Minnesota Valley Testing Laboratories, Inc.

Quality Manual

Version: 2026-0

Effective: 02 March 2026

See page 39 for revision details.

MVTL's mission is to provide value to its customers through on-time, quality testing with friendly service!

Minnesota Valley Testing Laboratories, Inc. (MVTL)

Minnesota Divisions

MVTL - Corporate Headquarters, Chemistry (Inorganic and Organic) and Microbiology Laboratories
Building 2
1126 North Front Street
New Ulm, Minnesota 56073
(507) 354-8517
(800) 782-3557

MVTL - Agricultural Receiving and Laboratory
Building 1
1126 North Front Street
New Ulm, Minnesota 56073
(507) 233-7147
FAX (507) 233-7127

MVTL - Feed Laboratory
Building 1
1126 North Front Street
New Ulm, Minnesota 56073
(507) 233-7156
FAX (507) 359-1688

MVTL - Field Services
219 16th Street South
New Ulm, Minnesota 56073
FAX (507) 233-7109

Iowa Location

MVTL – Soil and Manure Receiving
1201 Lincoln Highway
Nevada, IA 50201
(515) 382-5486
(800) 362-0855
FAX (515) 382-3885

North Dakota Laboratory

MVTL – Inorganic, Limited Microbiology, Energy Laboratory and Field Services
2616 East Broadway Ave
Bismarck, ND 58501
(701) 258-9720
(800) 279-6885
FAX (701) 258-9724

REFERENCES

- ISO/IEC 17025:2017 and A2LA R204
- The NELAC Institute (TNI) Standard: 2016

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QUALITY POLICIES AND OBJECTIVES

Minnesota Valley Testing Laboratories, Inc. (MVTL) provides independent laboratory testing services to a wide variety of customers and is committed to providing quality analytical services to these customers.

MVTL's mission is to provide value to its customers through on-time quality testing with friendly service. To meet this goal, the Chief Executive Officer of MVTL has issued the following statements to communicate the importance of quality to the employees:

- We are committed to assuring that our analytical testing processes and support services meet the specifications published by national and international standard organizations (including TNI and ISO 17025) and regulatory agencies while meeting the specific needs of our customers.
- We expect the highest professional standards and practices by each individual employed by MVTL. Each individual has been provided the policies and procedures to aid them in meeting the standards to produce the highest quality data possible.
- Our commitment is to provide the highest quality services possible for maximum value to each and every customer as stated in our mission statement.
- We, the management, are committed to ensure compliance with the regulations and standards and to continually improve the effectiveness of our quality management system.
- Our personnel are committed to understanding our quality management system and implementing its policies and procedures as stated in our written quality management system. Personnel are also given the charge of correcting and improving this system as necessary.

1. INTRODUCTION

1.1 Minnesota Valley Testing Laboratories (MVTL) was established in 1951 as a dairy testing laboratory in New Ulm, Minnesota. Branch laboratories were added in Nevada, Iowa in 1967 and Bismarck, North Dakota in 1977. MVTL is an independent laboratory with no ties to the manufacturing of a product and is legally responsible for all activities it undertakes. It is a privately held corporation owned by Colleen Skillings, Michael Grob, Jerry Balbach.

1.2 MVTL provides a broad range of services to industry, federal, state and local governments in areas of dairy, food, agribusiness, energy, environmental monitoring, pollution control, regulatory compliance monitoring, and industrial process control. The activities at MVTL are designed to satisfy the needs of its customers. This is achieved by following the ISO 17025 Standard for the analyses accredited under the MVTL A2LA scopes 2459.01 and 2459.02; current TNI Standard for state and federal environmental regulations; principles of GLP, GCP and GMP, and other regulatory authorities.

1.3 Corporate offices for MVTL are located at 1126 North Front Street, Building 2, New Ulm, Minnesota. Two laboratories – Chemistry (both Inorganic and Organic) and Microbiology are located at the corporate office location (~34,000 square feet), Building 2. The Soil Fertility and Soil Characterization Laboratory and the Feed Laboratory are located at 1126 North Front Street, Building 1 (~30,000 square feet). The New Ulm Field Services department is housed at 219 16th Street South in New Ulm.

1.4 The Nevada, Iowa office is located at 1201 Lincoln Highway. This facility serves as a courier and sample collection hub. Customers use this facility for supply pick-up, sample drop off, courier scheduling and delivery of samples to New Ulm.

1.5 The Bismarck, North Dakota laboratory is located at 2616 East Broadway Avenue. This laboratory provides Inorganic Chemistry, some Microbiology, coal quality and overburden analyses. There is also a field service department at the Bismarck location.

1.6 Table 1 provides a list of routine laboratory capabilities for each laboratory. This list may be expanded to meet the needs of our customers, industry demands and regulatory requirements. All locations are under the scope of this Quality Manual.

Table 1
LABORATORY CAPABILITIES

New Ulm, MN Field Service Department	Monitoring Wells Sampling Wastewater Sampling Wastewater Flow Studies Landfill Gas Monitoring Surface Water/Lake Sampling Soil Sampling Sewer Smoke Testing Equipment Rental Site Inspections Dust Sampling Aseptic on-site Sampling for Microbiological Analysis Meat Sampling following MICA Guidelines for Fat Claims
New Ulm, MN Microbiology & Food Laboratory:	Microbiological Examination of Drinking Water and Wastewater by EPA approved methods Microbiological Examination of Food, Dairy Products, Animal Feed and Supplements Pathogen Testing*: Salmonella, Listeria* and *E.coli O157:H7* and other STEC in Food, Dairy Products, Animal Feed and Supplements Live and Active Yogurt Cultures Customer Consulting, Diagnostic and Information Services Shelf-Life Studies Challenge Testing Cosmetic Challenge Studies Centers for Disease Control Approved Legionella Testing Next-Generation Sequencing
New Ulm, MN Soil Fertility and Characterization Laboratory	Soil Testing, including Particle Size, Cation Exchange Capacity, Sodium Adsorption Ratio and Moisture Nutrient Analysis, Plant Analysis Soybean Cyst Nematode Testing Corn Stalk Nitrate Analysis Lime Analysis

New Ulm, MN Inorganic Chemistry Laboratory	Analyses Under United States Food and Drug Administration (FDA) Good Laboratory Practices (GLP) following 21 Code of Federal Register (CFR), Part 58; Organization of Economic Co-operation and Development (OECD) Principles of GLP (1997); and Good Clinical Practices (GCP) VICH GL9 Metals by Inductively Coupled Plasma with Optical Emission Spectroscopy (ICP-OES) and Inductively Coupled Plasma Spectroscopy with Mass Spectrometry Detection (ICP-MS) Mercury by Cold Vapor Atomic Fluorescence (CVAF) Low Level Mercury by EPA 1631E Wastewater Analyses Surface Water, Drinking Water and Wastewater Analyses following EPA approved methods Nutritional Labeling and Proximate Analyses of Food, Ingredients and Finished Products Biosolid, Soil, Industrial Wastes by EPA Test Methods for Evaluating Solid Waste Methods (SW-846 – current version) Dry Milk Product Analyses and Complete Grading Physical Analyses Common Fluid Milk Analyses
New Ulm, MN Organic Chemistry Laboratory	PFAS by EPA 1633A and 8327 EPA Test Methods 624, 625 and 608 (current versions) SW-846 Methods 8015, 8260, 8270, 8081 and 8082 (current versions) Toxicity Characteristic Leaching Procedure (TCLP) Analysis for Organic Compounds Underground Storage Tank (UST): Gasoline Range Organics (GRO), Diesel Range Organics (DRO), Petroleum Volatile Organic Compounds (PVOC) usually benzene, toluene, ethyl benzene and xylenes (BTEX) by EPA 8015/8021 and Wisconsin Modified GRO and DRO methods 1, 4-Dioxane and Ethanol by GC/MS Minnesota Department of Agriculture List 1 Pesticide Studies under EPA GLP following 40 CFR, Part 160 Feed Analyses under FDA GLP following 21 CFR, Part 58 Fatty Acid Profiles, Cholesterol, Vitamins, Sugar Analysis, and Amino Acids in Foods and Feeds Allergen Testing Toxin Assay of Food, Feed and Pet Food Food Additives and Preservatives
New Ulm, MN Feed Laboratory	Feed and Pet Food Testing Proximate Analysis Trace and Macro Minerals and Nutrients Fat and Grease Quality Testing Particle Size Testing Mixer Studies Forage Testing Analyses following FDA GLP 21 CFR Part 58, OECD GLPs, and GCP VICH GL9 for Veterinary Products Manure and Fertilizer Analyses

Nevada, IA Laboratory	Receives samples for Soil Fertility Testing, Corn Stalk Nitrate Analysis, Soybean Cyst Nematode Testing Receives samples for Manure Testing
Bismarck, ND Laboratory	General Inorganic Chemistry including wastewater, drinking water and surface water following approved EPA methods from EPA, American Society for Testing and Material (ASTM) and United States Geological Survey Methods (USGS) Coal (Proximate, Ultimate and others) Waste Oil Analyses Overburden Analyses Shake Extraction for Water Metals by ICP-OES and ICP-MS following EPA, SW-846, ASTM and USGS SW-846 methods for solid waste analysis including TCLP and Synthetic Precipitation Leaching Procedure Analysis (SPLP) Soil, Biosolids, and Industrial Waste following SW-846 Field Services and Sampling Karl Fisher moisture Feed and Food Analysis

2. QUALITY MANAGEMENT SYSTEM

2.1 The MVTL quality management system is outlined in this manual, the Employee Handbook and MVTL standard operating procedures (SOPs). This quality management system is applicable to all activities conducted at MVTL's permanent facilities and in the fieldwork done by the MVTL field services departments. These documents are included as part of the training program and are made available to all employees. In some cases, these documents may be provided outside of MVTL upon request. Through annual training and meetings, MVTL communicates the expectations of management to meet the requirements of the quality management system to the staff. This communication ensures the analytical testing MVTL conducts is in conformance with the requirements of the regulations under which we work and meets the expectations of the customer.

2.2 Personnel are made aware of their roles and responsibilities in maintaining the quality management system and continuous improvement process through annual training and review. This review process helps to remind all employees of their part in the quality management system, the continuous improvement process, and any revisions that have occurred. Communication from management occurs through, but is not limited to, memorandums, training sessions, personnel reviews, e-mails, and verbal conversations with personnel. This communication continuously stresses the importance of meeting the customer's expectations while maintaining adherence to the statutory and regulatory requirements. Other modes of communicating the quality management system are participation of the managers in management reviews, internal and external audits, proficiency testing, corrective action procedures and preventive action processes.

2.3 Supporting documentation for the quality management system can be found in this manual, the Employee Handbook, MVTL SOPs and various external reference documents. MVTL internal documents are controlled and are made available through the Compliance Unit.

2.4 General roles and responsibilities of laboratory and quality management are summarized here. For complete descriptions and deputy roles, see the curriculum vita (CV) of each individual.

2.4.1 Executive Committee

2.4.1.1 Chief Executive Officer (CEO) of MVTL is responsible for all functions of the company - administrative, scientific, financial and sales and marketing activities.

2.4.1.2 Chief Financial Officer (CFO) directs the organization's financial planning and accounting practices as well as its relationship with lending institutions and the financial community either personally or through subordinate managers. This position is also accountable for the overall Human Resource functions including staffing, training, salary and benefit administrations and EEO compliance.

2.4.1.3 Chief Operations Officer (COO) has the responsibility for the overall operations of all the New Ulm MN, Bismarck ND and Nevada IA facilities. This includes oversight to ensure that analytical work meets objectives for corporate standards of quality, service and customer satisfaction by managing all the logistic and laboratory operations. Maintenance Department in New Ulm reports directly to the COO.

2.4.1.4 President oversees and performs sales, marketing and project management for the Minnesota, Iowa, North Dakota and Wisconsin locations.

2.4.2 Laboratory Production

2.4.2.1 Production Director of the Microbiology Laboratory: The responsibility for the overall operations and quality of data generated in the New Ulm Microbiology Laboratory lies with the Production Director of the Microbiology Laboratory. They oversee these operations to ensure that analytical work meets the objectives for corporate standards of quality, service and customer satisfaction. The Production Director is expected to manage resources such that sufficient qualified personnel and equipment are available to meet company needs. In the absence of a Microbiology Laboratory Manager, the Production Director of the Microbiology Laboratory may also approve and sign reports.

2.4.2.2 Production Director of the Chemistry Laboratory: The responsibility for the overall operations and quality of data generated in the New Ulm Chemistry Laboratory lies with the Production Director of the Chemistry Laboratory. They oversee these operations to ensure that analytical work meets the objectives for corporate standards of quality, service and customer satisfaction. The Production Director is expected to manage resources such that sufficient qualified personnel and equipment are available to meet company needs. In the absence of a Chemistry Laboratory Manager, the Production Director of the Chemistry Laboratory may also approve and sign reports.

2.4.2.3 Bismarck Laboratory Director: The responsibility for the overall operations and quality of data generated in the Bismarck Laboratory, including Bismarck Field Services, lies with the Bismarck Laboratory Director. They oversee these operations to ensure that analytical work meets the objectives for corporate standards of quality, service and customer satisfaction. The laboratory director is expected to manage resources such that sufficient qualified personnel and equipment are available to meet company needs. In the absence of a laboratory manager, the laboratory director may also approve and sign reports.

2.4.2.4 Laboratory Management: The laboratory managers are responsible for the overall laboratory operations of the laboratory they manage: the quality of data generated; implementing quality assurance programs; maintaining necessary certifications and accreditations; personnel and training; equipment; laboratory purchases; analysis and reporting; and safety. The managers also perform customer service duties as necessary to assure customer satisfaction.

2.4.2.4.1 Assistant Managers and Laboratory Supervisors: The assistant managers and laboratory supervisors serve as backup for the managers of the area they serve.

2.4.2.4.2 Laboratory Personnel: These individuals report to the laboratory manager of their area. Their responsibilities include assuring the quality of all the tasks they perform and the data they generate. It is their responsibility to ensure the accuracy of the work they complete while maintaining conformance with the requirements of the quality management systems described in this manual.

2.4.2.5 For the assignment of technical director and deputy technical director's status, check the organization chart and CVs.

2.4.3 Compliance Unit

The Compliance Unit is responsible for the oversight of the MVTL quality management system and functions as the quality unit for regulated work. The Compliance Unit monitors analytical work to assure facilities, equipment, personnel, methods, practices, records and controls are in conformance with regulations and guidance documents (federal, state, OECD, ISO, GLP, GCP, GMPs), TNI (The

NELAC Institute - NELAP National Environmental Laboratory Accreditation Program) and ISO 17025. This includes management of the processes for document control, records control, internal audits, management reviews, out-of-specification investigations, and corrective and preventive action processes. Additionally, the Compliance Unit reviews and approves all change control records, investigations of nonconforming analytical test results, equipment qualifications, method validations, and environmental monitoring activities. The Compliance Unit also is involved in the review and approval of all laboratory data for regulated product testing.

2.4.3.1 Compliance Director (Quality Manager): The Compliance Director is responsible for assuring that the quality management system is established, implemented and maintained in conformance with applicable regulations, accreditation standards and customer requests and contracts. As part of this oversight of the quality management system, changes and improvements to the quality management system are recommended and encouraged. The Compliance Director is responsible for maintaining the currency of this Quality Manual.

2.4.3.2 The Compliance Director reports directly to the Executive Committee. Through this line of supervision, the Compliance Unit is able to perform assessments independent of the areas where the assessment is taking place. While the Compliance Unit is the host for any outside assessment, they do not routinely have direct contact with the customers for routine laboratory analyses.

2.4.3.3 The Compliance Director is responsible for the oversight and review of QC data. This is accomplished through the review and approval of SOPs and forms that contain specific data limits and the periodic review of data during audits and for specific projects.

2.4.3.4 As change control happens, the Compliance Unit is responsible for approving all changes that occur. This includes review and approval of SOPs (with the exception of SOPs and other documents used solely for GLP studies), forms, manuals such as this Quality Manual, training presentations, method validations/verifications, instrument qualifications and other documents of the quality management system.

2.4.3.5 Qualifications for personnel in the Compliance Unit include a strong background in Chemistry or Microbiology and regulatory requirements. Ideally, personnel hired for the Compliance Unit come from the laboratory. This gives them a general knowledge of MVTL's laboratory policies and procedures, and a basic knowledge of the analytical work they are to review.

2.4.3.6 Quality Assurance Auditors: The auditors working under the Compliance Director are responsible for monitoring the processes and data quality for compliance to the applicable regulations, standards and MVTL policies and procedures. Any deviations or issues of non-compliance are reported to management. The auditors also review data and other documents of the quality management system.

2.4.4 Logistics Department: The logistics department provides support services for the MVTL laboratories. These support services include shipping and receiving, courier services, sample receipt, and log-in.

2.4.5 Purchasing and Supply Management: The Purchasing and Supply Management department provides support services for the MVTL laboratories by purchasing and maintaining all reagents, chemicals, supplies and consumable equipment used by the laboratories.

2.4.6 Cost Analysis and Controller (Accounting) Services: The accounting department oversees invoicing, accounts payable, accounts receivable and all other financial processes. The Controller reports directly to the CFO and provides support for the entire company.

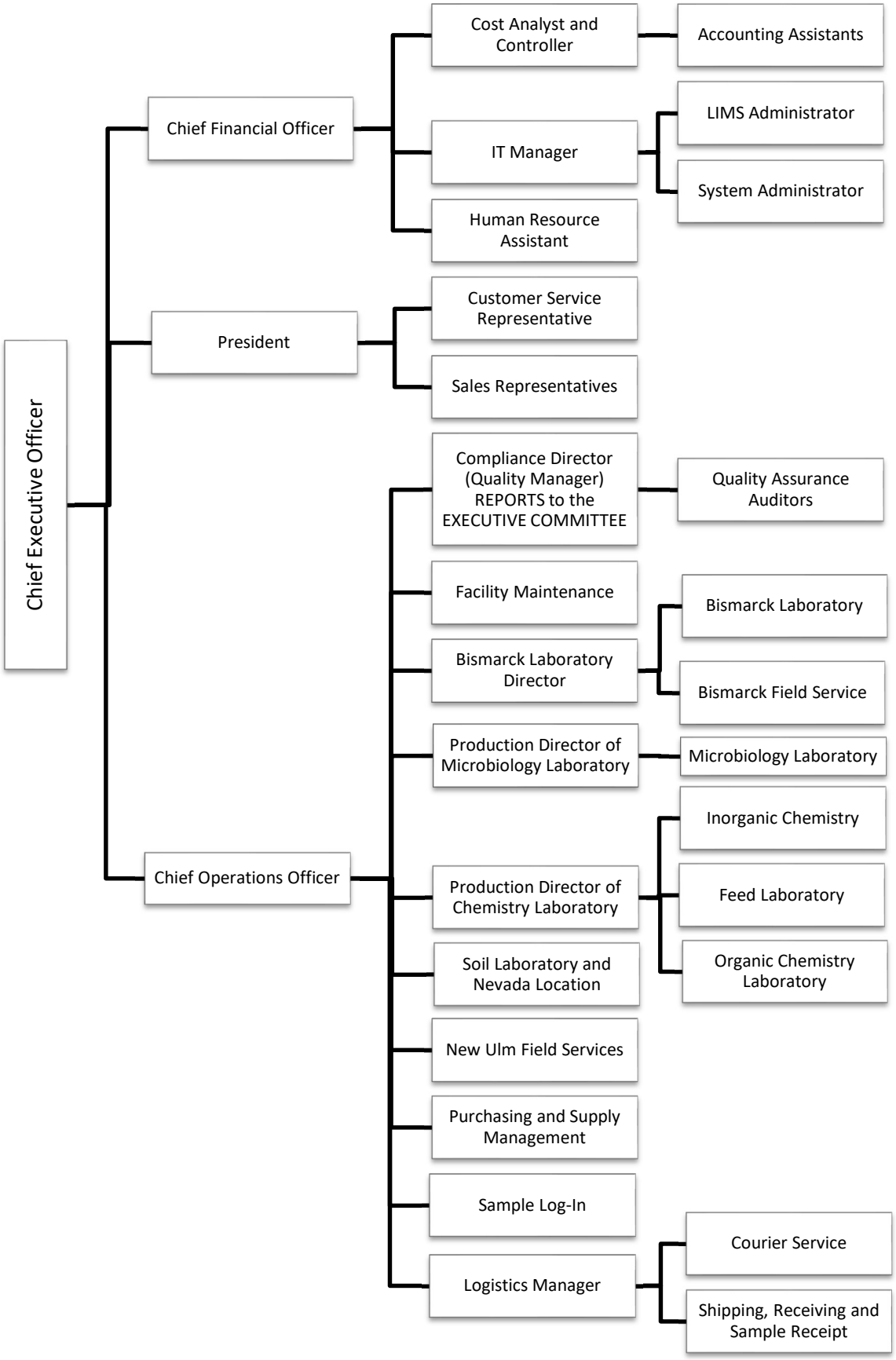
2.4.7 The Information Technology (IT) department is under the IT Manager and consists of Laboratory Information Management System (LIMS) and System Administration. IT is responsible for maintenance of all computers and software used by MVTL. LIMS maintenance and updates are also the responsibility of IT with any changes or special requests for customers included. IT also reports directly to the CFO and provides support for the entire company.

2.4.8 The management hierarchy for analyses and projects falling under GLP (both FDA and EPA), OECD, GCP VICH GL9, and GMP regulations follow a slightly different scheme. The appointed Project Manager is under the direct oversight of the COO with the Compliance Unit serving as the Quality Assurance Unit.

2.5 The organizational chart at the end of section 2 shows the hierarchy at MVTL. For a complete organizational chart with each staff member's name, contact the MVTL Compliance Unit.

2.6 By following the quality management system outlined in this manual, upper management maintains the integrity of the quality management system when changes to personnel, structure, policies and procedures are made. The determination of reporting lines and number of personnel reporting to the head of any area is determined by the complexity and diversity of analyses and operations conducted under that particular supervisor or manager.

2.7 The personnel at MVTL, management, laboratory and support services, are given the authority and the resources to carry out their duties, including the implementation, maintenance and improvement of the quality management system. Both managerial and technical personnel are involved in identifying departures from the quality management system and written procedures which are then documented following the corrective action procedure described in SOP 10-10002, "Corrective Action". All MVTL employees are responsible for halting work and notifying management when a non-conformance affects the results that are being generated. These non-conformance issues may be analytical in nature or an issue resulting from a support service. At that time, the area management will assess the non-conformance by investigating the problem and developing corrective action to fix the problem. Once the problem is assessed and corrected, work can be resumed.


Chief Executive Officer
Chief Financial Officer
Cost Analyst and Controller
Accounting Assistants
IT Manager
LIMS Administrator
System Administrator
Human Resource Assistant
President
Customer Service Representative
Sales Representatives
Chief Operations Officer
Compliance Director (Quality Manager) REPORTS to the EXECUTIVE COMMITTEE
Quality Assurance Auditors
Facility Maintenance
Bismarck Laboratory Director
Bismarck Laboratory
Bismarck Field Service
Production Director of Microbiology Laboratory
Microbiology Laboratory
Production Director of Chemistry Laboratory
Inorganic Chemistry
Feed Laboratory
Organic Chemistry Laboratory
Soil Laboratory and Nevada Location
New Ulm Field Services
Purchasing and Supply Management
Sample Log-In
Logistics Manager
Courier Service
Shipping, Receiving and Sample Receipt

3. CHANGE CONTROL

3.1 The quality management system at MVTL must keep up with the changing laboratory climate, yet change must be controlled to avoid unintended consequences. Effective change control results in continual improvement of the quality management system. To accomplish effective change control, MVTL has put in place processes such as document change and control (MVTL SOP 10-10013 "MVTL Document Approval and Control"), instrument qualification (MVTL SOP 10-10031 "Laboratory Instrument Qualification") method validation, verification and/or method transfer (MVTL SOP 10-10041 "Analytical Method Validation and Verification") and facilities change control (MVTL SOP 10-10042 "Change Control of Facilities").

3.2 Change control is accomplished by requiring review and approval by management and the Compliance Unit. Once the change to the policy and/or procedure has been made, it must undergo approval for technical content. Once the technical content has been reviewed and approved, it is then sent to the Compliance Unit for approval of the content for regulatory requirements. Final approval is then given after a review by senior management assuring it will meet the needs of MVTL. See the above referenced SOPs for additional information.

4. DOCUMENT CONTROL

4.1 At MVTL, both external and internal documents are controlled to assure that only the most current, approved version of these documents are used. External documents include regulations and standards, reference methods, software, specifications, and instructions not generated by MVTL. Lists of external documents used can be found in each SOP.

4.2 Internal documents are documents generated by MVTL for use in the quality management system. These include the Quality Manual, Employee Handbook, Chemical Hygiene Plan, Safety Manual, SOPs, Training Presentations, and Forms. All internal documents used at MVTL are reviewed and approved for use by management. They are reviewed at a frequency stated in SOP 10-10013 "MVTL Document Approval and Control" and revised as needed to assure continued suitability and compliance with applicable regulations and standards. An index of SOPs and Forms is maintained by the Compliance Unit. In addition, the Microbiology Laboratory maintains an index of the media preparation sheets they are currently using in the media preparation area.

4.3 See SOP 10-10013, "MVTL Document Approval and Control", for information on distribution of internal documents within MVTL.

4.4 SOPs and Forms are available online to all personnel. If an area or laboratory needs a paper copy of an SOP due to the unavailability of the online folders, they contact the Compliance Unit. A paper copy is then made and marked with the area of use or person it is assigned to. A record of the copy is made in the Compliance Unit SOP file.

4.5 As internal documents are revised, each area is responsible for destroying or removing from use all the copies of the obsolete document. The destruction of the document is documented by the area and forwarded to the Compliance Unit. The Compliance Unit then updates the copy records as necessary. The Compliance Unit marks the original copy of the document "Obsolete" with the date of obsoletion noted. The person marking the document then initials and dates the comment and prepares the document for archiving. It is the responsibility of the Compliance Unit to remove the online copy of the document from the shared drive.

4.6 Media Preparation Sheets (MPS) are assigned a unique alphanumeric designation and are reviewed and approved according to SOP 10-10013 (MVTL Document Approval and Control) . The original approval sheet for each MPS is maintained in the Compliance Unit (the actual working forms used in the laboratory are maintained in the laboratory records). It is the responsibility of the Microbiology Laboratory to assure that only current MPS are used and that the obsolete copies of these forms are removed from use.

4.7 The process for revising an internal document is the same as issuing the original document. The final revised edition of the document must be reviewed and approved by management and the Compliance Unit. Those revising and reviewing the document have access to pertinent background information and the reason for previous revisions. The reason for revision is given on the document so that there is a history for the changes noted. Once the document is revised and ready to be issued, the revision number is changed and the document is given to management for approval.

4.7.1 For the most part, MVTL does not utilize handwritten changes for revision of documents; however, it does in some cases use handwritten changes to make minor grammatical corrections or corrections to the document. A correction to the document may include a change to bring the procedure into compliance with an official reference. Another reason for handwritten corrections is to make a correction in the procedure if there is a typographic error that would invalidate the procedure. When handwritten corrections are used to bring the document into compliance, a revision of the document must be started immediately and effective as soon as management approval is given. An alternative to immediate revision is the use of the MVTL SOP deviation procedure as noted in SOP 10-10029 “Documenting Deviations to MVTL SOPs (non-GLP Procedure)”.

4.7.2 The change would follow the procedure for making changes to original observations which would include a single line through the text to be changed, a reason and the initials and date of the person making the change. The correct text would then be added next to the original text. These handwritten changes must be made on the original document and must not in any way change the intent or interpretation of the document, except as noted above. The word processing copy of the document will be corrected so that the subsequent revisions will be correct. A corrected copy is then scanned into the online review folder and also distributed to those holding paper copies of the document.

4.8 Obsolete documents generated for the MVTL quality management system are scanned into the GLP Cabinet of the ImageQuest (IQ) document storage system. Most documents such as SOPs, CVs, internal audits, Quality Manuals, equipment registration records, and GLP/GCP VICH GL9 documents are maintained permanently at this time. External audits, proficiency testing studies, management reviews and certification records are kept as long as necessary according to the certification program that governs them. See MVTL SOP 50-10004, “Compliance Unit Records”, for additional information.

5. CONTROL OF RECORDS

5.1 Technical records are from the accumulation of technical data and information resulting from an analytical procedure. The control of these technical records is described in MVTL SOP 10-10039 “Electronic Archives in the ImageQuest Document System”. The recording and maintenance of original observations is covered in MVTL SOP 10-10004, “Documentation and Handling of Original Observations (Raw Data) and Records”.

5.2 At this time MVTL scans current technical records into the ImageQuest (IQ) (see SOP 10-10039 "Electronic Archives in the ImageQuest Document System"), but there are older records in paper form. Those records that are still being maintained according to SOP 10-10017, "Maintenance of the non-GLP Physical (Paper) Archives". These paper records are being destroyed as their retention times expire.

5.3 Record retention times for electronically archived records are noted in SOPs 10-10039 "Electronic Archives in the ImageQuest Document System". While these retention times are specified, other record retention times of our customers will be considered and honored, as long as necessary records are retained according to any regulatory requirement under which the record was generated.

5.4 Quality assurance records initiated and maintained by the Compliance Unit are described in SOP 50-10004 "Compliance Unit Records".

6. REVIEW OF REQUESTS, TENDERS AND CONTRACTS

6.1 See SOP 20-10002, "Contract Review, Approval and Retention", for the procedure to follow for contract review and approval. In summary, all proposed contracts are first reviewed by the CEO, President or if necessary, the corporate attorney. If changes are needed in the contract, the MVTL sales representative will notify the customer of the necessary changes. Once approved, the contract shall be signed by an officer of the company. Copies of all approved contracts are stored at the corporate headquarters in New Ulm. Upon expiration, they are scanned into the ImageQuest system and maintained for at least 5 years after the expiration date.

6.2 During the contract approval process, the applicable laboratory manager or their designee will evaluate the contract to assure that the specifications of the contract can be met. This review needs to verify that:

- The customer requirements are understood and can be met, including any certification requirements.
- MVTL will have the personnel and resources available to meet the customer's needs.
- The appropriate procedures and/or methods are in place and will meet the customer's needs.
- Turnaround times can be met.
- Any subcontract work is approved by the customer before the work commences.
- Exceptions to routine sample disposal and data archiving can be met.

6.3 Any contract conflicts or deviations from the requirements must be resolved between MVTL and the customer before the work commences; all resolutions must be acceptable to both MVTL and the customer. If a deviation is requested by the customer, MVTL will perform an evaluation to ensure that it will not impact the integrity of the laboratory or the validity of the results.

6.4 The contract is then reviewed with all personnel that will be involved in the contract work to assure that expectations and exceptions are communicated to those who will be carrying out the work. If the contract needs to be amended after the work has commenced, MVTL will repeat the contract review and communication process. Any deviations from the contract will be communicated to the customer by the sales representative or laboratory manager as the deviations occur.

6.5 All contract reviews and conversations with the customer will be documented and this documentation will be maintained with the contract or the pertinent report.

6.6 On a daily basis MVTL accepts samples for analyses that are not covered by a contract. At the time of receipt, the MVTL log-in staff reviews the analysis request form or the chain of custody that is

submitted with the sample. Upon review of this information, the customer is contacted for any discrepancy noted on the submittal information; these discrepancies and customer contact are noted on the forms that have accompanied the sample. This review is noted in LIMS with the log-in personnel's name or initials and date automatically being captured by LIMS.

7. SUBCONTRACTING OF ANALYSES

7.1 If MVTL finds it necessary to subcontract analysis covered under any accreditation it holds, every effort will be made to subcontract to an accredited laboratory. If there is no laboratory available that holds the same accreditation as MVTL, the customer will be contacted for advice.

7.1.1 The need to subcontract work will be communicated to the customer in writing, asking their written approval. This notification will be given via customer service contact; and facsimile or e-mail of the scanned signature can be used to gain the subcontract approval in writing.

7.2 For analyses that are subcontracted on a routine basis to meet the needs of our customers, there is no need for written approval. Any work that is routinely subcontracted would be covered in the contract and is noted on the report. MVTL does assume all responsibility for its subcontractor's work except in cases where a customer has requested a specific subcontractor be used and of which MVTL has not approved. MVTL maintains a list of approved subcontractors and a record of evidence of accreditation or MVTL approval.

7.3 In some cases, work is subcontracted between the New Ulm and Bismarck facilities. When analyses are performed at a location different from the receipt location, a comment will appear on the report for all analyses under the MVTL scopes for A2LA and TNI. For samples subcontracted to a non-MVTL laboratory the data will be reported in one of two ways. The data from the subcontract laboratory is reported with MVTL data in which case the analyst will be listed as "OL" in the analyst column on the report and a comment listing the subcontract laboratory will be added to the report. The second way is to attach the subcontract laboratory report to the MVTL report.

7.4 In either case, the report issued to the customer will have the name of the laboratory and the contact information for the subcontract laboratory listed in the narrative portion of the report, as necessary, by customer contract or regulatory requirement. In addition, the accreditation number will be included with the listing. In some cases, the subcontract report may be included with the MVTL report; a copy of the report is maintained by MVTL. In cases where the subcontract report is not included, this report will be maintained in MVTL's records and is available upon request.

8. PURCHASING OF SERVICES AND SUPPLIES

8.1 MVTL has policies and procedures for the selection and purchasing of services and supplies, as well as the receipt, storage, and consumption of supplies. These policies and procedures are covered in the following SOPs:

- 10-10006 – Documentation Procedures for Registration of Equipment and Instruments
- 10-10028 – Requisitioning Small and Large Equipment
- 30-15001 – Receiving Supplies into Inventory
- 30-15003 – Inventory Cycle Count
- 70-14002 – Vendor Qualification Process
- 70-14003 – Purchasing Supplies

- 80-10013 – Procedure for the Requisition of the Laboratory Supplies Using the Clear Spider Inventory System(Bismarck Location)

8.2 Critical supplies and supplies that affect the quality of the test are evaluated and approved before use. Measures taken to ensure the integrity of reagents and other supplies are described in the individual SOP. All records of the evaluation and approval are kept in the area of use.

8.3 MVTL uses a purchase order form when ordering equipment – see SOP 10-10028 "Requisitioning Small and Large Equipment." These records are reviewed and approved before they are forwarded to the vendor.

8.4 MVTL uses a supply request form when ordering supplies – see SOP 10-10038 "Requisitioning Supplies." These records are reviewed and approved before the requests are processed.

8.5 MVTL purchases services and supplies from approved vendors only. Our vendors are approved and evaluated according to SOP 70-14002 "Vendor Qualification Process". The list of approved vendors is available through the purchasing department.

9. SERVICE TO THE CUSTOMER

9.1 MVTL allows customers, third party auditors and regulatory agencies to visit and inspect MVTL's performance in relation to the work performed for them. During these visits MVTL assures customer confidentiality is not compromised by storing confidential material in areas not visible to the visitors. Employees are aware of the seriousness of disclosing customer information to those outside the company. SOP 10-10009 "Procedure to Follow for an On-site Inspection/Audit" describes the procedure for on-site visits by regulatory agencies and customers. During these inspections MVTL seeks both positive and negative feedback from the auditor/inspector. In addition to this feedback, the MVTL sales personnel gather feedback from surveys and sales interaction with the customers. This feedback is analyzed and used to improve the quality management system, testing procedures and customer service.

9.2 Customers may make special requests for reporting, whether it is a special format, or a discontinuation of testing previously requested. MVTL has adopted the following policies relative to such requests:

- MVTL will customize reports as the customer requests. This may include reporting results on separate pages and sending courtesy copies. The customer file must retain clear written documentation of the customer request. All customizations must still follow any certification and accreditation requirements.
- If the customer wishes to halt an analysis previously requested, for any reason, the direction from the customer must be in writing and retained in the customer file. Subject to applicable law, MVTL will immediately discontinue the analysis for that analyte, and will not for any purpose perform any additional analysis on the analyte. Any analyses that have been completed and are ready to report will be reported to the customer. Any testing that has been started and/or completed is subject to applicable charges.

9.3 All requests for changes, as outlined in this policy, must be in writing from a responsible (authorized) party of the customer's company. An e-mail from this person is acceptable. All of the samples, raw data and documentation of this request will be retained according to MVTL sample retention (SOP 40-10010 "Sample Storage and Disposal for the Microbiology, Feed, Organic Chemistry, Inorganic Chemistry and Bismarck Laboratories") and data storage policies (SOP 10-10039 "Electronic Archives in

the ImageQuest Document System"). In all cases in which a customer requests discontinuance of testing, MVTL management must be notified in writing.

10. COMPLAINTS

10.1 Any complaints received from our customers are recorded by the person taking the call using form 10-90002 (Complaint Form). Once the form is completed, it is reviewed to determine if it is a valid complaint; for valid complaints, corrective action is put into place to resolve the problem; for invalid complaints, the reason for being considered invalid is documented and reviewed. This process is covered in MVTL SOP 10-10011 "Complaints and Customer Feedback".

11. CONTROL OF NON-CONFORMING WORK

11.1 MVTL's procedure for correcting and preventing non-conforming work is described in MVTL's SOP 10-10002 ("Corrective Action") and 40-10014 ("Investigation of Out of Specification (OOS) Results for Customer Samples"). All personnel at MVTL are given the responsibility for determining when work needs to be stopped due to non-conformance. When a non-conformance occurs that requires work to be halted, the applicable laboratory manager is notified for assessment of the problem. Depending on the nature of the non-conformance, senior management and the Compliance Unit may be notified. If the problem is such that senior management and the Compliance Unit are involved, the responsibility for determining when work can continue is based on their decision.

11.2 When the results or analytical procedures do not conform to MVTL written policies and procedures or the requirements of the customer, work is immediately halted, and management is notified. The significance of the non-conformance is evaluated, including the determination of the number of analyses and samples that are affected. If it is determined that the testing process is the problem, it is corrected at the time of the discovery and a decision is made to determine the acceptability of the results generated with the non-conforming procedure. If the results are deemed unacceptable and have been reported to the customer, the customer is notified in writing with an explanation of the non-conformance. An amended report will accompany this written notification.

11.3 If an evaluation indicates that the non-conformance could recur or there is doubt about the compliance of the operations at MVTL, corrective action is implemented.

12. IMPROVEMENT

12.1 MVTL provides evidence of their commitment to continually improve the effectiveness of the quality management system through the use of quality policies, quality objectives, audits, data review, corrective and preventive actions and management reviews.

13. CORRECTIVE ACTION

13.1 MVTL's procedure for documenting corrective action is described in SOP 10-10002 "Corrective Action". When non-conformances are found, corrective action is taken to prevent recurrence of the problem. All employees at MVTL are responsible for notifying management and halting work if non-conformances occur. The manager of the area where the non-conformance occurs is responsible for assessing the problem and taking appropriate action as dictated by SOP 10-10002. Corrective action taken must be appropriate for the magnitude of the problem and the likeliness of the problem reoccurring.

13.2 When corrective action has been assigned, the investigation of the problem will include a root cause analysis. Once the root cause is determined, potential corrective actions can be decided. The action

most likely to prevent a recurrence and eliminate the problem will be implemented. Any changes made as a result of the corrective action are documented. All corrective actions are verified for effectiveness by an audit assigned by the Compliance Director. When the identification of a non-conformance or a departure from set procedures casts doubt on MVTL's compliance with its policies and procedures or outside standards, an internal audit is scheduled as discussed in section **15. INTERNAL AUDITS**.

13.3 While the goal is to report only results that have all quality control parameters within the acceptance limits, there are times when results will be reported even though the quality control parameters are not met. See SOP 10-10002 "Corrective Action" for the procedure in handling these quality control failures. When a quality control failure occurs and the data is reported, the data is qualified to meet the needs of the program requirements or end data user. At times, there are customers who wish to have these qualifiers removed from their reports. If the sample results are being reported under no program requirements, the customer will be accommodated as long as the request is in writing from the customer and is maintained in their file; if the results are being reported under a program requiring these qualifiers, the qualifiers cannot be removed from the report.

13.4 Corrective action documentation is maintained by the Compliance Unit. These records are scanned into the GLP cabinet of ImageQuest and maintained for at least 5 years. The records include the investigation, root cause analysis, action to be taken and the follow-up audit documentation.

14. PREVENTIVE ACTION

14.1 SOP 10-10012 "Preventive Action and Action Planning" covers the procedure for preventive action. Preventive action is taken to eliminate potential problems and identify potential sources of adverse events. It is a proactive process for improvement rather than a reaction to a problem or complaint. Preventive actions are discussed during the management review and the effectiveness of preventive actions taken is determined.

14.2 Once an opportunity for improvement is identified through a risk assessment, a plan of action is determined with tasks assigned to specific personnel. The documentation of action taken for preventive actions is stored in the Compliance Unit until it is archived into the GLP cabinet of the ImageQuest system.

15. INTERNAL AUDITS

15.1 The Compliance Director schedules audits for both the quality management system and the testing activities at MVTL. Using a risk-based assessment and by adhering to the different requirements of the accreditation programs under which MVTL operates, audits are scheduled as follows: all sections of the quality management system are covered annually, as well as each technology under the MDH MNELAP-TNI and A2LA-ISO accreditation. All other analyses are covered on a three-year cycle as time allows. Audits may be conducted more often as necessary or as requested by laboratory management. These audits will be assigned to Compliance Unit personnel, but personnel independent of the area being audited may conduct audits after adequate training.

15.2 Upon completion of an audit, all findings will be documented in an audit report. Critical and major findings will also be issued as a corrective action to the appropriate laboratory manager, area supervisor or technician. Minor findings are reported in the audit report. When the audit report is issued, the person receiving the audit report will take the necessary action and document the action taken in the response section of the audit report. As appropriate, findings can be forwarded by the recipient to other personnel for resolution if someone else is a better fit for the resolution. If an issue of non-compliance is found that will affect the quality of an analysis (critical finding) the appropriate manager will be notified for

immediate corrective action. If it is found that the issue of non-compliance has affected any analytical result, the customer will be notified immediately, and an amended report issued.

15.3 The Compliance Unit will maintain records of each audit. The audit report will include the phase audited, the auditor, the dates of the audit and a summary of the audit; audits conducted for a GLP/GCP VICH GL9 study will include the study information. Any corrective action (CA) forms issued as critical or major findings will be referenced in the audit report. CA forms include the CA number, date the CA is initiated, the reason the CA is issued, the name of the auditor (CA initiated by), the department the CA is issued to, the audit number, the critical or major finding, the due date for the CA response and who the CA is assigned to. Suggestions and recommendations are noted on the audit report and must be acknowledged by the person responding to the audit. Comments are also noted on the audit report. These include any findings that were corrected either during the audit or before the audit report was issued; no response is necessary for these comments. See SOP 10-10002 "Corrective Action" for responding to the CAs issued from an audit and SOP 10-10020 "Responding to Internal and External Audits" for responding to an audit.

15.4 Any actions taken in response to audit findings are verified upon completion to check for implementation and effectiveness. If the action was ineffective or not implemented, it is noted on the audit report and a CA form is issued to the person responsible for completing the corrective action. See section **13. CORRECTIVE ACTION** for additional information.

16. MANAGEMENT REVIEWS

16.1 MVTL's management meets at least once every year to review MVTL's quality management system, discuss trends, changes, or improvements to the system and evaluate its effectiveness. This review includes a review of:

- Changes in internal and external issues that are relevant to the laboratory
- Fulfilment of quality policies and objectives
- The suitability of policies and procedures
- The outcome of recent internal audits
- Corrective and Preventive actions
- Assessments by external bodies
- Changes in the volume and type of the work
- Customer and personnel feedback
- Complaints, internal and external (deemed valid by senior management)
- Effectiveness of implemented improvements
- Adequacy of resources
- Risk assessments and results
- Validity of results (data integrity and data quality)
- Proficiency testing
- Determination of action items and wishlist items

Reports from laboratory management containing the above-mentioned items are submitted to the Compliance Director before the meeting. This information is then organized and distributed to the meeting attendees before the meeting.

16.2 In each of the sections, but especially for Non-Conformances, Customer and Personnel Feedback, and Complaints, managers must consider and note any trends within their departments.

16.3 Additionally, the records of non-conformances (OOS Forms and Corrective Action Forms), and Customer and Personnel Feedback and Complaints (Complaint Forms) for each of the previous three years will be presented at the meeting and evaluated for trends within these records.

16.4 During the meeting the attendees will sign the attendance sheet so that a record is maintained of attendance. The CEO, COO, President, and Compliance Director are required to attend the annual management review. Laboratory managers are encouraged to be in attendance to present their reports and offer changes and improvements to the quality management system. The Compliance Director will preside and one or more of the attending members will keep minutes. Findings from the management review and new action items, with responsibility and due dates assigned, are established and documented in the minutes. Minutes of the meeting are inserted into the final copy of the booklet after they are approved by the CEO, COO, President, and Compliance Director. Following the meeting, the approved minutes and new action items are sent to the attendees. Depending on the findings or action items, additional meetings may be held to review these items and assign timelines and responsibilities. The Compliance Director will report the status of these findings or action items to Executive Management as necessary to ensure that these items are completed within the agreed timelines.

16.5 MVTL works to resolve the tasks and responsibilities by holding operations meetings. At these meetings, the timelines that are set in the management review are reviewed and noted when the task is completed. Also, these meetings serve to communicate policies, as reminders of policies and procedures, and as training for the operations managers attending these meetings. It also gives the managers an opportunity to explore ways to accomplish corrective action and to seek advice on interpretations of requirements from other members of the operations staff.

17. TECHNICAL REQUIREMENTS

17.1 Many factors determine the accuracy and reliability of the tests performed at MVTL. These factors include contributions from the following:

- **PERSONNEL**
- **ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS**
- **TEST METHOD AND METHOD VALIDATION**
- **EQUIPMENT**
- **MEASUREMENT TRACEABILITY**
- **SAMPLING**
- **HANDLING OF SAMPLES**

17.2 The extent to which these factors contribute to the total uncertainty of the measurement may differ considerably between tests. MVTL takes into account all the above factors in developing procedures, training and determining necessary qualifications of personnel, and the selection of equipment used. For the actual calculation of measurement uncertainty, see MVTL SOP 40-10011 “Calculation of the Estimation of Measurement Uncertainty”.

18. PERSONNEL

18.1 MVTL employees are the key to MVTL's success. Each employee brings a broad range of education and abilities into their daily tasks and the services offered to our customers. The laboratory meets all local, state and federal requirements for hiring specific laboratory personnel. The MVTL technical staff includes chemists, microbiologists, and soil scientists, with support staff in sales and marketing, field services, accounting, and computer science. Together, the technical and support staff play an active role in assuring the high quality of standards are met for MVTL and our customers.

18.2 The training program at MVTL consists of training in basic laboratory skills, analyte specific procedures, equipment usage, company policies, safety, and regulatory procedures. The management staff of MVTL has established various personnel policies designed to enhance the quality of work produced by the employees. In-house training seminars are held for a variety of topics, including safety, hazardous material handling, regulatory updates, and other policies. In addition, all employees are encouraged to be active participants in professional societies and to further their education through seminars, laboratory related courses and other sources of continuing education. See MVTL SOP 10-10019 "Training Documentation" for additional information.

18.3 Annual training for customer confidentiality, ethics and data integrity, and regulatory requirements are completed either by training sessions or individual review of policies. With the annual review of policies and procedures, each employee must attest they have read, understood, and will follow the policies and procedures as written.

18.4 As new employees are hired, they are provided with a mentor for their training period. The mentor is someone MVTL's management considers competent and familiar with all SOPs, procedures, and policies in the area where the new employee is to work. The training period of a new employee lasts until management deems the new employee is proficient in the analyses they perform and authorizes the employee to conduct analyses without direct supervision. See MVTL SOP 10-10010 "New Employee Training" for the new employee training process. Proficiency in the laboratory must be shown with appropriate demonstrations of capability as defined in regulations, referenced methods and/or MVTL SOPs and policies. See SOP 40-10021 "Qualifying Laboratory Personnel for Laboratory Analysis."

18.5 Each employee's curriculum vitae (CV) describes the employee's responsibilities, educational background, and employment history. Each CV also has the employee's signature and initials to serve as the person's identity when signing or initialing records. Each CV also has the manager's signature to show that the CV is reviewed annually by both the employee and their manager. The CVs are maintained by the Compliance Unit with the employee's training documentation. CVs are available upon request.

18.6 Job descriptions kept by Human Resources list the minimum requirements and qualifications that management requires for any given position. Laboratory managers ensure individuals have the required knowledge, skills, and abilities to adequately perform their jobs. Laboratory personnel are selected and trained to ensure technical competency. Laboratory managers provide supervision by experienced personnel for new employees undergoing training. Training may include the complete SOP or only designated portions that employees are responsible for performing. Managers or their designee observe and evaluate the initial and ongoing competence of employees. The initial competence of an employee is noted by the signature of the employee, signature of the trainer, and authorization of the manager in the training record along with the date that the employee was authorized to begin work without supervision. Continued competence of staff is monitored using appropriate means.

18.7 Annually each laboratory employee (or work group) must show continued proficiency by either participating in a proficiency testing study or having at least four acceptable consecutive analyses of a laboratory control sample. While these are not the only way to demonstrate continued proficiency, these are the most common means used at MVTL. Other demonstrations of continued proficiency may include acceptable performance on blind samples, another initial demonstration of capability or analyzing a sample another analyst has analyzed and getting an acceptable duplication of the result. See SOP 40-10021 "Qualifying Laboratory Personnel for Laboratory Analysis" for ongoing demonstrations of capabilities.

18.8 Laboratory managers formulate goals with respect to education, training, and skills of the employee and develop training sessions to meet the employee's goals. Training records contain the documentation that each employee has the required knowledge, skills, and abilities to adequately perform their assigned tasks.

18.9 MVTL uses only personnel they employ or they have contracted. See Section 18.5 for information on employee CVs. Initial training records, which include authorization to perform the procedure without immediate supervision, are scanned into the GLP cabinet of the ImageQuest electronic archives as they are completed and reviewed by the Compliance Unit.

19. ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS

19.1 Procedures for the storage, use and disposal of chemicals, reagents and samples can be found in the Chemical Hygiene Plan. These procedures follow the regulatory requirements for chemicals. Safety data sheets (SDS) are maintained electronically in the ImageQuest system and are available to all employees through any computer station throughout the labs.

19.2 All floors and work surfaces in the Microbiology Laboratory are non-absorbent and easy to clean and disinfect. Management ensures that all work surfaces are adequately sealed and that there are sufficient storage areas. The laboratory is maintained so that all areas are clean and free from dust accumulation.

19.3 Laboratory managers assure that the laboratory has adequate environmental resources within the laboratory to conduct the analysis as needed. These conditions are monitored in direct ways when possible and sometimes in indirect ways. Direct measurements are documented as an original observation in a logbook dedicated to each measurement. Indirect measurements include quality control sample analysis and acceptable support records.

19.4 MVTL monitors environmental conditions daily. Activities are stopped when conditions could be detrimental to an analysis. A commonsense approach is taken for this monitoring. If equipment or an analysis is performing within the set acceptance ranges, the conditions are considered acceptable.

19.5 To prevent cross-contamination or compromise of testing, laboratory managers have established effective separation where there are incompatible activities occurring in an area. When areas of restriction are necessary, the policy and procedure will be covered in an SOP. MVTL SOP 10-10027 "Microbiology Laboratory Access Policy" covers the policy and procedure for limited access to the Microbiology Laboratory.

19.6 When equipment is installed or moved to a new location within the laboratory, the laboratory manager must address the equipment specification needs. This includes potential contamination, electrical accessibility, appropriate venting, accessibility for maintenance, cleaning and calibration, and

any other specifications given from the equipment manufacturer. See SOP 10-10031 "Laboratory Instrument Qualification" for IQ, OQ and PQ procedures.

19.7 All personnel are responsible for general housekeeping of their areas. In some cases, specific cleaning assignments are documented.

19.8 Each facility used by MVTL is monitored and controlled by air conditioning and heating units. A floor plan for each facility is located in the Safety Manual.

19.9 Only authorized persons are allowed direct access into the laboratory. Warning signs are posted in each area that may pose a safety risk to employees. In addition, MVTL (all facilities) is secured with all doors locked against outside entry, with the exception of the customer entrances during business hours. Doors are allowed to remain unlocked if there are MVTL personnel within direct eyesight of the door, at all times, to monitor a breach of security.

19.10 To ensure the safety of all visitors at MVTL, all visitors will enter and leave the facilities through the front office where they are required to sign in and out. The receptionist will arrange to have the visitor escorted while in the facility. Visitors are required to abide by the following policies during their visit at MVTL:

- All visitors must sign in at the reception area.
- Glasses and/or protective eyewear must be worn in the laboratory.
- No smoking is allowed on any MVTL property.
- No eating or drinking is allowed in the laboratory.
- No photography is allowed in the laboratory without prior permission from a member of the Executive Committee.
- Family members waiting for an employee must wait in the lunchroom or reception area until the employee completes the assigned work and is ready to leave.

19.11 Outside vendors and maintenance personnel (non-MVTL maintenance) may not be required to sign in at the reception area. These persons' presence is documented in appropriate maintenance logs or with invoices for service.

20. TEST METHODS AND METHOD VALIDATION

20.1 MVTL uses appropriate, approved reference methods and procedures that meet the needs of the customer for its testing. Any modifications to these reference methods are listed in the MVTL SOP. Any major deviation from the reference method must be shown to be equivalent and must be validated before use, according to MVTL SOP 10-10041 "Analytical Method Validation and Verification". When MVTL uses an internally developed procedure, suitable validation is performed for that procedure. A validation plan, appropriate for the scope of work to be covered by the analysis, must be written and approved for these MVTL developed procedures according to MVTL SOP 10-10041 and 10-10013 "MVTL Document Approval and Control."

20.2 When a customer does not specify the method to be used, MVTL selects the appropriate method. MVTL informs its customers when a proposed method is out of date or is not considered appropriate for the analysis. This is done during the contract review; for the analyses not covered under a contract, the method is listed on the sample report, serving as notification to the customer which method was used.

20.3 The estimation of uncertainty of measurement for any analysis done at MVTL can be given upon customer request. The process for determining this estimation is found in SOP 40-10011, "Calculation of the Estimation of Measurement Uncertainty".

20.4 As laboratory personnel enter data in the LIMS, they must assure that the data transcriptions are checked for accuracy. It is the responsibility of the LIMS management to assure that automated entry and data manipulations are validated and accurate. When computers or automated equipment are used for the acquisition, recording, processing, reporting, storage, and retrieval of data, the processes must be validated for accuracy and protection. This validation must be described in the validation plan along with the testing of the processes before the system is put into use. The operating conditions must be shown to maintain the integrity of the data for the time required for data storage and that the data is retrievable as necessary. Also, if any off-the-shelf software undergoes any changes including configuration or modifications, these must be authorized, documented, and validated.

21. STANDARD OPERATING PROCEDURES

21.1 Standard operating procedures (SOPs) are an important part of laboratory operations at MVTL. SOPs are written procedures for the general activities conducted in each laboratory. These procedures include the operation and maintenance of equipment and analytical instruments, sample handling, inventory procedures, log-in and reporting, standardization and labeling of solutions, basic laboratory skills, safety, sample preparations, temperature monitoring, recording and handling of raw data, archiving procedures, quality assurance procedures, training and use of the LIMS, and analytical procedures. These SOPs are approved by management and reviewed at a frequency listed in SOP 10-10013 "MVTL Document Approval and Control".

21.2 The majority of analytical procedures used by MVTL have been documented by professional organizations or societies as approved methodologies. When these approved methodologies are not available, MVTL may work to find an established method from a variety of recognized sources. Non-standard methods are not used for repetitive testing without first being subject to a validation study, see SOP 10-10041 "Analytical Method Validation and Verification". When a method is to be validated, a suitable reference for validation, such as USP, will be used. This reference must include appropriate procedure and documentation requirements.

21.3 The Compliance Unit maintains a file of all current and historical SOPs as well as a current index. Only current SOPs are kept in the procedure manuals in the laboratory and the online review folder. Those SOPs in the procedure manual and in the online review folder are available to all bench personnel. A current list of SOPs is available by contacting the Compliance Unit.

21.4 Annually all personnel read for knowledge maintenance, the SOPs and company policies that are applicable to them. This process is a means of assuring all SOPs are up-to-date. Each person is provided with a comment sheet in their annual review packet. Personnel are instructed that this sheet is provided for them to write any updates or changes they feel are necessary to the documents they read. These comments are then forwarded to the appropriate personnel for the necessary updates. This annual process not only provides a means for updating the SOP, but it also provides annual re-training for SOPs and company policies. The annual review includes Ethical Behavior, Client Confidentiality, GLP, GCP and GMP training, Safety review, Quality Manual, company-wide SOPs, and analytical and/or departmental SOPs that are applicable to each individual.

21.5 Each facility has a technical reference library which houses the method reference texts, as well as technical books and publications. To remain abreast of the various state and federal regulations, MVTL receives various state publications and has access to the Code of Federal Regulations.

22. EQUIPMENT

22.1 MVTL maintains a full range of modern equipment and instrumentation. Equipment ranges from very simple to automated and highly specialized instruments. Equipment used for testing is identified by registering the equipment with the Compliance Unit. Upon this registration, the equipment is assigned a unique identification number according to SOP 10-10006, "Documentation Procedures for the Registration of Equipment and Instruments". A list of all equipment, their unique identifications, and their locations is available from the Compliance Unit.

22.2 MVTL controls all the equipment it uses whether it is purchased or leased. Equipment and software used are tested for accuracy and compliance with the specifications of use. MVTL's SOPs describe the use, maintenance, and calibration procedures for each piece of equipment. All equipment is calibrated and verified before use. Whenever possible the calibration standards used are traceable to a national standard.

22.3 Maintenance, both routine and non-routine, is performed as necessary by the analyst using the instrument. If a problem is encountered which the analyst cannot correct, it is reported to the supervisor and a service representative is called as necessary. All maintenance, whether performed by MVTL personnel or a service representative, is recorded in the instrument's maintenance logbook. Maintenance records for each piece of equipment are kept by the laboratory. These records include the MVTL assigned identity of the equipment, the revision of the software and/or firmware (if applicable), the manufacturer's name, the type or model, serial number or other unique manufacturer's identification, and the location of the equipment. In addition, when maintenance is performed on the equipment, whether routine or non-routine, the date of procedure, who did the procedure, what was done, if the procedure followed the SOP (for routine maintenance), what SOP was followed, the nature of the malfunction (if non-routine), what was done to fix the malfunction and if it corrected the malfunction, is recorded in the appropriate maintenance logbook. Maintenance done by service personnel outside of MVTL will be documented by MVTL personnel using the service receipt as part of the documentation.

22.4 For new equipment, records will be maintained to show the installation date and that it complies with the installation qualifications for the equipment. As it is used, it needs to be shown that the operational and performance qualifications are met and continue to be met over time. The manufacturer's instructions should be available for use by the operator for reference if there is a malfunction and for determining the maintenance schedule and installation, operational and performance qualifications. See MVTL SOP 10-10031 "Laboratory Instrument Qualification".

22.5 Personnel must be authorized by management to use equipment without supervision, at the completion of their training. Relevant SOPs and operator's manuals are readily available for use by the laboratory personnel to aid in training and use during analysis.

22.6 Procedures for the safe handling, transport, storage, use, and maintenance of equipment can be found in the manufacturer's instructions and the MVTL SOP for that particular piece of equipment. In most cases when a piece of equipment is installed, it is not moved. Therefore, the instructions for safe handling, transport, and storage are not applicable and will not be included in the equipment SOP. But use and maintenance will still be addressed in the SOP. For equipment that is portable, the safe handling, transport, storage, use, and maintenance will be covered in the SOP.

22.7 When equipment is found to be operating outside the specified limits or is giving suspect results, the equipment will be taken out of service. All out-of-service equipment will be tagged as "OUT OF SERVICE". The laboratory manager will evaluate if the out of specification equipment had any impact on previous tests or reported results. If it is determined that results have been affected, the Corrective Action process will be started and the customer will be notified. See SOP 10-10002 for more information about starting a CA form and for the process of contacting customers. Before placing the equipment back into service, the equipment will be tested to assure that it is again within the specified limits and is no longer giving suspect results. All calibration and verifications will be performed to document the equipment is meeting the specifications.

22.8 Whenever practical, equipment requiring calibration is identified by a sticker that shows calibration status, equipment identification, the date of calibration, and date for next calibration. When equipment leaves the control of MVTL, the equipment will be checked to assure it is working satisfactorily before it is returned to service at MVTL.

22.9 Check the SOP index for individual SOPs describing equipment use, calibration, and maintenance.

23. MEASUREMENT TRACEABILITY

23.1 Laboratory managers develop a calibration schedule for each piece of equipment to meet the requirements of the MVTL SOP, the manufacturer's recommendations, and the regulatory requirements. Calibration and maintenance are documented as they are performed.

23.2 Standards used for equipment calibration checks, such as thermometers and weight sets, will be sent annually to an organization meeting the ISO/IEC 17025 standards whenever possible, and the certificates of calibration are maintained according to the document retention requirement set by MVTL. The reference thermometers are maintained by the Compliance Unit and are not used for daily temperature monitoring. They are only used to perform calibration verification on the temperature monitoring devices used for daily temperature monitoring.

23.3 Reference materials used for daily or routine calibration are traceable to certified reference materials. In addition to calibration materials, certified reference materials may be used for quality control samples (QCS) during an analysis. When possible, a different source is used for calibration materials than the QCS as a counter check for each of the materials. These reference materials are labeled with a unique identification upon arrival at MVTL. The receipt date, expiration date, chemical name or description, manufacturer's lot number, assigned laboratory number and the initials of the person taking the responsibility of the material will be recorded in the laboratory logbook. The MVTL analytical SOP should describe the storage and use of the reference materials to protect the integrity of the material. Upon use of a new batch of reference material, it should be noted by the analyst if the material is behaving in the same manner as the previous standards; this can also be noted with the use of reference materials from a second source. All reference material used will have the accompanying certificate of analysis maintained in the laboratory records.

24. SAMPLING

24.1 MVTL analyzes samples which have been collected by MVTL personnel as well as its customers.

24.2 When MVTL personnel perform the sample collection, recognized and approved sampling protocols and SOPs are followed. The sampling plan and method will be available at the site where the sampling is undertaken. If a circumstance arises where the sampling procedure deviates from the

approved protocol or SOP, the deviation is documented on the chain of custody form or on the sampling form. The appropriate field quality control samples are collected when required. MVTL personnel perform field analyses as requested. Field analyses include, but are not limited to, pH, Eh, specific conductance, temperature, appearance, dissolved oxygen, residual chlorine, ORP and water elevations.

24.3 MVTL has policies and procedures in place for sub-sampling and homogenization to ensure that a representative test portion of the sample is used for each analysis. When MVTL takes the samples at a customer's request, the sampling is done according to established procedures and appropriate records are maintained. When customers request MVTL to deviate from the MVTL SOP, it is documented on the appropriate forms and communicated to the appropriate personnel by the laboratory manager.

24.4 Correct sample handling procedures are an integral part of the quality assurance program at MVTL, from sample collection to sample disposal. MVTL has policies and procedures for the transportation, receipt, handling, protection, storage, and disposal of samples. These are covered in MVTL SOP 10-10008 "Sample Receipt and Log-in for the New Ulm Laboratory", 80-10010-1 "Sample Receipt and Log-in in the Bismarck Laboratory", SOP 40-10010 "Sample Storage and Disposal for the Microbiology, Feed, Organic Chemistry, Inorganic Chemistry and Bismarck Laboratories" and this manual.

24.5 Preservation of samples collected by MVTL personnel will be completed on site according to the requirements of the analysis. This preservation is noted on the chain of custody or the sampling forms.

24.6 Sample preservation is dependent upon the matrix and analytical parameter. Required preservation can be found in the Sampling and Preservation Guide posted on the MVTL website under the Customer Resources - Forms tab, on the sampling instruction sheets included with coolers and sampling kits, and in 40 CFR Part 136, as are container size and volume needed for the analysis. Maximum holding times and light-sensitive parameters are also noted in the Sampling and Preservation Guide and in 40 CFR Part 136.

25. SAMPLE HANDLING

25.1 The laboratory has procedures for the transportation, receipt, handling, protection, storage, retention, and disposal of all samples. These policies and procedures are to protect the interests of the laboratory and the customer.

25.2 For sample receipt see MVTL SOP 10-10008, "Sample Receipt and Log-in for the New Ulm Laboratory" and 80-10010, "Sample Receipt and Log-in in the Bismarck Laboratory."

25.3 All samples are properly stored from the time they come into MVTL's custody until they are disposed. For all samples requiring refrigeration for preservation, storage is ≤6°C until the analyses are complete and the holding time has expired.

25.4 At log-in, the samples are given a unique identification number and a work order number. This identification is maintained through the life of the sample in the laboratory. The sample labels are firmly attached to each portion of the sample. They are resistant to fading, autoclaving, sample and reagent spillage, and reasonable extremes of temperature and humidity. The work order number is also assigned to each batch of samples received, assuring that these samples are reported and invoiced at the same time. Both numbers are recorded on the chain of custody at the time of assignment.

25.5 In addition to the assignment of a unique identification and work order number, the following information is noted in the MVTL database (LIMS) or on the sample receipt forms:

- Date and time the sample was received
- Temperature upon receipt and any comments for samples received above the specified temperature, if applicable
- The date and time sampled, if applicable
- Customer information including contact name, company name (if applicable), address, telephone number, facsimile number, e-mail address and where any copies should be sent, if applicable
- The sample matrix, if applicable
- The sample identification or sample description given by the customer
- Location of collection, if provided
- Collector's name, if provided
- The analyses requested
- Any other pertinent information for the laboratory analyst analyzing the sample
- Any abnormalities, damaged conditions, or other departures from the normal sample protocol or contract. In these cases, the customer is contacted for further instruction on whether the samples will continue with analysis as outlined in SOP 10-10008 and 80-10010.

Note: As this information is entered into the LIMS, the identity of the person who added this information is automatically captured by the system.

25.6 After the samples are logged into the LIMS, the samples are ready and available for analysis in the laboratory. Status of any sample or group of samples can be checked at any time using LIMS. When all analyses are complete, the analytical report will print. These reports are reviewed and approved by the appropriate laboratory manager or their designee before being released to the customer.

25.7 Analyses are usually completed within seven to ten working days. Seasonal increase in sample load may cause an increase in turnaround time, as may equipment failure. MVTL makes every effort to reduce the turnaround time for all samples and to notify the customer of any delays. Samples will not be analyzed beyond the prescribed holding time except at the customer's request.

25.8 MVTL has policies and procedures in place for sample retention and disposal. These are covered in MVTL SOP 40-10010 "Sample Storage and Disposal for the Microbiology, Feed, Organic Chemistry, Inorganic Chemistry and Bismarck Laboratories". Sample holding times, preservation, and storage conditions are found in the Sampling and Preservation Guide posted on the MVTL website under the Customer Resources - Forms tab and are also communicated to the customer so that all parties are aware of sample availability for re-testing and retrieval.

25.9 Employees associated with sample receipt, log-in, handling, storage, and disposal receive training on the administration process they are involved with. The training is documented appropriately.

25.10 MVTL's facilities are controlled access with environmental controls to safeguard the security and integrity of the samples. Each laboratory has designated areas for sample storage to minimize the risk of cross contamination by storing only samples in those areas – reagents and standards are stored away from samples to avoid cross contamination. These areas allow for samples to be stored for ease of retrieval and to avoid damage.

26. ASSURING THE QUALITY OF THE TEST RESULT

26.1 MVTL has quality control (QC) policies and procedures for monitoring the validity of the test results. Each analysis has a specific set of QC parameters listed in the MVTL SOP for that analysis. These

QC parameters are established from regulatory requirements and official reference methods on which the MVTL SOPs are based. Examples of QC procedures are: the use of certified reference materials, participation in proficiency testing programs, use of replicates or duplicates as reproducibility checks in each batch, matrix spikes and matrix spike duplicates, laboratory control samples, method blanks, calibration verifications and reporting limit verifications. See each individual analytical SOP for the specific QC parameters and batch definition. When incorporating different QC elements and criteria into SOPs, if it is not apparent if the requirements of the ISO or TNI modules or the requirements of the mandated methods or regulations are more stringent, the QC in the mandated method or regulation will be followed.

26.2 While certified reference materials (CRM) are used when available, for some analytes CRM cannot be found. In these cases, MVTL will choose a representative material and determine a true value by other means. These other means may be using a calculated range from a label value or a range determined by a proficiency study. At times CRM are cost prohibitive to use on a daily basis; with these assays, the standard used for daily analysis will be qualified against the CRM to determine the true value for daily use.

26.3 Quantitative QC samples are evaluated by the technician with each analysis batch and when the QC samples are found to be outside the established acceptance limits, an appropriate action is taken. This action may be to re-analyze the samples in the analytical batch, re-analyze a percentage of the samples in the analytical batch, report the samples in the analytical batch with qualifiers, or in some cases a corrective action form is issued. In some instances of repeat QC failures, the laboratory manager will be consulted to determine which action is necessary on a case-by-case basis. For some re-analyses the customer will not necessarily be notified; this information may be included in a narrative if a narrative is routinely included in the customer report. For any particular analysis, the appropriate action for out-of-control QC is listed in the MVTL SOP for that analysis.

26.4 Qualitative QC samples are analyzed in the microbiology laboratory for testing that is reported as presence or absence.

26.5 With each analysis, the reagents used are specified in the MVTL SOP. Any special reagents that need to be qualified before use, or any minimum standards to be met, will be clearly stated in the SOP. In the microbiology laboratory, the sterility of equipment and reagents to be used must be verified before use. Certificates of sterility and cleanliness from the manufacturer may fulfill this requirement. Media prepared in the Microbiology Laboratory are checked for sterility, productivity (with a positive culture), pH and the appearance of each batch. This information is documented on the media preparation sheets for each batch. In addition to these checks, any rapid test kits, ID systems and test reagents are checked for positive and negative reactions with each new lot.

26.6 Data is reviewed by peers, manager and/or the Compliance Unit when required by regulatory requirement, customer or contract request and/or at the request of management. Otherwise, data is reviewed by the analyst generating the data for accuracy and completeness. Peer review is done by someone who has experience with the analysis and who would recognize problems with the analysis.

26.7 Out of specifications (OOS) investigations are covered in MVTL SOP 40-10014 “Investigation of Out of Specification (OOS) Results for Customer Samples”. OOS investigations are handled two different ways at MVTL:

- For some customers their specifications are sent with the samples MVTL is testing. If the test results MVTL generates are outside of the given specifications, the customer is contacted, and a re-analysis is started. How the result is reported is dependent on the discussion with the

customer. If the re-analysis result is similar, it is up to the discretion of the customer which is reported; if the re-analysis result is dissimilar both results are reported.

- For other customers, their specifications are not communicated to MVTL at the time the samples are submitted. These customers may contact MVTL upon receipt of their analytical report and ask for a re-analysis due to OOS results.

Whichever way an OOS result comes to the attention of MVTL, they are considered OOS results by MVTL, but only upon request from the customer is a formal investigation documented and provided to the customer.

27. PROFICIENCY TESTING (PT)

27.1 MVTL participates in external Proficiency Testing (PT) programs to meet the requirements for certification programs and to monitor the proficiency of MVTL's analyses. The PT programs MVTL participates in are offered multiple times per year; participation in multiple studies aids the rotation of the PT analysis to all analysts. It is the responsibility of the laboratory to ensure that all analysts performing an analysis routinely analyze a PT on a set schedule. PT studies are purchased so that all accreditation parameters are included on the basis of test/method/technique.

27.2 Each PT sample is treated in the same manner as a customer sample. Upon arrival, the PT sample is logged into LIMS and the analysis is performed routinely. For analysis of low-level PT samples, the samples are treated in the same manner as any routine samples with concentrations at low levels. If the sample is below the reporting limit for our low-level analyses, it will be reported as less than the reporting limit. An "unacceptable" result requires corrective action with a root cause analysis. The Compliance Unit is responsible for maintaining the PT program at MVTL. The PTs are ordered, distributed, and reported through the Compliance Unit. Upon completion of a study, the results are reviewed by the Compliance Director who sees that corrective action is performed and remedial PTs are ordered as necessary. It is through the Compliance Unit that PT results are distributed as necessary to regulatory agencies and customers.

27.3 MVTL participates in a variety of PT programs. These programs include:

- For environmental programs the most common vendors used by both Bismarck and New Ulm locations are:
  - Environmental Resource Associates (ERA)
  - Phenova
  - Absolute Standards, Inc.

  These PTs are ordered as needed for biannual acceptable results for each certified parameter.
- For feed testing the following programs are used by the New Ulm Feed Laboratory:
  - National Forage Testing Association (NFTA) - eight samples per year
  - Association of American Feed Control Officials, Inc. (AAFCO) - monthly for animal feed program and quarterly programs for pet food, mycotoxin contaminates, and minerals.
  - American Oil Chemist Society (AOCS)-four rounds per year with two samples per round.
- For manure testing the Minnesota Department of Agriculture provides two sets of samples per year to the New Ulm Feed Laboratory.
- For soil testing the following are used in the New Ulm Soil Laboratory:
  - North American Proficiency Testing (NAPT) – four sets of both plant and soil samples per year. This program also provides Performance Assessment Program which is a means to assess and improve laboratory accuracy and precision.

- Agricultural Laboratory Proficiency Program (ALP) through Collaborative Testing Services (CTS) provides three sets of samples per year of both plant tissue and soil samples.

- For food testing at the New Ulm location:
  - LGC for Food Microbiology with various matrices and studies throughout the year.
  - LGC for Food Chemistry with various matrices and studies throughout the year.
- For coal testing the Bismarck location:
  - Interlab Coal Round Robin Program is done monthly in the Bismarck laboratory.
- For Legionella testing in the New Ulm Microbiology Laboratory:
  - PTs are provided by the Wisconsin State Hygiene Laboratory for the Center for Disease Control (CDC) certification of their approved cultural method and molecular method MVTL uses for Legionella. MVTL participates in two rounds per year to maintain the CDC certification.

27.4 For a schedule of Proficiency Testing samples for the current year or results from past studies, contact the Compliance Unit.

28. LABORATORY CERTIFICATION AND ACCREDITATION

28.1 Certification and accreditation is a formal process by which MVTL is evaluated by an accrediting authority, with respect to established criteria, for its ability to perform various types of analyses. Below is a list of certifications and accreditations that are held by MVTL. Contact the Compliance Unit for current certificates.

- Minnesota Department of Health (MDH) MNELAP
  - New Ulm, Minnesota Laboratory (Laboratory ID#027-015-125): Clean Water Act; Safe Drinking Water Act; Resource Recovery and Conservation Program; Underground Storage Tank Program; MDA List 1 pesticides in water.
  - Bismarck, North Dakota Laboratory (Laboratory ID#038-999-267): Clean Water Act; Safe Drinking Water Act; Resource Recovery and Conservation Program.
- North Dakota Department of Environmental Quality (NDDEQ)
  - New Ulm, Minnesota Laboratory (Laboratory ID#R-040): Reciprocal certification based on the Minnesota Department of Health Certification for Clean Water Act, Safe Drinking Water Act and Resource Recovery and Conservation Program.
  - Bismarck, North Dakota Laboratory (Laboratory ID#ND-016): Reciprocal certification Clean Water Act; Safe Drinking Water Act; Resource Recovery and Conservation Program based on Minnesota Department of Health certification with some analytes under North Dakota primary certification.
- South Dakota Department of Environment and Natural Resources (SDDENR)
  - Bismarck, North Dakota Laboratory: Reciprocal certification for Safe Drinking Water Act based on the Minnesota Department of Health certification.
- Iowa Department of Agriculture and Land Stewardship List of Certified Soil Testing Laboratories.
  - New Ulm, Minnesota Soil Laboratory
- Minnesota Department of Agriculture
  - New Ulm, Minnesota Chemistry Laboratory: List 1 Pesticides in water and soil and nitrogen analyses
  - New Ulm, Minnesota Feed Laboratory: Manure Analysis Program (MAP)
  - New Ulm, Minnesota Soil Laboratory: Soil Testing Certification Program
- ISO 17025 from A2LA-Scopes 2459.01 and 2459.02 for Food Chemistry and Food Microbiology.

- New Ulm, Minnesota Microbiology Laboratory
- New Ulm, Minnesota Chemistry Laboratory
- New Ulm, Minnesota Feed Laboratory

28.2 Pertinent customers will be notified of loss of certification through revocation or voluntary withdrawal. A search for customers who have had analysis done under the specific certification within the last 18 months will be conducted through the LIMS and the customers will be notified of the change in certification.

29. REPORTING THE RESULTS

29.1 MVTL does not consider reports final until they have been approved by authorized personnel. Authorized personnel have access to a password protected LIMS menu; only through this menu can reports and certificates of analysis be approved, printed, and transmitted. Depending on the analytical laboratory, a unique staging system is used to indicate the status of the samples. This allows MVTL to release results either on a sample basis or a workorder basis.

29.2 MVTL utilizes several reporting formats (both paper and electronic) to issue results to the customer. The reporting formats are based on regulatory requirements, guidance from the official reference method and customer requests. This ensures that the results of each test or series of tests performed by MVTL are reported accurately, clearly, unambiguously, objectively and in accordance with regulatory requirements.

29.3 Reports and certificates of analyses may be printed directly onto company letterhead. This letterhead is protected by storing it in secure areas of each office location. Only authorized personnel are allowed direct access to these facilities and the stored letterhead. Reports and certificates of analysis can only be printed through a password protected LIMS menu.

29.4 MVTL also utilizes electronic letterhead in cases where the customer requests all reports be sent electronically without a paper copy provided. This electronic letterhead along with the approval signatures that appear on the electronic reports and certificates of analysis is protected from unauthorized use through the LIMS system and the use of password protected LIMS menu. These reports are equivalent to the reports described in 29.3.

29.5 Other types of electronic files, such as “csv” and “xml”, can be used for reporting the results. These files are protected from unauthorized use through a password-protected LIMS menu. The electronic file that is generated is retained and stored on a secure server. A written agreement with the customer must be received before the results are reported in this manner.

29.6 In some cases it is necessary for the laboratory to issue a “partial” or a “preliminary” report or certificate of analysis. When this is done, “Partial” or “Preliminary” appears before the title of the report or certificate of analysis. A statement about the status of the results also appears on the report or certificate of analysis, noting that the contents of the report or certificate may change since the management approval has not occurred.

29.7 For reports under TNI (NELAC) Standards and ISO 17025 Standards the following is included:

- Title (“Final Report” or “Certificate of Analysis”).
- Name and address of MVTL in the letterhead. It is noted on the report if the analysis was completed at a laboratory other than MVTL.

- The workorder number that uniquely identifies the final report or certificate appears on each page of the report in order to assure that each page is recognized as part of the final report.
- The unique laboratory identification of the sample that MVTL assigns.
- The name and address of the customer.
- The page number and total number of pages (paper and electronic version).
- Report date (date the report is issued).
- The identification of the reference method used for each analysis, if necessary due to regulatory requirement.
- The description of the sample.
- The condition of the sample upon receipt.
- The date of receipt.
- The date of analysis and time of analysis if holding time is <72 hours
- A reference to any sampling plan if the sampling was performed by MVTL.
- The test result(s) with the units of measurement.
- The name, function and signature, or equivalent of the person(s) authorizing the final report or certificate of analysis.
- A statement specifying that the report may not be reproduced, except in full, without approval from the laboratory.
- As relevant, a statement to the effect that the results relate only to the item tested and the item was tested as it was received unless otherwise noted on the report.

29.8 In addition to these items, additional information may be necessary for the interpretation of the results. The following may be added at the request of the customer:

- Deviations from, additions to, or exclusions from the reference test methods and information on the specific test conditions such as environmental conditions.
- A statement of compliance or non-compliance with requirements and specifications from the customer.
- A statement of the estimated uncertainty of the measurement, if requested by the customer.
- Opinions and interpretations with the documentation on which these opinions and interpretations are based.
- Customer generated results are provided, at times, and included in the MVTL report. These are designated by “Client” in the analyst column or the analyte column of the report. These results have no bearing on the validity of the MVTL result. If the customer result would have a bearing on the validity of the result, a narrative will be added to discuss this affect.

29.9 Sampling information is also added as applicable:

- Sampling date.
- As applicable, the unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate)
- Identification of the sampler.
- Location of sampling.
- Reference to the sampling plan used.
- Environmental conditions at the sampling location.
- Information required to evaluate measurement uncertainty for subsequent testing, if requested.

- Any standard for the sampling method and any deviations from this standard.

29.10 When it is necessary to amend a final report or certificate of analysis, "AMENDED" will be added to the report or certificate of analysis with an explanation of why the report or certificate was amended and the date of amendment. This information may be found at the top of the report, the bottom of the report or in the narrative of the report.

29.11 If a final report or certificate of analysis is being amended at the customer's request, a full communication record, including a written request, must be maintained with the original and amended report. This communication serves as a bridge to close any gaps produced when issuing final reports that do not match all descriptions and information on the samples and paperwork received.

29.12 If the amendment includes a change to the sample description, the original description and the updated description will be contained within the report, if possible. Note, for some certificates of analysis, this requirement may not be possible, as this would render the certificate of analysis unusable to the customer. In all circumstances, the original report and the full communication record must be retained to maintain a complete audit trail.

29.13 As necessary and if possible, a full description of what was changed will be included on the amended report. Note, for some certificates of analysis, a full description of the change may not be possible, as this would render the certificate of analysis unusable to the customer. In all circumstances, the original report and the full communication record must be retained to maintain a complete audit trail.

30. CONFIDENTIALITY

30.1 MVTL policy provides for the protection of itself and its customers concerning proprietary rights and confidentiality. All reports are submitted as the confidential property of our customers. Authorization for the publication of statements, conclusions or extracts from or regarding our reports is reserved pending written approval from MVTL.

30.2 MVTL considers the organization or individual paying for the laboratory service to be the customer. Data generated by MVTL is sent only to the customer. If the customer would like a copy of the report sent to additional parties, MVTL will comply with the customer's wishes upon receiving a written request. This request can be stated on the chain of custody and submitted at the time the samples are submitted, or a customer service representative can be contacted for a form to be used.

30.3 To maintain customer confidentiality through any subcontracted work, MVTL makes every effort to send the samples to a laboratory that holds the same level of certification. This ensures the subcontract laboratory also has a confidentiality policy that would cover all samples.

30.4 Customer lists and other compiled business data containing customer information are not disclosed outside of MVTL. MVTL employees are not permitted to disclose this information without written permission from the customer. Should a prospective customer wish to see recommendations from current customers, MVTL will make every effort to secure these recommendations, but current customers' names and information will only be released upon written permission from the customer.

30.5 At MVTL, while we must maintain customer confidentiality, we also wish for our customers to be able to monitor our laboratory processes through customer visits. These visits from our customers give

MVTL the opportunity to exhibit our abilities and capabilities, while serving as a means for improvement of our processes.

30.6 To maintain security for customers through e-mail, reports are only sent to a recipient who provides their e-mail. When a customer contacts MVTL through a telephone call, contact information is confirmed before the report is sent via e-mail, facsimile or other means. When customers request access to their reports through the MVTL web portal, these accounts are set up for an individual user into a secure account to which access is available only through the set account number and a password.

31. ETHICS AND DATA INTEGRITY

31.1 It is the expectation of management that all work conducted at MVTL is done with honesty, integrity, impartiality, and responsibility. It is also expected that any analytical result reported is legally defensible; and that fraudulent activities observed in the laboratory are reported to management immediately. In addition, MVTL expects its employees to perform their duties in a manner that does not diminish our customers' confidence in the work that is performed. It is important to understand that pressures and influences that may impact employees can come from internal as well as external sources. MVTL aims to educate our employees about all forms of influence and actively works to eliminate or minimize these factors. Employees are required to understand that consequences of data integrity infractions may include civil and/or criminal prosecution.

31.2 Ethics and data integrity training is part of initial training and is conducted annually for employees. During the presentation employees are provided an electronic copy to review; a paper copy of the presentation is available to the employees as necessary. Topics of ethics and data integrity training include: the expectation of MVTL's management for full honesty and disclosure of data integrity issues, the consequences of a breach of integrity, the importance of documentation and care with each analysis, importance of review of data and examples of improper laboratory practices. Upon completion of the training each employee is required to sign a training summary which includes a statement of understanding and compliance.

31.3 Prohibited practices are listed below. While this list is extensive, it does not preclude other activities from being prohibited.

- Fabricating, falsifying or misrepresenting data. Examples of this are creating data for an analysis that was not performed; creating information for a sample that was not received; using a subcontract laboratory and reporting the results as performed by MVTL.
- Improper clock setting (time traveling) or improper date/time recording. Examples of this are resetting the internal clocks on an instrument to make it appear that a sample was analyzed within holding time when it was not; changing the actual time or recording a false time to make it appear that holding times were met; or changing times for sample collection, extractions, or other preparation steps to make it appear that holding times were met.
- Manipulating samples, software, or analytical conditions in an unwarranted manner. Examples of this are unjustified dilution of samples; manipulating GC/MS tuning data to produce an ion abundance result that appears to meet specific QC criteria; changing the instrument conditions for sample analysis from the conditions used for standard analysis or treating the sample differently from the standards or QC; manipulating software so that operational codes are deleted; calibrating using regressions that are altered from linear to second or third order at will; subtracting backgrounds inappropriately; manipulating baselines; disabling the full audit trail of software.

- Misrepresenting or misreporting QC samples. Some examples are reporting QC samples as digested or extracted when an instrument spike has been used; using previous calibration curves or QC samples in place of a failed calibration or failed QC; failing to prepare or analyze method blanks or LCS in the same manner as the samples; tampering with the QC samples and results, including over or under spiking the fortified QC samples; adjusting the volumes or weights to account for higher or lower recoveries; incubating or drying QC samples longer or shorter to adjust for possible failure; performing extra QC samples until one meets the acceptance criteria rather than taking necessary corrective action; not documenting unacceptable data; deleting non-compliant QC data to conceal the fact that calibration or other QC analyses were non-compliant.
- Calibrating improperly, such as discarding points in the initial calibration to force the calibration to be acceptable with no documentation or reason; discarding MDL replicates without reason to force the MDL to meet a specific level; failing to use the most current calibration; using a run sequence that gives the impression of an acceptable calibration when the calibration is not acceptable; performing improper manual integrations, including peak shaving, peak enhancing or baseline manipulation to achieve acceptable calibrations or QC; not doing corrective action as needed.
- Concealing a known analytical problem or a known problem with a sample.
- Concealing a known improper laboratory practice or unethical behavior.
- Failing to report the occurrence of a prohibited practice or unethical behavior to the appropriate management personnel at MVTL.

31.4 The laboratory management is committed to producing results in an impartial manner. MVTL is an independent laboratory with no ties to the manufacturers or producers of the samples analyzed at MVTL. This keeps potential conflict of interest at a minimum. Personnel are discouraged from receiving gifts or favors from customers and others outside the company; they are also discouraged from giving gifts or favors. Any questions on the acceptability of a gift are referred to human resources or senior management for a decision. Correspondence and contact with customers are handled by management and customer service so that personnel generating results are not burdened with undue pressure and influences from the customer. MVTL works very hard not only to assure there is no conflict of interest, but also to assure there is no perceived conflict of interest.

31.4.1 Employees of MVTL are informed about the policies of employment with our customers and also employment of family members with our customers. Employment of MVTL personnel and family members with our customers is allowed, but MVTL must be informed so that a determination of conflict of interest can be made and procedures put in place to avoid any potential conflict of interest.

31.5 All the described actions, when discovered, must result in a thorough investigation by MVTL management. Termination of employment with MVTL will result for personnel confirmed to have participated in prohibited laboratory practices or unethical behavior. When data integrity issues are discovered, the situation will be resolved and customers will be notified as appropriate, by MVTL's executive management.

31.6 It is the expectation of MVTL's management that any questionable situation involving client confidentiality, ethical behavior or conflict of interest be reported to a supervisor and a member of Human Resources immediately.

31.6.1 Additionally, these matters may be reported confidentially and anonymously. Anyone wishing to report anonymously may do so by calling Colleen Skillings' direct line at 507-233-7112 after hours and leaving a message.

32. INTERNAL INVESTIGATIONS OF BREACH OF POLICIES

32.1 Upon discovery of inappropriate activity, with regard to MVTL polices on confidentiality, ethics, data integrity, and conflict of interest, an internal investigation will be conducted. This investigation will be conducted confidentially until the results of the investigation are clear and action to be taken can be determined.

REVISION HISTORY

2026-0 (02 March 2026)

Page 2: Added References section
Table I: Laboratory Capabilities – updated
Page 12: Updated Organizational Chart
Page 15: Updated 6.3 to discuss evaluating customer requested deviations
Page 17: Added 8.4 for supply purchasing
Page 19: Updated 15.1 to include that audits are scheduled on a risk-based assessment.
Page 22: Updated 18.1 with local, state, and federal requirements for personnel
Page 26: Updated 22.3 to include firmware version
Page 27: Updated 22.7 for evaluating out of specification equipment and possible effected results.
Page 29: Added bullet point to 25.5 for location collected and collector's name, if available
Page 30: Updated 26.1 to requirements of TNI V1M2 5.9.3.c
Page 34: Updated 29.9 with the second and seventh bullet
Page 35: Updated and added to 29.11, 29.12, 29.13 for additional report amendment requirements
Page 35: Added 30.3 for confidentiality of subcontracted samples
Page 36: Updated 31.1 to include both internal and external pressure

2024-0 (31 May 2024):

Page 2: Updated "Soil" Lab to "Agricultural" Lab
Page 4: Updated ownership
Page 9: Updated 2.4.2.1 to limit this role to just Production Director of Microbiology Laboratory and added Production Director of the Chemistry Laboratory as 2.4.2.2
Page 9: Changed Bismarck Production Director to Bismarck Laboratory Director to be consistent across multiple documents
Page 9: Updated roles of 2.4.2.2-Bismarck Laboratory Director
Page 10: Added 2.4.3.3.
Page 11: removed purchasing from the logistics department and made a new section 2.4.5 for Purchasing and Supply Management
Page 12: Updated general organizational chart
Page 14: Removed procedure of how to number MPS in 4.6 and just referenced SOP 10-10013
Page 23: Added 19.2
Page 25: Added final sentence of 20.4
Page 27: Added to 24.2
Page 28: Added SOP 80-10010
Page 28: Added 25.1
Page 28: Added "and time" to 25.5 bullet point 1
Page 29: Added "Note" to section 25.5
Page 30: Added "by the technician" to 26.3
Page 30: Added management consultation for some QC failures to 26.3
Page 31: Removed Neogen Gliadin PTs from section 27.3
Page 33: Added "and time of analysis if holding time is <72 hours" to bullet point 12 of 29.7
Page 34: Added a bullet point to 29.7 limiting the reproduction of reports except in full
Page 35: Added understanding of civil/criminal prosecution to 31.1

2022-0 (15 July 2022):
Page 6 – Added PFAS to Organic Lab capabilities
Page 20,21 – Added the need to review management meeting items for trends, 16.2 and 16.3.
Page 31 – Removed Hemp PT program
Page 34 – Added 29.11 for amending reports
Page 37 – Added 31.6 and 31.6.1 regarding the reporting of questionable situations involving ethical behavior and conflict of interest; including doing so in a confidential and anonymous manner.

2021-0 (2 August 2021):
Page 4 – Added "17025" to first bullet to read ISO17025 instead of just "ISO".
Page 4 – Updated square footage in 1.3.
Page 5 – 7 – In Table 1 split New Ulm Chemistry into Inorganic and Organic.
Page 9 – In section 2.4.3.1, the responsibility of maintaining the currency of the Quality Manual was stated as belonging to the Compliance Director.
Page 10 – Added sample receipt and log-in under Logistics in 2.4.4.
Page 12 – Updated organizational chart to reflect change in Logistics.
Page 14 – Deleted 4.6 since this is covered in SOPs elsewhere; renumbered section 4.
Page 18 – In 10.1 added the title of form 10-90002.
Page 18 – In 11.1 corrected the title of SOP 40-10014.
Page 19 – Changed the number of years CAs are maintained in IQ from 10 years to 5 years since data is only maintained 5 years (section 13.4).
Page 19 – In 15.1 changed A2LA analytes to the annual audits instead of every other year; deleted the note that facility audits not performed are re-scheduled since this appears that annual audits are missed.
Page 20 – Added the last bullet under 16.1 – Determination of action items and wishlist items; addition of internal feedback and internal complaints to the list.
Page 22 – Deleted "conflict of interest in 18.3 since that is now covered under ethics and data integrity training.
Page 23 – Added that SDS are also maintained in IQ.
Page 25 – Update of 21.4 to indicate this process is for knowledge maintenance not necessarily the biennial technical review; deleted Conflict of Interest annual review.
Page 29 – Expanded 25.9 to include storage of samples away from reagents and standards.
Page 30 – Corrected SOP title of SOP 40-10014 in 26.7.
Page 32 – Added that NDDH Bismarck certification is based on MDH except for a few analytes that are still covered under primary NDDH.
Page 36 – Removed Conflict of Interest as a separate section 32; added that information to section 31 Ethics and Data integrity as section 31.4 and 31.4.1; re-numbered; added last sentence in new section 31.5 to note that customers will be notified if there are data integrity issues, as appropriate.
Page 36 – Renumbered Internal Investigations of Breach of Policies as section 32.
Page 38 – removed revision history of version 2016-0 and 2017-0.

For Revision information prior to this, see the historic archived record.

Document Approval Form

OBSOLETE DATE_____

Initials/Date:

Document Type: Quality Manual

Document Number: Quality Manual 2026-0

Document Title: MVTL Quality Manual

Supersedes: Quality Manual 2024-0

Summary of Changes: See page 39-Revision History

Technical Writer: David Luiken

Effective Date for New/Revised Document: 02 March 2026

Signing below indicates that you have reviewed and approved this document for use. If you choose to use a designee to approve in your place, complete the table below the final approval.

Technical Approval: Jerry Balbach, President

Jerry Balbach Date: 13 Feb 2026

Technical Approval: Michael K. Grob, Chief Operations Officer

Date: 16 Feb 2026

Compliance Approval: David Luiken, Compliance Director

Date: 13 Feb 2026

Final Approval: Colleen Skillings, Chief Executive Officer

Colleen Skillings Date: 13 Feb 2026

Please note the use of a designee for the listed approver (see SOP 10-10013)	
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Reviewed By:	Date of Review:	Check if this document must be revised: