Minnesota Valley Testing Laboratories, Inc. (MVTL) Quality Manual

ISO 17025

TNI 2009

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See page 36 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

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New Ulm, Minnesota 56073
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(800) 782-3557
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MVTL - Soil Receiving and Laboratory
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1126 North Front Street
New Ulm, Minnesota 56073
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MVTL - Feed Laboratory
Building 1
1126 North Front Street
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(507) 233-7156
FAX (507) 359-1688

MVTL - Field Services
219 16th Street South
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Iowa Location

MVTL – Soil and Manure Receiving
1201 Lincoln Highway
Nevada, IA 50201
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Wisconsin Sales Office

MVTL – Sales only
PO Box 424
Oak Creek, WI 53154
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North Dakota Laboratory

MVTL – Inorganic, Limited Microbiology, Energy Laboratory and Field Services
2616 East Broadway Ave
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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 process and support services meet the specifications published by national and international standard organizations (including TNI-NELAC and ISO) 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 Thomas R. Berg.

1.2 MVTL provides a broad range of services to industry, federal, state and local governments in areas of dairy, food, agribusiness, 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 ISO17025 Standard for the analyses accredited under the MVTL A2LA scopes 2459.01 and 2459.02; current TNI (NELAC) 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 (~30,000 square feet), Building 2. The soil fertility and soil characterization laboratory and the feed laboratory are located at 1126 North Front Street, Building 1 (~32,000 square feet). The 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 Licensed and Certified Septic System Inspections and Sampling
New Ulm, MN Chemistry Laboratory	<u>Inorganic:</u> Analyses Under United States Food and Drug Administration (FDA) Good Laboratory Practices (GLP) following 21 Code of Federal Register (CFR), Part 58 and United States Environmental Protection Agency (EPA) GLP following 40 CFR, Part 160); Organization of Economic Co-operation and Development (OECD) Principles of GLP (1997); Good Clinical Practices (GCP) and GLP Guidelines for Veterinary Products (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 Bio-solid, Soil, Industrial Wastes by EPA Test Methods for Evaluating Solid Waste Methods (SW-846) Dry Milk Product Analyses and Complete Grading Physical Analyses Common Fluid Milk Analyses

Table 1
LABORATORY CAPABILITIES

New Ulm, MN Chemistry Laboratory (continued)	Organic: EPA Test Methods 624, 625 and 608 SW-846 Methods 8260, 8270, 8081 and 8082 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 and Wisconsin Modified GRO and DRO methods 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 Good Manufacturing Practices Testing (cGMP) Fatty Acid Profiles, Cholesterol, Vitamins, Sugar Analysis, and Amino Acids in Foods and Feeds Allergen Testing Toxin Assay of Food, Feed and Pet Food
New Ulm, MN Microbiology & Food Laboratory:	Microbiological Examination of Drinking Water and Wastewater by EPA approved methods Microbiological Examination of Food and Dairy Products Pathogen Testing: *Salmonella, Listeria* and *E.coli O157:H7* in Food and Dairy Products Customer Consulting, Diagnostic and Information Services Shelf Life Studies Challenge Testing Cosmetic Challenge Studies Centers of Disease Control Approved Legionella Testing
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

Table 1
LABORATORY CAPABILITIES

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 Manure and Fertilizer Analyses (AOAC) Mixer Studies Forage Testing Analyses following FDA GLP 21 CFR Part 58, OECD GLPs, GCP and GLP following VICH GL9 for Veterinary Products Fertilizer Analyses (Association of Official Analytical Chemists- AOAC- Methods)
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 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, Bio-Solids, Soil and Industrial Waste following SW-846 Field Services and Sampling Crude Oil Testing – limited scope 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 SOPs (standard operating procedures). 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 department. 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 we work under 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.

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: The responsibility for the overall operations and quality of data generated in the New Ulm Chemistry, Microbiology, Feed, Soil and Bismarck laboratories and the Nevada location lies with the production director. 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 laboratory manager, the production director may also approve and sign reports.

2.4.2.2 Laboratory Management: The laboratory managers of MVTL report to the production director and 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.

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

2.4.2.2.2 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 assure the accuracy of the work they complete while maintaining conformance with the requirements of the quality management systems described in this manual.

2.4.2.3 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), NELAP (National Environmental Laboratory Accreditation Program through The NELAC Institute) 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 investigations. 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.

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 As change control happens the compliance unit is responsible for approving all changes that occur. This includes review and approval of standard operating procedures, forms, manuals such as this quality manual, training presentations, method validations/verifications and instrument qualifications and other documents of the quality management system.

2.4.3.4 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.

2.4.3.5 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 (see 2.4.3.3) of the quality management system.

2.4.4 Logistics Department: The logistics department provides support services for the MVTL laboratories. These support services include purchasing, shipping and receiving, field services, courier services and maintenance. The logistics director reports directly to the COO.

2.4.5 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.

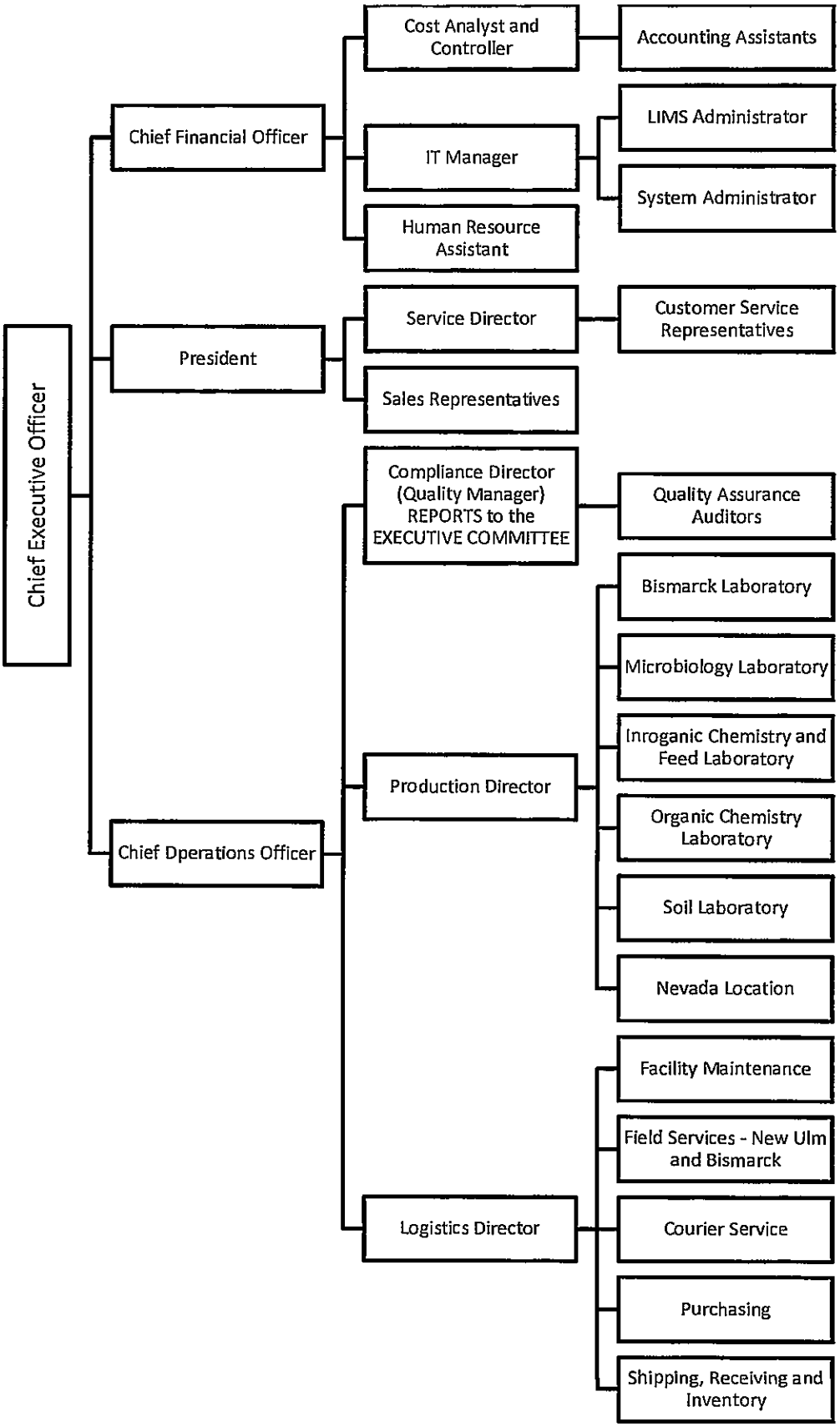
2.4.6 The information technology (IT) department is under the IT Manager and consists of Laboratory Information Management System (LIMS) and System Administration. IT is responsible for maintenance of all computers and software used by MVTL. LIMS maintenance and updates are also the responsibility of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

2.4.7 The management hierarchy for analyses and projects falling under GLP (both FDA and EPA), OECD and GCP VICH GL9 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
Service Director
Customer Service Representatives
Sales Representatives
Chief Dperations Officer
Compliance Director (Quality Manager) REPORTS to the EXECUTIVE COMMITTEE
Quality Assurance Auditors
Production Director
Bismarck Laboratory
Microbiology Laboratory
Inroganic Chemistry and Feed Laboratory
Organic Chemistry Laboratory
Soil Laboratory
Nevada Location
Logistics Director
Facility Maintenance
Field Services - New Ulm and Bismarck
Courier Service
Purchasing
Shipping, Receiving and Inventory

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") and method validation, verification and/or method transfer (MVTL SOP 10-10041 "Analytical Method Validation and Verification").

3.2 Change control is accomplished by requiring review and approval by management and compliance. 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 SOP 10-10013 for MVTL Document Approval and Control and SOP 10-10042 for Change Control.

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 by the staff. 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 and forms. All internal documents used by the staff 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 kept 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 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 SOPs and forms are uniquely numbered using the format XX-YYZZZ-A, where XX-YY is applicability to the personnel it affects; ZZZ is the sequential number assigned for that particular applicability; and A is the revision number. The original revision is designated as "0". All SOP and form numbers are assigned by the compliance unit. In addition, each SOP and form is paginated to indicate the page number and the total number of pages (Page X of Y) to indicate if a page is missing. After each SOP or form is approved by management for use, an effective date is assigned.

4.7 Media preparation sheets (MPS) are assigned a unique alphanumeric number in the format X-#, where "X" is the first letter of the media and "#" is the sequential number of the media starting with that letter. MPS numbers are assigned by the microbiology laboratory. Each MPS has a revision number, with the original revision designated by "Original". The MPS are reviewed and approved according to SOP 10-10013 (MVTL Document Approval and Control), with an effective date assigned after approval. The original approval sheet for each MPS form 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.

4.8 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. 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.

4.8.1 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.

4.8.2 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.

4.9 Obsolete documents generated for the MVTL quality management system are scanned into the GLP cabinet of the ImageQuest document storage system (IQ). Most documents such as SOPs, CVs, organization charts, 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 GLP and non-GLP Physical (Paper) Archives". The paper records are being destroyed as their retention times expire. Those paper records that need to be maintained permanently are being scanned into IQ as time allows.

5.3 Record retention times for archived records are noted in SOPs 10-10039 "Electronic Archives in the ImageQuest Document System" and 10-10017 "Maintenance of the GLP and non-GLP Physical (Paper) Archives". 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 IQ 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 need to 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. This includes state 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.

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 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 which MVTL has not approved. MVTL does maintain 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 NELAC-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
- 70-14002 – Vendor Qualification Process
- 70-14003 – Purchasing Supplies
- 30-15001 – Receiving Supplies into Inventory-Front Street Location Only
- 30-15002 – Consuming and Deleting Supplies from Inventory
- 30-15003 – Physical Inventory Procedures
- 80-10013 – Procedure for the Requisition of the Laboratory Supplies (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 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 and/or third party auditors 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 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 in writing. This may include reporting results on separate pages and sending courtesy copies. The customer file must retain clear written confirmation of the customer request.
- 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.

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 (SOP 40-10010 "Sample Storage and Disposal for the Microbiology, Feed Organic Chemistry, Inorganic Chemistry and Bismarck Laboratories") and data storage policies (SOP 10-10017 "Maintenance of the GLP and non-GLP Physical (Paper) Archives" and SOP 10-10039 "Electronic Archives in the ImageQuest Document System"). In all cases in which a customer requests reporting in a special format or 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. 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 Client 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. Once the non-conformance has been assessed, the manager can determine if the work can be resumed or if further investigation is needed. The decision to resume work is based on the magnitude of the problem and the risk of the problem reoccurring. 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 should 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 **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 IQ and maintained for at least 10 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 non-conformances. 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, 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 IQ system.

15. INTERNAL AUDITS

15.1 The compliance director schedules audits for both the quality management system and the testing activities at MVTL. The schedule is set so that all sections of the quality management system are covered annually, as well as each technology under the Minnesota Department of Health accreditation; any facility audit not performed as scheduled will be re-scheduled by the compliance director. Laboratory analyses covered under the ISO 17025 scopes are covered every other year. 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 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 on 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 **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 changes or improvements to the system and evaluate its effectiveness. This review includes a review of the quality policies and objectives, the suitability of policies and procedures, the outcome of recent internal and external audits, corrective and preventive actions, the results of proficiency testing, changes in the volume and type of the work load, complaints, customer feedback, recommendations for improvements and relevant factors, such as quality control activities, resources and staff training and data integrity. Reports from laboratory management, containing the above-mentioned items, are submitted to the quality manager before the meeting. This information is then organized and distributed to the meeting attendees with enough time for review before the meeting.

16.2 During the meeting the attendees will sign the attendance sheet so that a record is maintained of attendance. The CEO, CFO, 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 (quality manager) 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 during the annual management review and are documented in the minutes. Minutes of the meeting are inserted into the final copy of the booklet after they are approved by the CEO 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 (quality manager) will report the status of these findings or action items to the executive management as necessary to ensure that these items are completed within the agreed timelines.

16.3 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 for 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 personnel 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 for 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 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 conflict of interest, customer confidentiality, ethics and data integrity and regulatory requirements is done 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 used in the area of training, and procedures and policies of 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 – "Qualification of 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/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 includes all SOPs, portions of SOPs and procedures that employees are responsible for performing. Managers or their designee observe and evaluate the ongoing competence of employees. 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 "Qualification of 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. Included in each employee's CV file is initial training records and initial of authorization by the manager.

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 are maintained in each laboratory and are available to all employees.

19.2 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.

19.3 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.

19.4 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 a SOP. MVTL SOP 10-10027 "Microbiology Laboratory Access Policy" covers the policy and procedure for limited access to the microbiology laboratory.

19.5 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

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

19.7 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.

19.8 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.

19.9 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.

19.10 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 deviation from these reference methods is 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 "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 for 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.

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 Review".

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 "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 review the SOPs and company policies that are applicable to them. This annual review 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 review. These comments are then forwarded to the appropriate personnel for the necessary updates. This annual review 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, Conflict of Interest, 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 and software, the revision of the software, 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 many 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". 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 for comparison to check the temperature monitoring devices used for daily temperature monitoring.

23.3 Reference materials used for daily or routine calibration are traceable to certified reference material. 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 its 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. 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 New Ulm MN Front St Building 2, Bismarck ND Chemistry Laboratory and Oak Creek WI Office", 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 done 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 MVTL Fee Schedule, MVTL sampling instruction sheets and 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 preservation table and 40 CFR, Part 136.

25. SAMPLE HANDLING

25.1 For sample receipt see MVTL SOP 10-10008, "Sample Receipt and Log-in for the New Ulm MN Front St. Building 2, Bismarck ND Chemistry Laboratory and Oak Creek WI Office".

25.2 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 completed and the holding time has expired.

25.3 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 of these numbers are recorded on the chain of custody at the time of assignment.

25.4 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 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.
- 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.

25.5 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.

25.6 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.

25.7 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". Minimum sample retention periods and storage conditions are documented in the MVTL Fee Schedule and are communicated to the customer so that all parties are aware of sample availability for re-testing and retrieval.

25.8 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.

25.9 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. 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.

26.2 While certified reference materials (CRM) are used when available, for some analytes CRM cannot be found. In these cases, MVTL will use a 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 is 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 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. For these 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 For some customers, MVTL is given the specifications for their particular product. If during an analysis of one of these samples, there is a failure to meet the specification criteria given it is considered an out of specification (OOS) result and the sample will be re-analyzed. The customer will be contacted when an OOS is generated to determine the course of action MVTL should take when reporting the result(s). MVTL considers any re-analysis upon customer request, whether MVTL has the expected result prior to analysis or after the report is generated, to be an OOS re-analysis.

26.6 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 is 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.

26.7 Data is reviewed by peers, manager or compliance 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.

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 assure 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 lowlevel 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 lowlevel 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)
  - Sigma-Aldrich/Resource Technology Corporation (RTC)
  - 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.
  - Agricultural Laboratory Proficiency Program through Collaborative Testing Services provides three set 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.
  - American Oil Chemist Society (AOCS)-four rounds per year with two samples per round.

27.4 For a schedule of PTs 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)
  - 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 Health (NDDH)
  - 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): Clean Water Act; Safe Drinking Water Act; Resource Recovery and Conservation Program.
- South Dakota Department of Environment and Natural Resources (SDDENR)
  - Bismarck, North Dakota Laboratory: Reciprocal certification for Safe Drinking Water Act based on the North Dakota 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
- A2LA-ISO 17025 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 work order 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 reported under TNI (NELAC) 2009 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 work order 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).
- 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.

- A reference to any sampling plan if the sampling was done 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.
- As relevant, a statement to the effect that the results relate only to the item tested.

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.

29.9 Sampling information is also added as applicable:

- Sampling date.
- Identification of the sampler.
- Location of sampling.
- Reference to the sampling plan used.
- Environmental conditions at the sampling location.
- 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. This information may be found at the top of the report, the bottom of the report or in the narrative of the report.

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 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.

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

30.5 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 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.

31.2 Ethics and data integrity training is part of initial training and also 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 of this misreporting 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/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 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.

32. CONFLICT OF INTEREST

32.1 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.

32.2 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.

33. INTERNAL INVESTIGATIONS OF BREACH OF POLICIES

33.1 Upon discovery of inappropriate activity with regard to MVTL polices on confidentiality, ethics and 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. This confidentiality must be strictly adhered to in order for the employees involved in reporting to management a potential breach is protected; it is equally important for the respect of the employee being investigated.

REVISION HISTORY

2018-0 (15 September 2018):

Page 2 – updated addresses: addition of Building 1 and 2, deletion of Center and German streets addresses and the soil receiving building.
Page 4 – reworded 1.4.
Page 7 – Table 1 deleted Wear Metals in Oil.
Page 8 – "deputy roles" added to 2.4.
Page 12 – removed Process Director from the organizational chart; reorganized chemistry into inorganic and organic.
Page 14 – revision of 4.8.2 to meet A2LA requirements.
Page 16 – revision of 7.3 to accurately reflect the process.
Page 19 – rewording of 13.3.
Pages 23 - 24 – rewording of 19.9.
Page 24 – addition of frequency of review to section 21.1.
Page 30 – revision of 27.1; deletion of AOAC Salmonella in Egg PT from 27.3 since that has been discontinued; change from API to LGC.
Page 31 – deletion of WiDNR certification from section 28.1.

2017-1 (15 August 2017):

Changed Management System to Quality Management System throughout the manual.
Updated SOP information (titles and numbers) throughout the manual.
Page 2 – Update address of Soil and Feed laboratory to new location.
Page 4 – Removed approval signatures since they will be on the document approval form.
Page 4 – Updated 1.3 with new location.
Page 5 – Updated 1.4 by removing preparation of samples from the Nevada IA location and added the shipment of samples to New Ulm Soil Laboratory.
Page 8-10, section 2.4 – Names of management were removed, leaving only the position titles.
Page 9-10, section 2.4.3 – Additional duties added to the compliance unit.
Page 13, section 3 – Addition of change control; rest of document re-numbered.
Page 14, section 4.7 - Added approval of MPS by compliance; also, assignation of effective date after approval.

2017-0 (31 March 2017):

Page 4 – the second bullet under Quality Policies and Objectives was re-worded.
Page 5, section 1.4 – removed "drying and grinding only" from the Nevada laboratories, since they only receive samples.
Page 9, section 2.1 – reworded the third sentence.
Page 10, section 2.4.2.2 - updated the microbiology laboratory manager to Mike Smoley.
Page 13, section 3.3 – updated the SOP title.
Page 15, section 5.1 – deleted "moved to MVTL archives" since the documents are only moved to IQ.
Page 16, section 6.3 – changed "other locations" to "Bismarck location".
Page 17, section 8.3 – updated the SOP title.
Page 24, section 20.2 – the section was reworded.
Page 27, section 23.4 and 24.2 – updated the SOP titles.
Page 30, section 26.3 – added Absolute Standards, Inc to the list of environmental PTs; added quarterly mycotoxin and minerals to AAFCO.
Page 33, section 28.9 – removed the reference to a sampling plan since this is not on reports.

2016-0 (1 March 2016):
Addition of Legionella Testing to Table 1 for New Ulm Microbiology Laboratory.
Removal of Mold Testing from Table 1 for Bismarck Laboratory.
Addition of titles to the SOPs throughout the manual.
Addition of 20.4, re-numbered 20.5.
Added peer review to 25.7.
Section 28.10: Re-worded to more accurately reflect all report scripts.

2015-0 (30 October 2015):
Deleted Organic Lab fax number.
Section 1: Added approximate square footage for New Ulm locations.
Page 6 – 7: Moved fertilizer testing from the Chemistry laboratory to the Feed Laboratory.
Page 7: Added receipt of manure samples to the scope of the Nevada IA location.
Page 8: Addition of Karl Fisher moisture and feed and food analysis.
Page 8: Addition of "Limited Scope" to Crude Oil testing
Revised section 2.3 to compliance with the change in external document control (SOP 10-10013).
Split section 2.4.5 into 2.4.5 for Cost Analysis and Controller and 2.4.6 for IT. Section 2 was re-numbered to accommodate this additional section.
Section 3.1 revised to reflect the change in external documents (SOP 10-10013).
Corrected 3.8.1 for typographic/grammatical errors.
Section 4.1 and 4.2 were revised to remove the reference to SOP 40-13011 since it was retired; updated the title of SOP 10-10017; added SOP 10-10039 for IQ.
Section 5.1: Updated title of SOP 20-10002.
Added section 6.3 and revised section 6.4 to clarify subcontractors' reporting on MVTL reports.
Section 7: Updated Purchasing SOP and added the Bismarck purchasing SOP to the list (80-10013).
Section 8.3 was revised to update the title of SOP 10-10017 and added SOP 10-10039.
Section 16.2: Updated title of SOP 40-10011.
Section 17.9: Removed redundancy about CVs.
Section 18.1: Updated to "Safety Data Sheets".
Section 18.6 was moved to 18.9 and section 18.9 was revised to add the security of our facilities.
Section 18 was renumbered after the change.
Section 23.2: Added ORP to the list of field testing parameters.
Corrected 26.1 for typographic/grammatical errors.
Updated PT vendors for environmental PTs in section 26.3
Updated certification list in section 27, by removing drinking water certification from WI DNR.
Removed section 28.10 since it is covered in Section 6; re-numbered the section following 28-10.
Replaced "Preventative" with "Preventive" to be consistent with MVTL SOPS throughout the Quality Manual.

2014-0 (15 May 2014):
Page 4 – ". . . . to communicate the importance of quality to the employees:" was added to the second sentence of the second paragraph on this page
Page 7 – removed List 2 and Herbicide testing in soil and water and plant materials from organic laboratory capabilities
Page 8 – Added crude oil testing to the capabilities of the Bismarck laboratory
Section 2.1 – addition of the second sentence

Page 12 – Re-format of organizational chart
Section 3.5 – deletion of the last sentence of this paragraph stating that the obsolete copies of SOPs in the online review folder are moved to the compliance unit drive since this is no longer the case
Section 3.8.1 – addition of a time frame for documents needing handwritten corrections
Sections 3.9, 4.2, 5.1 – revision to include the scanning of documents into IQ
Section 12.1 – addition of last two sentences
Section 12.4 – addition of last two sentences
Section 13.2 – addition of the entire paragraph
Section 14.1 – revision to note that each technology will be audited each year rather than each procedure
Section 14.2 – revision to describe the changes in the audit report format
Section 14.3 – deletion of the statement that all findings in an audit will be issued as a CA form; changed to follow new procedure
Section 14.4 – added second sentence to describe that CA forms will be issued when corrective action from an audit is not completed or is ineffective
Section 17.3 – addition of last sentence
Section 17.4 – addition of last sentence
Section 17.7 – addition of last sentence
Section 20.3 – addition of third sentence
Section 22.2 – addition of last two sentences
Section 22.3 – addition of last sentence
Section 24.4 – addition of " . . . or on the sample receipt forms:" at the end of the sentence; addition of last bullet
Section 24.9 – addition of last two sentences
Section 25.1 – addition of last sentence
Section 25.2, 25.4 – addition of these two sections
Section 26.1 – addition of PT schedule; addition of last sentence.
Section 26.3 – addition of quarterly AAFCO pet food sample
Section 27.1 – addition of three bullets under A2LA ISO17025 Scopes
Section 28.4 – addition of last sentence
Section 29.5 – addition of this section

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

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By Signing below indicates that you have reviewed and approved this document for use.

Compliance Approval: David Luiken, QA Team Leader

Date: 21 August 2018

Technical Approval: Michael K. Grob, COO

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Technical Approval: Colleen Skillings, CFO

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Technical Approval: Jerry Balbach, President

Date: 22 august 2018

Final Approval:
Thomas R. Berg, CEO

Thomas R Berg

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Return the Document Approval Form to the Compliance Unit

Periodic Review Frequency: Annually

Periodic Review: The signatures below indicate that this document has been reviewed and determined to be current. Revisions are not required.

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