewer's comments, the QA Officer will set-up a meeting within 5 working days to address any concerns. The QA Officer will document any additional discussions or decisions made at the meeting. The QA Officer reviews all open CAIs on a quarterly basis.

16.0 Customer Feedback

Customer feedback regarding data quality or service provided by the Laboratory should be placed in writing and addressed to the Laboratory Director (e-mails or letters are acceptable). The Director will evaluate the nature of the complaint and may initiate a corrective action.

The Director must respond to the complaint in writing and in a timely fashion. Complaints and responses are maintained on file. When a customer is not satisfied with the Laboratory's response the customer has the option of bringing the complaint to the VAEL Governance Board.

An electronic customer satisfaction survey is distributed to all clients with the reporting of all results.

Feedback is voluntary. It is reviewed annually by lab management to identify areas for expansion, growth, or improvement. Feedback may result in the initiation of a corrective action. It is the Lab Director's responsibility to ensure the issue is resolved.

17.0 Quality System Review

17.1 Quality Assurance Reports to Management

The QA Officer shall make available to the Laboratory Supervisors and Director, the following information:

- The VAEL Quality Systems Manual (QSM) Updates (annually or as needed).
- Proficiency Test results
- Corrective action investigation reports
- QA office goals and objectives for the upcoming year (annual performance evaluation/work plan).
- Internal audit reports (annual)
- Standard Operating Procedure (SOP) updates/status
- Review all lab quality control samples (quarterly), control limits (annually), and MDLs where applicable (annually)

VAEL Quality Systems Manual			Page 36 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

17.2 Annual Review of Quality System

Annually, all staff review

- The VAEL Quality Systems Manual
- Preventative Action Plans for all methods they have active DOCs in
- Corrective Action Investigation Reports they participated in
- The outcome of internal audits for all methods they have active DOCs in
- External Audit Reports
- All SOPs for methods they have active DOCs in

The QA Officer also reviews.

- All SOPs
- All internal audit reports.
- All corrective action investigation reports (quarterly)
- Proficiency test results
- Staff training documents

17.3 Management Review

The Laboratory Director reviews the laboratory's management system and testing activities annually to ensure their suitability and effectiveness and to introduce necessary changes or improvements. The "Management Review Checklist Template" is used to review the suitability of policies and procedures, lab supervisors reports (where applicable), the outcome of the year's internal audits, corrective and preventative actions effectiveness, external assessments (NELAC, FDA, NATTS, APHIS, etc.), proficiency test results, interlaboratory comparisons, changes in the volume and type of work being done, customer feedback/complaints, improvement recommendations and any other relevant factors, including quality control activities, resources and staff (cross) training. Any corrective actions issued because of this review will be managed as in 15. The management review is shared with VAEL management and staff for the purpose of laboratory strategic planning.

VAEL Quality Systems Manual			Page 37 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

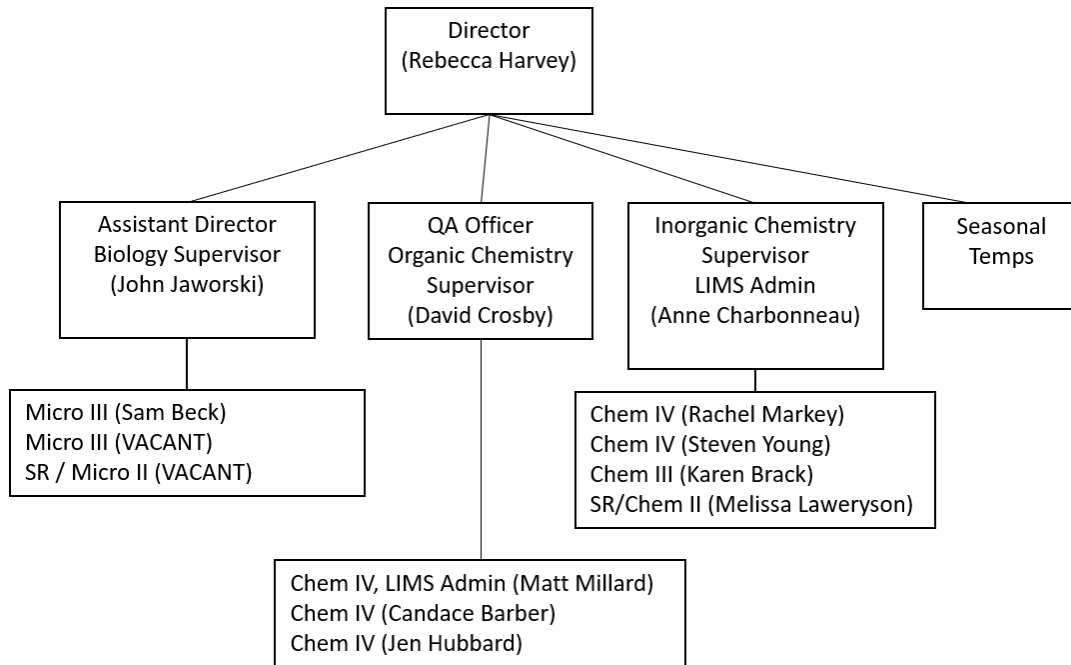
Appendix A: Laboratory Positions and Personnel

A.1 Summary Table

Present Specialty	Name	Position Title	Education Level: Degree & Major	Years of Experience
Laboratory Director	Rebecca Harvey	Laboratory Director	B.A. Chemistry M.S. Environmental Science and Policy Ph.D. Chemistry	6
Laboratory Assistant Director, Biology Supervisor	John Jaworski	Biology Lab Supervisor	B.S. Chemistry M.S. Forensic Chemistry MPA Public Admin.	39
Laboratory QA Officer, Organic Chemistry Supervisor	David Crosby	QA Officer, Technical Director, Organic Chemistry	B.S. Chemistry B.S. Geology	19
Organic Chemistry LIMS Administrator	Matthew Millard	VAEL Chemist IV	B.S. Chemistry	9
Chemistry, Wet Lab, Metals, Feed & Fert.	Rachel Markey	VAEL Chemist IV, Technical Director Wet Lab	B.S. Environmental Science B.S. Forestry	5
Chemistry, Metals, Feed & Fert, Inorganic Chemistry Supervisor LIMS Administrator	Anne Charbonneau	VAEL Chemist V Technical Director, Metals	B.S. Biochemistry	31
Organic Chemistry	Candace Barber	VAEL Chemist IV	B.S. Animal Science	22
Organic Chemistry	Jen Hubbard	VAEL Chemist IV	B.A. Chemistry	14
Chemistry, Nutrients, VAEL Safety Officer	Steven Young	VAEL Chemist IV Technical Director, Nutrients	B. S. Chemistry	5
Chemistry, Nutrients	Karen Brack	VAEL Chemist III	B.S. Chemistry B.S. Environmental Science	8
Microbiology	Sam Beck	VAEL Microbiologist III Technical Director, Microbiology	B.S. Microbiology	3
Chemistry, Wet Lab, Sample Receiving	Melissa Laweryson	VAEL Chemist II/SR	B.S. Diversified Agriculture	3
Laboratory Technicians	Seasonal	VAEL Seasonal Analyst I or II	varies	varies

VAEL Quality Systems Manual		Page 38 of 53	
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

A.2 Vermont Agriculture and Environmental Laboratory Organizational Chart



UNCONTROLLED

VAEL Quality Systems Manual			Page 39 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

Appendix B: Standard Operating Procedures

1.0 Procedural/Administrative SOPs

#	Title	Pages	Rvs #	Date
QA-001	VAEL Quality Systems Manual	59	26	2021-06-04
CHP-001	Chemical Hygiene/Safety Plan	27	1	2020-12+30
1.1	Chain of Custody Samples	na	draft	draft
1.2	Recertification of Expired Reagents and/or Standards	7	0	2020-05-18
1.3	Temperature Checks for Refrigerators and Freezers	5	0	2020-05-29

2.0 Metals

#	Title	Ref. Method	Pages	Rvs #	Date
2.1	Determination of Mercury by ICP-MS EPA Method 6020B	EPA 6020B	20	4	2020-07-10
2.2	Mercury Determination in Solid and Semi-Solid Waste by Cold Vapor Atomic Absorption Spectrometry		17	2	5-2017
2.3	Mercury Determination in Waters by Cold Vapor Atomic Absorption Spectrometry	EPA 245.1	14	6	2021-03-10
2.4	Metals Analysis by ICP-MS	EPA 6020B	26	12	2020-08-27
2.5	Metals Analysis of Feed and Fertilizer	AOAC 985.01	17	5	2020-06-25
2.6	Extraction of 47mm Teflon Air Filters for Metals Analysis RETIRED	EPA IO-3.1	10	2	1-2015
2.7	Metals Analysis of Air Filters by ICP-MS	EPA IO-3.5 and IO-3.1	21	12	2020-06-08
2.8	Preparation of Monomeric Aluminum	In-house	7	0	2020-06-16

3.0 Biology, Microbiology / Dairy Microbiology

#	Title	Ref. Method	Pages	Rvs #	Date
3.6	Escherichia coli (E. coli) and Total Coliform Quanti-Tray Method	SM 9223B 21 st Ed	16	10	2020-07-17
3.8	Microbiology Quality Assurance		10	3	1-2009
3.9	Enumerating Total Coliform Bacteria in Dairy Products RETIRED		9	5	11-2013
3.10	Microbial Analysis of Pasteurized Milk Containers		6	7	10-2019
3.11	Direct Microscopic Somatic Cell Count		10	5	1-2017
3.12	P/A Test for E. coli and Total Coliform in Dairy Waters by Colilert Chromogenic Substrate (MMO-MUG) Procedure		5	5	1-2017
3.13	Electronic Somatic Cell Count using Bentley Somacount RETIRED		10	1	7-2007
3.14	Multiple Tube Fermentation Test for P/A of Total Coliform Bacteria in Dairy Cooling Water System RETIRED		4	1	11-2013
3.15	3M Petrifilm Aerobic Count method for Determination of Heterotrophic bacterial populations in raw and pasteurized milk products		17	3	10-2019
3.16	Detection of Antibiotic Residue in Raw and Pasteurized Dairy		7	7	10-2019

VAEL Quality Systems Manual			Page 40 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

	Products utilizing-Delvotest P-5 Pack Procedure			
3.17	Examining raw commingled bovine, camel and goat milk for the presence of Betalactam Antibiotic Residue via IDEXX NEW Beta-Lactam SNAP (Penicillin G, Ampicillin, Amoxicillin, Cephapirin, Ceftiofur)	9	3	10-2019
3.18	Charm II competitive Sulfa Drug Test (Sulfadiazine, Sulfadimethoxine, Sulfamethazine, and Sulfathiazole) RETIRED	9	3	9-2007
3.19	Charm II Competitive Tetracycline Test (Chlorotetracycline, Oxytetracycline, and Tetracycline) RETIRED	9	2	1-2002
3.20	Detection and Quantitation of Alkaline Phosphatase Enzyme in Pasteurized Dairy Products utilizing Charm II Analyzer – LSC 6600	16	7	1-2017
3.21	Detection of Betalactam Antibiotic Residue in Raw Commingled Bovine, Ovine and Caprine Milk via Charm Sciences SLBL Test (Amoxicillin, Ampicillin, Ceftiofur, Cephapirin, and Penicillin G) using EZ reader	8	6	12-2019
3.22	Electronic Milk component Quantification-Foss FT120	13	0	
3.36	Collection, Storage and Disposal of Hazardous Chemical Waste, non-Hazardous waste, Laboratory Samples and Commercial test kits	7	7	4-2019
3.37	Collection, Storage and Disposal of Biological Waste via Steris sterilizer 630LS (Model LS-136H)	4	6	4-2019
3.38	Logging Dairy, Water and Empty Container Samples	6	4	1-2017
3.39	Maintenance of Dairy, Water and Pasteurized Milk Container Samples	3	2	1-2017
3.40	Handling Dairy, Water and Pasteurized Milk Container Samples	3	2	1-2017
3.41	Disposal of Dairy, Water and Pasteurized Milk Container Samples	3	2	1-2017
3.42	Enumeration of Total Coliform in Dairy Products utilizing Charm Peel Plate Coliform and High-Volume Sensitivity Coliform Procedure	8	1	1-2017
3.43	Enumeration of Bovine, Caprine and Ovine Somatic cells via Bentley Somacount FC	6	1	1-2018
3.44	Tube Fermentation Test for Presence of Total Coliform bacteria in Cooling Water System, Non-Source Water	4	2	11-2018
3.45	Detection of Tetracycline Group Antibiotic Residue in Raw Commingled Bovine Milk via Charm SL Tetracycline Test (Tetracycline, Oxytetracycline and Chlorotetracycline)	8	2	10-2019
3.46	Media Preparation and Associated Quality Control	9	8	4-2019
3.47	Operation of Sterilizer – AMSCO-Steris 630LS series, Model LS-136H	5	5	5-2019
3.48	Operation/Calibration of Orion Star A111 pH Meter	4	8	2-2019
3.49	Balance Calibration Checks	3	3	1-2010
3.50	Verify Dual Species Self-Contained Biological Indicators – for routine monitoring of steam sterilization processes	3	1	1-2017
3.51	Annual Thermometer Check Procedure	5	3	1-2017
3.52	Pipettor Calibration Check Procedure			

VAEL Quality Systems Manual			Page 41 of 53		
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05		

3.53	Detection of Sulfonamides Antibiotic Residue in Raw Commingled Bovine Milk via Charm SL ROSA SULF Test		8	2	10-2019
------	--	--	---	---	---------

3.0 Biology, Animal Health

#	Title	Ref. Method	Pages	Rvs #	Date
3.23	Identification of Mastitis Causing Pathogens in Ruminant Milk				
3.24	Classification and Enumeration of Microbes in Bulk Tank Milk				
3.25	Detection of Antibodies in Brucella Abortus by Buffered Antigen Plate Agglutination Test				
3.26	Detection of Antibodies in Brucella Abortus by Rivanol				
3.27	Detection of Antibodies in Brucella Abortus by Standard Plate Agglutination Test				
3.28	Detection of Antibodies in Brucella Abortus by Standard Tube Test				
3.29	Detection of Antibodies in Brucella Abortus by Card Test				
3.30	Detection of Antibodies to Equine Infectious Anemia by Agar Gel Immune Diffusion Method				
3.31	Detection of Antibodies to Equine Infectious Anemia by ELISA				

3.0 Biology, Molecular

#	Title	Ref. Method	Pages	Rvs #	Date
3.32	Extraction of Tick-borne Pathogen Total Nucleic Acids for <i>Ixodes scapularis</i> utilizing Applied Biosystems MagMAX Pathogen RNA/DNA kit		4	1	3-2017
3.33	<i>Ixodes scapularis</i> Homogenization and Lysis:		3	1	3-2017
3.34	Detection of <i>B. burgdorferi</i> , <i>B. miyamotoi</i> , <i>A. phagocytophilum</i> and <i>Ba. microti</i> in <i>Ixodes scapularis</i> via Quadplex Qualitative Real Time Polymerase Chain Reaction		5	1	3-2017
3.35	Detection of Deer Tick Virus (Powassan virus – Lineage II) in <i>Ixodes scapularis</i> via Qualitative Real Time Reverse Transcriptase Polymerase Chain Reaction		4	1	2-2017

4.0 Organics

#	Title	Ref. Method	Pages	Rvs #	Date
4.1	Gas Chromatography Mass Spectrometry for Volatile Organics (Method 8260) RETIRED		47	9	6-2014
4.6	Aromatic Volatiles by Gas Chromatography (Modified Method 8021) RETIRED		20	6	1-2013
4.7	Total Petroleum Hydrocarbons – Diesel Range Organics (DRO) – Modified Method 8015 RETIRED		51	6	1-2013
4.9	Toxic Organic Compounds (Carbonyls) in Ambient Air	TO-11A	21	10	2019-12-20

VAEL Quality Systems Manual			Page 42 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

4.10	Volatile Organic Compounds in Ambient Air (TO15)	TO-15	22	7	2020-11-04
4.14	Cleaning Organic Glassware		6	2	1-2013
4.15	Peak Integrations and for the Manual Manipulation of Computer-Generated Data		7	0	12-2007
4.16	Gasoline Range Organics (GRO) – Modified Method 8015 RETIRED		22	2	1-2013
4.17	Neonicotinoids, Corn Herbicides, and Metabolites in Water			0	Draft
4.18	Potency in Hemp	AOAC 2018.11	22	0	2021-03-09
4.19	Canister Cleaning and Qualification				Draft

5.0 Inorganic Non-Automated / Wet Lab

#	Title	Ref. Method	Pages	Rvs #	Date
5.1	Alkalinity and pH	SM 2320B, SM 4500-H+B	16	14	2020-03-12
5.2	Biochemical Oxygen Demand (BOD) – 5 Day RETIRED	SM 5210B	15	14	2020-03-24
5.3	Chemical Oxygen Demand (COD) – (Micro Method)	Hach 8000	14	13	2020-04-23
5.4	Chlorophyll a	EPA 445.0	16	10	2020-06-09
5.5	Conductivity	SM 2510B	10	15	2020-06-30
5.7	Dissolved Oxygen - Winkler Method	SM 4500-O C	9	11	2019-04-30
5.10	Total Dissolved Solids (TDS)	SM 2540C	11	9	2020-03-24
5.11	Total Suspended Solids (TSS)	SM 2540D	11	14	2020-07-01
5.12	Turbidity	SM 2130B	11	15	2020-10-05
5.18	pH Electrometric ---RETIRED	SM 4500 H+B	13	6	1-2015
5.19	Chlorine, Total Residual ---RETIRED	Hach 8167	1	3	1-2015
5.20	Alkalinity by Auto-Titrator	SM 2320B, SM 4500 H+B	13	1	2020-05-27
5.21	Gran Alkalinity/ANC and Conductivity by Autotitrator	VAEL SOP 5.21	13	1	2021-03-17

6.0 Automated Inorganic Lab

#	Title	Ref. Method	Pages	Rvs #	Date
6.1	Inorganic Anion Determination by Ion Chromatography	EPA 300.0	18	12	2020-03-23
6.2	Determination of Chloride in Water by Flow Injection Analysis (Mercury Thiocyanate Method)	SM 4500-Cl ⁻ G, Lachat	17	10	2020-08-03
6.3	Determination of Ammonia in Waters by Flow Injection Analysis (Automated Phenate Method)	SM 4500-NH ₃ H, Lachat 10-107-06-1-B	20	10	2020-07-22
6.4	Determination of Silica in Water	SM 4500-SiO ₂ E	18	10	2020-06-23
6.5	Determination of Nitrate/Nitrite Nitrogen in Waters (Cadmium Reduction Method)	SM 4500-NO ₃ ⁻ I	22	11	2020-06-23
6.6	Determination of Phosphorus by Flow Injection Analysis (Acid	SM 21 st 4500-	21	9	2020-08-06

VAEL Quality Systems Manual			Page 43 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

	Persulfate Digestion Method)	P H			
6.7	Determination of Total Nitrogen by Flow Injection Analysis (Persulfate Digestion Method)	SM 4500-N C	24	9	2019-04-29
6.8	Determination of Orthophosphate by Flow Injection Analysis	SM 21 st 4500-P G	18	4	2021-03-26
6.9	Determination of Total/Dissolved Organic Carbon by the analysis of Total Carbon and Inorganic Carbon & Non-Purgeable Organic Carbon	SM 5310B	16	0	2020-04-28
6.10	Determination of Chloride in Water by AQ400	SM 20 th 4500-Cl ⁻ E	17	0	2020-10-07
6.11	Determination of Silica in Water by AQ400	SM 4500-SiO ₂ D	16	0	2020-10-23
6.12	Determination of Ammonia in Waters by AQ400				draft

7.0 Feed and Fertilizer

#	Title	Ref. Method	Pages	Rvs #	Date
7.1	Determination of Crude Protein and Nitrogen by Combustion	AOAC 968.06	12	2	2020-05-05
7.2	Crude Fat Analysis in Feed, Meat and Processed Meat Samples RETIRED	AOAC 960.39	14	4	2018-08-21
7.3	Standard Operating Procedure (SOP) for Determination of Salt (Volhard's Method)	AOAC 935.47	11	4	2018-08-21
7.4	Moisture Determination in Feed and Meat Samples	AOAC 930.15	9	2	12-2016
7.5	Crude Fiber Analysis in Feed Samples	AOCS Ba 6a-05	10	5	2021-03-24
7.6	Moisture Determination in Wet Feeds and Meat Products	AOAC 950.46	10	4	2020-02-03
7.7	Crude Fat in Feed and Pet Foods by Acid Hydrolysis (Mojonnier)	AOAC 922.06	12	2	12-2016
7.8	Crude Fat Analysis in Feed and Meat Samples, ANKOM Technology	AOCS Am 5-04	13	1	2020-01-10
7.9	Ash Determination in Feed Samples and Pet Foods	AOAC 942.05	9	2	2016-12

8.0 Miscellaneous Lab Procedures

#	Title	Ref. Method	Pages	Rvs #	Date
8.1	Glassware Cleaning and Bottle Order Preparation---RETIRED		11	1	8-2005
8.2	Standard Operating Procedure Guidance Document---RETIRED		10	4	12-2010
8.3	Unknown ---RETIRED				
8.4	Percent Solid Procedure ---RETIRED	SM 2540G	8	4	4-2011
8.5	Unknown ---RETIRED				
8.6	Unknown ---RETIRED				
8.7	VAEL Milli-Q Lab Water Filtration System				draft
8.8	Vermont DEC Laboratory Sample Handling and Receiving		16	5	1-2009

VAEL Quality Systems Manual			Page 44 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

	Protocol RETIRED				
8.9	Solids, Total Volatile ---RETIRED	SM 2540G	8	2	4-2011
8.10	Employee Quality Control and Ethics Training ---RETIRED		7	1	1-2009
8.11	Sample Receiving		23	2	2020-09-28

UNCONTROLLED COPY

Appendix C: Sample Submission Forms

C.1 Sample Submission Plan


VAEL SharePoint\Quality Assurance\VAEL Client Project Agreement\Sample Plan_YYYY_Program-Project.xlsx

Sample Submission Plan																																																											
Calendar Year: 2021		Project Leader Name:				Project Leader Phone:		Project-specific QA/QC Required?																																																			
Program Name:		Program Number (###):				Project Number (###-###):		Sample delivery method:																																																			
Project Name:		Project Number (###-###):				Sample delivery method:		Rain Event Sampling Program?																																																			
<small>A list of available tests and parameters can be found here. Please send completed Sampling Plan to: agr.vael@vermont.gov</small>																																																											
Week Beginning (Monday)	Test	Total # Samples	Dec	Jan	Jan	Jan	Jan	Feb	Feb	Feb	Mar	Mar	Mar	Mar	Mar	Apr	Apr	Apr	Apr	May	May	May	May	May	Jun	Jun	Jun	Jun	Jun	Jul	Jul	Jul	Jul	Jul	Aug	Aug	Aug	Aug	Aug	Sep	Sep	Sep	Sep	Sep	Oct	Oct	Oct	Oct	Oct	Nov	Nov	Nov	Nov	Nov	Nov	Dec	Dec	Dec	Dec
Enter any comments here:																																																											

UNCONTROLLED

C.2 Client Registration Form:

<http://cloud.agriculture.vermont.gov/VaelClientForm/RegistrationPage.aspx>



VERMONT
AGENCY OF AGRICULTURE, FOOD & MARKETS

Accessibility Policy | Privacy Policy

Agency/Organization

If there is no Division or Department then type NA

Agency

Address City State Zip

Department

Division

Program Title

Program Manager

Name

Phone

Email

Program Invoice Contact

Name

Phone

Email

Project Details

Project Name

Start Date

Project Description Maximum 140 Characters

Project Team

Manager

Name

Phone

Email

Sample Collector

Name

Phone

Email

Sample Collector

Name

Phone

Email

Sample Collector

Name

Phone

Email

Sample Collector

Name

Phone

Email

List any other Person who will need to review results

Name

Email


Name

Email

Name

Email

Retype the characters from the picture:



Submit

A Vermont Government Website Copyright © 2020 State of Vermont. All rights reserved
Accessibility Policy | Privacy Policy

COPY

C.3 Pet Food Sample Submission Form

Pet Food Label Guarantee Sample Submission Form

Vermont Agricultural and Environmental Laboratory

163 Admin Drive, Randolph Center, VT 05061

Customer Information

Name:	
Company Name:	
Address:	
Phone:	
Email:	

Sample Information

Product Name/Recipe	Is sample baked (Yes or No)	Sample Number (lab use only)	Analyses (lab use only)				
			Protein	Fat	Fiber	Moisture	Ash
			Protein	Fat	Fiber	Moisture	Ash
			Protein	Fat	Fiber	Moisture	Ash
			Protein	Fat	Fiber	Moisture	Ash
			Protein	Fat	Fiber	Moisture	Ash

Note: Please be sure that each sample size is at least 3 ounces, in a zipper baggie or original packaging, and, if submitting more than one sample, that each sample is in a separate bag.



Revised 04-2019

UNCLAS

VAEL Quality Systems Manual			Page 48 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

Appendix D: Calibration Procedures

D.1 Support Equipment

All equipment outside of operational tolerances is deemed defective and must be clearly labeled as “out of service” until it can be repaired. Once repair is complete and demonstration that the instrument is operating within tolerances is documented (recorded in laboratory notebook) then the instrument may be placed back in service. If it is unable to be repaired, it will be clearly marked for disposal.

D.2 Thermometers

Thermometers used in the Laboratory are calibrated prior to initial use or annually against a NIST-traceable thermometer. The NIST thermometer is re-certified by Thermco Products Inc. (Lafayette, NJ) annually. Correction factors are required when NIST and laboratory thermometers differ by 0.2°C or more. Correction factors are noted on thermometers. Correction factors, date calibrated, temperatures of both thermometers and thermometer serial numbers are documented in an electronic logbook on the VAEL SharePoint. Laboratory thermometers with correction factors of 2.0°C or more are taken out of use and replaced. Infrared thermometers are certified annually by an ISO 17025-certified calibration service.

D.3 Refrigeration / Freezer Units

Refrigeration and freezer temperatures are checked on days the laboratory is open in accordance with SOP 1.3. Temperatures are recorded on a log sheet attached to each unit and should be 0-6 °C for refrigeration units and -15 °C or colder for freezers. Specific methods preservation requirements outside of these ranges are noted on the log sheet. Thermometers are submersed in an appropriate solution within each unit. If temperatures exceed these limits the unit is monitored for corrective action. If temperatures remain outside established limits, then equipment is taken out of service.

Dairy refrigerators (0-4.5°C) and freezers (-15.0°C or below) are checked AM/PM of each business day. Each refrigerator has at least two thermometers, (top and bottom shelves), large refrigerators have three thermometers.

D.4 Incubators/Water Baths/Ovens/Dry Incubator Blocks

Dairy and e-Coli incubator temperatures (top and bottom of each unit) are recorded AM/PM daily (at least 4 hours apart) in a log. Temperatures must remain within a method-specified range. Oven temperatures for tests requiring a specified temperature are checked each day of use. The Mercury Sample digestion water bath temperature ($95^{\circ} \pm 2^{\circ} \text{C}$) is checked and recorded at the beginning and end of the digestion. The Delvotest water bath temperature $64^{\circ} \pm 2^{\circ} \text{C}$ is checked and recorded in the analysis spreadsheet at the beginning of analysis. The Alkaline Phosphatase dry incubator block temperature ($35^{\circ} \pm 1^{\circ} \text{C}$) is checked and recorded in the logbook at the beginning of analysis.

D.5 Balances

VAEL uses factory-calibrated and NIST-certified balances. Calibration of analytical balances is performed annually by an ISO 17025 certified calibration service. When a new balance is purchased, its calibration is verified using a set of NIST traceable Class 2 weights prior to being placed into service.

Balance calibrations are verified by the analyst on days of use with NIST traceable Class 2 weights. Analysts verify the check has been completed for the weight range they are utilizing before use.

VAEL Quality Systems Manual			Page 49 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

Balance checks are recorded either in a bench sheet or logbook. Balance checks include date and time, initials, balance number, serial number of the weight kit used, nominal value of weight, measured value of weight. When measurement falls outside of acceptable range, balance is recalibrated. The weights are sent biennially to an ISO 17025 certified calibration service for verification. A second set of weights has been purchased for use when others are sent for verification.

D.6 Automated Pipettes and Dispensing Devices

All multi-volume dispensing devices are checked quarterly. Records are kept in a spreadsheet on the VAEL SharePoint (SharePoint- Quality Assurance\Calibration Records\pipette calibrations). These devices are checked/calibrated with the solvent they measure, typically water, at designated minimum and maximum volumes, with 10 measurements at each point. The measurements are weighed, and the volume calculated using the temperature corrected density of the solvent.

Automated multi-volume dispensing devices are uniquely labeled with a letter to indicate the section of the lab the device is used in followed by a number.

Organics Section: O##

Nutrients Section: N##

Metals Section: M##

Wet Chem: W##

D.7 Computer Software

Computer software is purchased either to support new instrumentation, to upgrade the performance of existing equipment or to manage the tracking of data. Software manufacturer validation is kept on file with the instrument.

VAEL Quality Systems Manual			Page 50 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

Appendix E: Internal Audit Template:

VAEL SharePoint \ Quality Assurance\Internal Audits\2020_InternalAuditWorksheet.docx

Vermont Agriculture and Environmental Laboratory
 163 Admin Drive
 Randolph Ctr, VT 05061

VAEL Internal Audit Report

Laboratory Section:
Technology:
Analysis:
Auditor:
Employees Present for Audit:
Date of Audit:

To be completed before laboratory audit:

Technical Overview: Please schedule time with the Technical Director and/or QA officer of the section prior to the audit to learn about on-going or specific issues that may be affecting this section.

Comments:

Irregularity Reports and Corrective Actions: Please contact the section Technical Director and/or QA officer to check whether this lab section been issued any directives to complete irregularity reports or corrective actions in the past year. If so, please choose up to three for review.

Criteria:	Yes	No	Comments:
Were there Corrective Actions in this section during the past year?			
Has the analyst responded?			
Were the root causes determined?			
Were measures taken to address the root causes?			
Were the reports completed and closed?			
Were follow-up reviews conducted after at least 3 months to verify the			

[https://vermontgov.sharepoint.com/teams/AGR-VAEL/QA/Internal Audits/2020_InternalAuditWorksheet.docx](https://vermontgov.sharepoint.com/teams/AGR-VAEL/QA/Internal%20Audits/2020_InternalAuditWorksheet.docx)
 Page 1 of 8

COPY

Appendix F: Corrective Action Investigation Report

Corrective-Action-Investigation-(CAI)-Form → Page 1 of 1

Corrective-Action-Template.docx

Type-of-Issue: → Analytical → → Quality-Sys → → Process

Date-Opened:κ	Date-Due:κ	Date-Closed:κ
<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
Opened-by:κ	Assigned-to:κ	Reassigned-to:κ
<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>

A. → Brief-Description-of-Issue:

B. → Probable-Causes: (please list from most to least probable)

1. → There an issue with the batch-QC.
2. →
3. →

C. → Outline-of-investigation-to-be-done: (please list in order of operation)

1. → Check the batch-QC.
2. →
3. →

D. → Results-of-investigation: (please attach data, photos, and other supporting documentation, as needed)

1. →
2. →
3. →

E. → Outline-of-corrective-action(s)-to-be-taken: (please attach data, photos, and other supporting documentation, as needed)

F. → 3-month-follow-up: (please describe the effectiveness of corrective measures at least 3 months post closure)

G. → Closing-Sign-off:

The undersigned verify that the root causes of the findings in this Corrective Action have been identified and addressed. All necessary updates and changes have been made to the VAEL Quality System Manual, Standard Operating Procedures and other laboratory documentation, as required by all accrediting agencies.

a. → Assigned-Staff: → → → → →	Date: →
b. → QA-Officer: → → → → →	Date: →
c. → Lab-Director: → → → → →	Date: →

Vermont Agriculture and Environmental Laboratory (VAEL)
163 Admin Drive, Randolph Center, VT 05061

COPY

VAEL Quality Systems Manual			Page 52 of 53
Doc. No. QA-001.26 Revision No. 26	Approved By: John Jaworski Owner: David Crosby	Date: 2021-04-05 Date: 2021-04-05	Date Effective: 2021-04-05

Appendix G: Preventative Action Plan

SharePoint/QA/Preventative Action Plans/Preventative Action Template.docx

Vermont Agriculture and Environmental Laboratory
 163 Admin Drive
 Randolph Ctr, VT 05061

Preventative Action Plan

Opened by: _____

Date Opened:	Response Due Date (+ 2 weeks):	Date Closed:

Description of Laboratory Improvement Needed:

Recommended Preventative Action:

Supervisor Response:

