

Minnesota Valley Testing Laboratories, Inc. (MVTL)

Quality Manual

ISO 17025

NELAC 2003 and TNI 2009

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See last page for revision details.

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

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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 CEO of MVTL has issued the following statements:

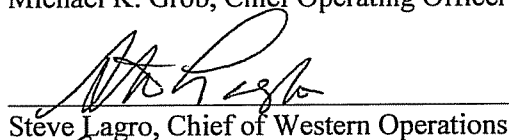
- We are committed to assuring that our analytical testing process and support services meet the specifications published by national and international standard organizations (including NELAC, TNI and ISO) and regulatory agencies while meeting the specific needs of our customers.
- We are committed to the highest professional standards and practices by each individual employed by MVTL. We have policies and procedures in place to assure each analytical test result meets these standards.
- 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 management system.
- Our personnel are committed to understanding our management system and implementing its policies and procedures as stated in our written quality system. Personnel are also given the charge of correcting and improving this system as necessary.



Michael K. Grob, Chief Operating Officer

20 Sept 2010

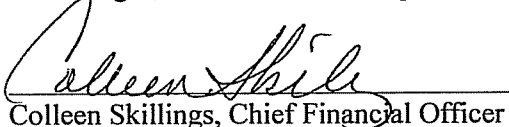
Date



Steve Lagro, Chief of Western Operations

3 Sept 2010

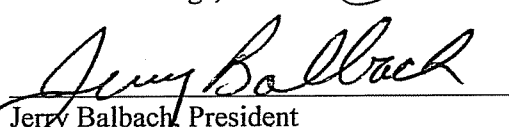
Date



Colleen Skillings, Chief Financial Officer

15 Sept 2010

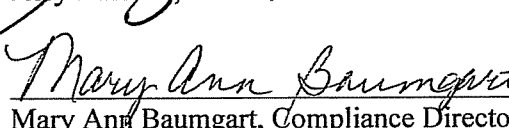
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Jerry Balbach, President

10 Sept 2010

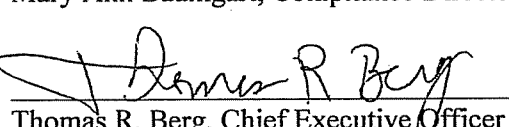
Date



Mary Ann Baumgart, Compliance Director

7 September 2010

Date



Thomas R. Berg, Chief Executive Officer

14 Sept 2010

Date

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 ISO17025 scopes 2459.01 and 2459.02; current 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, New Ulm, Minnesota. Two laboratories – chemistry (both inorganic and organic) and microbiology are located at the corporate office location. The soil fertility and soil characterization laboratory is located at 326 Center Street in New Ulm and the feed laboratory is located at 2 North German Street in New Ulm. The field services department is housed at 219 16th Street South, Unit 2 in New Ulm.

1.4 The Nevada, Iowa Laboratory is located at 51 L Avenue. Inorganic chemistry testing, soil fertility and soil characterization testing, food microbiology and proximate analyses are performed at this facility.

1.5 The Bismarck, North Dakota laboratory is located at 1411 South 12th Street with the field services department housed at 1223 South 12th Street. This laboratory provides inorganic chemistry, coal quality and overburden analyses.

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

| | |
|---|---|
| <p>New Ulm, MN Field Service Department</p> | <p>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</p> |
| <p>New Ulm, MN Chemistry Laboratory</p> | <p><u>Inorganic:</u> Metals by ICP and ICP MS Mercury by CVA Low Level Mercury by 1631E Wastewater Analyses Surface Water Analyses Drinking Water Analyses Fertilizer Analyses (AOAC Methods) Analyses Under FDA (21 CFR Part 58) and EPA (40 CFR Part 160) GLP, GCP, and VICH GL9 Regulations Nutritional Labeling and Proximate Analyses of Food, Ingredients and Finished Products Bio-solid, Soil, Industrial Wastes (SW-846 Methods) Dry Milk Product Analyses and Complete Grading Physical Analyses Common Fluid Milk Analyses <u>Organic:</u> EPA and SW-846 Methods 8021B (Soil only), 624/8260, 625/8270C, 608/8081, 8082 TCLP Analysis for Organic Compounds UST: GRO, DRO, PVOCs by 8015B and 8015C and WI LUST Minnesota Department of Agriculture List I and List II Herbicide testing in soil and water and plant materials Pesticide Studies under EPA GLP regulations (40 CFR Part 160) Feed Analyses under FDA GLP regulations (21 CFR Part 58) GMP Testing Nutritional Labeling Fatty Acid Profiles, Cholesterol, Vitamins, Sugar Analysis, and Amino Acids in Foods and Feeds Toxin Assay of Food, Feed and Pet Food</p> |

Table 1
LABORATORY CAPABILITIES

| | |
|---|---|
| <p>New Ulm, MN Microbiology & Food Laboratory:</p> | <p>Microbiological Examination of Drinking Water and Wastewater Microbiological Examination of Food and Dairy Products Pathogen Testing: <i>Salmonella</i>, <i>Listeria</i> and <i>E.coli O157:H7</i> in Food and Dairy Products Customer Consulting, Diagnostic and Information Services Shelf Life Studies Challenge Testing Cosmetic Challenge Studies</p> |
| <p>New Ulm, MN Soil Fertility and Characterization Laboratory</p> | <p>Soil Testing, including Particle Size, CEC, SAR and Moisture Nutrient Analysis, Plant Analysis, Soybean Cyst Nematode Testing Corn Stalk Nitrate Analysis Lime Analysis Manure and Fertilizer Analyses (AOAC Methods)</p> |
| <p>New Ulm, MN Feed Laboratory</p> | <p>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 Methods) Mixer Studies Forage Testing Analyses Under FDA GLP (21 CFR Part 58) , OECD GLP, GCP and VICH GL9 Regulations</p> |
| <p>Nevada, IA Laboratory</p> | <p>General Inorganic Chemistry Wastewater, Surface, and Drinking Water Analyses Manure Nutrient Analyses Field Services and Sampling Soil Fertility Testing Corn Stalk Nitrate Analysis Soybean Cyst Nematode Testing Food Microbiology and Proximate Assays</p> |
| <p>Bismarck, ND Laboratory</p> | <p>General Inorganic Chemistry Coal (Proximate, Ultimate and others) Waste Oil Analyses, Wear Metals in Oil Overburden Analyses Metals by Flame AA, ICP and ICP-MS (EPA, SW-846 and ASTM Methods) Extensive Capabilities in Wastewater Analyses SW-846 Methods including TCLP Analysis Surface Water Soil, Bio-Solids, Soil and Industrial Waste (SW-846 Methods) Drinking Water Analyses Field Services and Sampling Mold Testing</p> |

GLOSSARY FOR TABLE 1

| | |
|------------|--|
| AA: | Atomic Absorption Spectroscopy |
| AOAC: | Association of Official Analytical Chemists |
| ASTM: | American Society for Testing and Materials |
| CEC: | Cation Exchange Capacity |
| CFR: | Code of Federal Register |
| CVAF: | Cold Vapor Atomic Fluorescence |
| DRO: | Diesel Range Organics |
| EPA: | United States Environmental Protection Agency |
| FDA: | United States Food and Drug Administration |
| GLP: | Good Laboratory Practices |
| GCP: | Good Clinical Practices |
| GMP: | Good Manufacturing Practices |
| GRO: | Gasoline Range Organics |
| ICP: | Inductively Coupled Plasma Spectroscopy |
| ICP-MS: | Inductively Coupled Plasma Spectroscopy with Mass Spectrometry Detection |
| ISO 17025: | International Organization for Standardization Laboratory Standards |
| NELAC: | National Environmental Laboratory Accrediation Conference |
| OECD: | Organisation for Economic Co-operation and Development |
| PVOCs: | Petroleum Volatile Organic Compounds (usually benzene, toluene, ethyl benzene and xylenes) |
| SAR: | Sodium Adsorption Ratio |
| SW-846: | USEPA Test Methods for Evaluating Solid Waste |
| TCLP: | Toxicity Characteristic Leaching Procedure |
| UST: | Underground Storage Tank |
| VICH GL9: | Good Laboratory Practice Guidelines for Veterinary Products |
| WILUST | Wisconsin Leaking Underground Storage Tank Program |

2. MANAGEMENT SYSTEM

2.1 The MVTL management system is outlined in this manual, the Employee Handbook, and MVTL SOPs. These documents are included as part of the training program and are made available to all employees (others outside MVTL may be provided these documents upon request). Through annual training and meetings, MVTL communicates the expectations of management to meet the requirements of the 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 with the expectations of the customer.

2.2 Personnel are made aware of their roles and responsibilities in maintaining the management system and continuous improvement process through annual training and review. This review process helps to remind all employees of their part in the management system and 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 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 management system can be found in this manual, the Employee Handbook, MVTL SOPs and various external reference documents. All the documents are maintained on a master document list to assure document control and to avoid an obsolete document being used.

2.4 General roles and responsibilities of laboratory and quality management are summarized here. For complete descriptions see the CV of each individual.

2.4.1 Executive Committee

2.4.1.1 Chief Executive Officer (CEO): As the CEO of MVTL, Thomas R. Berg is responsible for all functions of the company-administrative, scientific, financial and sales and marketing activities. Mr. Berg also oversees the operations of the Bismarck Laboratory.

2.4.1.2 Chief Financial Officer (CFO): Colleen Skillings as 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. She 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): Responsibility for the overall operations and quality of data generated by personnel in the Chemistry Laboratory, Microbiology Laboratory, Feed Laboratory, Soil Laboratory and the Nevada Laboratory lies with the COO, Michael K. Grob. This includes oversight to ensure that analytical work meets objectives for corporate standards of quality, service and customer satisfaction by managing all the laboratory resources.

2.4.1.4 President: Jerry Balbach as president oversees and performs sales, marketing and project management for the Minnesota, Iowa, North Dakota and Wisconsin locations.

2.4.2 Laboratory Management (Technical Directors): The Chemistry (New Ulm and Nevada), Microbiology, Feed, Soil and Bismarck Laboratories are managed by Jason Smith, Jesse Portner, Joel Sieh, Brent Hanson and Stephen Lagro, respectively. These managers report to Michael K. Grob and are responsible for the overall laboratory operations, 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.

2.4.2.1 Assistant Managers (Deputy Technical Directors): The assistant managers serve as backup for the managers of the area they serve.

2.4.2.2 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 management and quality systems described in this manual.

2.4.3 Compliance Director (Quality Manager): Mary Ann Baumgart serves in the position of quality manager with Bryan Brock as the deputy for purposes of the ISO17025 and David Luiken serves as the deputy for NELAC and TNI purposes. The compliance director is responsible for assuring that the management system is established, implemented and maintained in conformance with applicable regulations, accreditation standards and customer requests/contracts. As part of this oversight of the quality system, changes and improvements to the management system are recommended and encouraged.

2.4.3.1 The compliance director reports directly to the Chief Operations Officer, a member of 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.

2.4.3.2 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.

2.4.3.3 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 and reporting to management any

deviations or noncompliance concerns. The auditors also review data upon request, either a customer/contract request or an internal request.

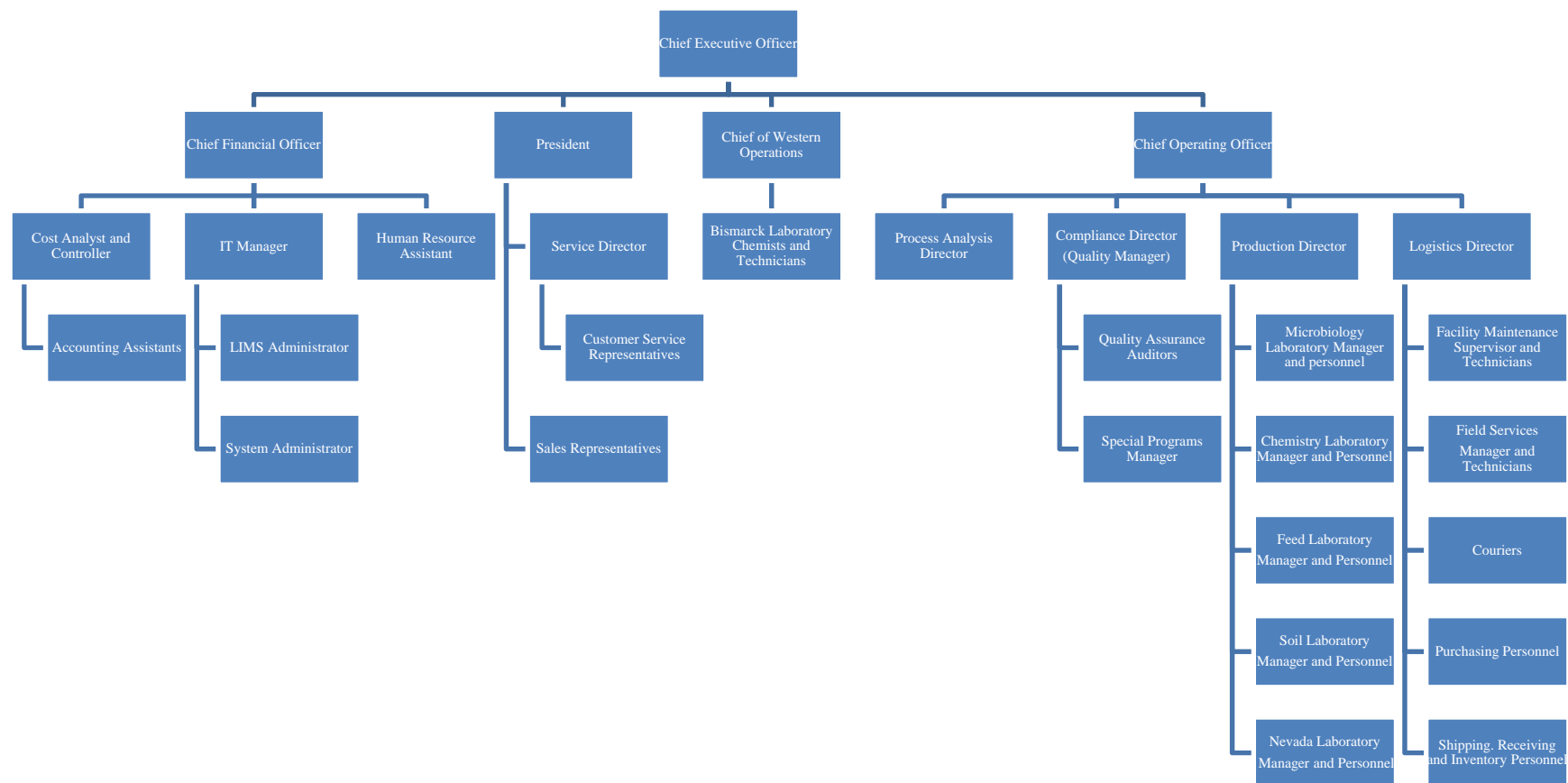
2.4.4 Logistics Department: The logistics department, under the supervision of director Carla Walden, provides support services for the MVTL laboratories. These support services include purchasing, shipping and receiving, field services, courier services and maintenance and falls under the Chief Operations Officer.

2.4.5 Accounting and Information Technology Services: The accounting department is led by Lori Allen. The information technology department is under Steve Bowen. Both these departments report directly to Colleen Skillings. These departments provide support for the entire company.

2.4.6 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.

2.5 By following the management system outlined in this manual, upper management maintains the integrity of the management system when changes to personnel, structure, policies and procedures are made.

2.6 The personnel at MVTL, both 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 management system. Both managerial and technical personnel are involved in identifying departures from the management system and written procedures which are then documented following the corrective action procedure described in SOP 10-10002, "Corrective and Preventative 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.



3. DOCUMENT CONTROL

3.1 At MVTL, both external and internal documents are controlled to assure that only the most current and/or 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. Each department at MVTL maintains a list of external documents; this list identifies the document name, revision/version and the location of the document. See SOP 10-10013, "MVTL Document Control", for information on distribution of internal and external documents within MVTL.

3.2 Internal documents are documents generated by MVTL for use in the management system. These include the Quality Manual, Employee Handbook, Chemical Hygiene Plan, methods, SOPs and forms. All internal documents used by the staff at MVTL are reviewed and approved for use by management. They are reviewed annually and revised as needed to assure continued suitability and compliance with applicable regulations and standards. An index of SOPs, methods and forms is kept by the compliance unit. In addition, the microbiology laboratory maintains an index of the media preparation sheets they maintain for use in the media preparation area.

3.3 SOPs, methods, forms and media preparation sheets 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.

3.4 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 it becomes obsolete 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; these obsolete copies are maintained in the online folder for obsolete documents.

3.5 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.

3.6 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 by the microbiology laboratory manager or their designee, who then assigns the effective date after approval. For MPS that have more than one page the forms are paginated to indicate the page number and the total number of pages (Page X of Y). 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.

3.7 The process for revising an internal document is the same as issuing the original document. The final revised edition of the document must be reviewed and approved by management. 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.

3.7.1 For the most part, MVTL does not utilize handwritten changes for revision of documents; however, it does in some cases use handwritten changes to make minor grammatical corrections or corrections to the format of the document. 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. The word processing copy of the document will be corrected so that the subsequent revisions will be correct. Depending on the correction, a corrected copy may not be distributed to those holding paper copies of the document. However, the corrected document will be posted in the on-line review.

3.8 Obsolete documents generated for the MVTL quality system are kept in the GLP archives until it is determined they may be discarded. Most documents such as SOPs, methods, 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/accreditation records are kept as long as necessary according to the certification/accreditation program that governs them. See MVTL SOP 50-10004, "Compliance Unit Records", for additional information.

4. CONTROL OF RECORDS

4.1 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 10-10017, "Non-GLP/GCP/VICH GL9 Archiving Procedures" and 40-13011, "Maintenance of the GLP Archives Facility". The recording and maintenance of original observations is covered in MVTL SOP 10-10004, "Documentation and Handling of Original Observations (Raw Data) and Records".

4.2 At this time MVTL does not store data electronically, all the laboratory's technical records are maintained as paper copies. A new LIMS system is currently in development and should be ready in 2011. By March 2011 SOPs for the new LIMS system will be in place or the information addressing the new LIMS will be added to this manual.

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

5. REVIEW OF REQUESTS, TENDERS AND CONTRACTS

5.1 See SOP 20-10002, "Client Specific Contract Review", 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. They are moved to the MVTL archives for a period of 10 years after the expiration date.

5.2 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.

5.3 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.

5.4 The contract is then reviewed with all personnel that will be involved in the contract work to assure that 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.

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

5.6 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.

6. SUBCONTRACTING OF ANALYSES

6.1 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.

6.2 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 communication can be used to gain the subcontract approval in writing.

6.3 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.

6.4 The report issued to the customer will have the subcontracted laboratory listed as "OL" in the analyst column on the report. The name of the laboratory and the contact information for the subcontractor will be listed in the narrative portion of the report. 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.

7. PURCHASING OF SERVICES AND SUPPLIES

7.1 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 New Equipment and Instruments
- 70-14001 – Performance Evaluations for Critical Supply Vendors
- 70-14002 – Supplier Qualification for Critical Supply Purchases
- 30-15001 – Receiving Supplies into Inventory-Front Street Location Only
- 81-45 – Consuming and Deleting Supplies from Inventory
- 81-46 – Physical Inventory Procedures

7.2 Critical supplies and supplies that affect the quality of the test are evaluated and approved before use. These records are maintained in the laboratory.

7.3 MVTL uses a purchase order form when ordering equipment and supplies. See SOP 81-20. These records are reviewed and approved before they are forwarded to the vendor.

7.4 MVTL purchases services and supplies from approved vendors only. Our vendors are approved and evaluated according to SOPs 70-14001 and 70-14002. The list of approved vendors is available through the purchasing department.

8. SERVICE TO THE CUSTOMER

8.1 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 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 management system, testing procedures and customer service.

8.2 Customers may make special requests for reporting whether it be 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 result 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.

8.3 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 (MVTL SOP 81-63 "Sample Storage and Disposal") and data storage policies (MVTL SOP 10-10017 "Non-GLP/GCP/VICH GL9 Archiving Procedure"). In all cases in which a customer requests reporting in a special format or discontinuance of testing, MVTL management must be notified in writing.

9. COMPLAINTS

9.1 All the complaints received from our customers are recorded by the person taking the call using form 10-90002. Once this 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.

10. CONTROL OF NON-CONFORMING WORK

10.1 MVTL's procedure for correcting and preventing non-conforming work is described in MVTL's SOP 10-10002 ("Corrective and Preventative 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 is involved, the responsibility for determining when work can continue is based on their decision.

10.2 When the results or analytical procedures do not conform to MVTL written policies and procedures or the requirements of the customer, work is 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 the customer is notified in writing explaining the non-conformance. An amended report will accompany this written notification.

10.3 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.

11. IMPROVEMENT

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

12. CORRECTIVE ACTION

12.1 MVTL's procedure for documenting corrective action is described in SOP 10-10002. When non-conformances are found, corrective action is taken to prevent re-occurrence 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.

12.2 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 as effective 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 **14. INTERNAL AUDITS**.

12.3 While the goal is to report only results that have all quality control parameters within the acceptance limits, there are times where results will be reported even though the quality control parameters are not met. See SOP 10-10002 for the procedure in handling these quality control failures. When a result is reported with quality control failures, the data is qualified according to the requirements of the program under which the analysis is performed. At times, there are customers who wish to have these qualifiers removed from their reports, if these sample results are being reported under no program requirements the customer will be accommodated as long as the request is noted in the customer file; if the results are being reported under a program requiring these qualifiers, the qualifiers will not be removed from the report.

12.3 Corrective action documentation is maintained by compliance unit personnel. These records are archived as necessary in the GLP archives and maintained for at least 10 years.

13. PREVENTATIVE ACTION

13.1 SOP 10-10002 covers the procedure for preventative action. Preventative 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. Preventative actions are discussed during the management review and the effectiveness of preventative actions taken are determined.

14. INTERNAL AUDITS

14.1 The compliance director schedules audits for both the management system and the testing activities, at MVTL. The schedule is set so that all sections of the management system are covered annually, as well as each parameter under the Minnesota Department of Health accreditation; any facility audit not performed as scheduled will be re-scheduled by the compliance director with the reason being noted on the master audit schedule. Laboratory analyses covered under the ISO 17025 scopes are covered every other year. All other analyses are covered on a three year cycle. Audits may be conducted more often as necessary or 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.

14.2 Upon completion of an audit, a report will be issued to the appropriate laboratory manager or area supervisor. Audit for compliance of ISO/IEC 17025 sections will be issued to the Chief Operations Officer (COO) for response and a copy will be forwarded the chief executive officer (CEO); as appropriate, findings will be forwarded by the COO to personnel for resolution. If an issue of non-compliance is found that will affect the quality of an analysis 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.

14.3 The compliance unit will maintain written and signed records of each audit. These records will include the date of the audit, the scope of the audit and the name of the auditor. The body of the audit report will include any findings or problems found by the auditor, any recommendations the auditor has (these may be investigated as preventative action by the area of concern) and a date for a return audit if necessary. After the audit is issued, the recipient of the audit will take action to address each finding to resolve the problem. In addition, a corrective action form may need to be issued to further investigate the root cause of the finding.

14.4 Any actions taken in response to audit findings are audited upon completion to verify implementation and effectiveness. If the action was ineffective or not implemented it is noted in the audit and corrective action is taken. See the **12. CORRECTIVE ACTION** for additional information.

15. MANAGEMENT REVIEWS

15.1 MVTL's management meets at least once every year to review MVTL's 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. 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.

15.2 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 management system. The quality manager will preside and one or more of the attending members will keep minutes. Findings from the management review and new action items that are established during the annual management review are documented in the minutes. Minutes of the meeting are inserted into the final copy of the booklet after they are approved by the CFO or COO. Following the meeting the approved minutes and new action items are sent to the attendees. Depending on the findings or action items, additional meeting may be held to review these items and assign timelines and responsibilities. The quality manager will follow these action items and report the status to the executive management as necessary to ensure that these items are completed within the agreed timelines.

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

16. TECHNICAL REQUIREMENTS

16.1 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**

16.2 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 of the Estimation of Uncertainty".

17. PERSONNEL

17.1 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, microbiologist 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 standards of MVTL and our customers are met.

17.2 The training program at MVTL consists of training in basic laboratory skills, analyte specific training, equipment specific training, training in company policies, safety and regulatory training. 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. Annual training sessions are held for conflict of interest, customer confidentiality, ethics and data integrity and regulatory requirements. 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.

17.3 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 standard operating procedures (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.

17.4 Each employee's curriculum vita (CV) describes the employee's responsibilities, educational background, employment history, list of honors, professional memberships and training. Each CV also has the employee's signature and initials to serve as the person's identity when signing/initialing records. At the beginning of each year, each employee's CV is updated and maintained by the compliance unit with the training the employee has undergone for the year. CVs are available upon request.

17.5 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 and/or mentors observe and evaluate the ongoing competence of employees. Competence of an employee is noted by the signature of the employee, mentor 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.

17.6 Annually each laboratory employee must show continued proficiency by either participating in a proficiency testing study or having at least four acceptable consecutive analysis 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 sample, another initial demonstration of capability or analyzing a sample another analyst has analyzed and getting an acceptable duplication on the result.

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

17.8 MVTL uses only personnel they employ or they have contracted. A job description is maintained for each employee on their CV which is maintained by the compliance unit. The CV also contains a list of experience and education. Department managers authorize personnel to perform specific tasks relevant to their competence, educational qualifications, training, skills and experience. This information is readily available and includes the date of authorization by the manger.

18. ACCOMMODATIONS AND ENVIRONMENTAL CONDITIONS

18.1 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. Material safety data sheets are maintained in each laboratory and are available to all employees.

18.2 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 within the original observations or in a logbook dedicated to each measurement. Indirect measurements include quality control sample analysis and acceptable support records.

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

18.4 To prevent cross-contamination, laboratory managers have established effective separation where there are incompatible activities occurring in an area.

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

18.6 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.

18.7 To ensure the safety of all visitors at MVTL, access to the facility is controlled and limited. 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 in any MVTL facility.
- 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 their work and is ready to leave.

19. TEST METHODS AND METHOD VALIDATION

19.1 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. When MVTL uses a procedure it has developed, 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 management approved for these MVTL developed procedures.

19.2 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.

19.3 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".

19.4 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 and retrievability of the data for the time required for data storage.

20. STANDARD OPERATING PROCEDURES

20.1 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 senior management and reviewed annually for procedural corrections and updates as well as for training purposes.

20.2 The majority of analytical procedures used by MVTL have been documented by various professional organizations or societies as approved methodologies. When approved methodologies are not available, MVTL employs current, well established, validated methods from a variety of recognized sources. Non-standard methods are not used for repetitive testing without first being subject to a validation study. 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.

20.3 For a current list of SOPs, contact the compliance unit.

20.4 Each facility has a technical reference library which houses the method reference texts, as well as a variety of 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.

21. EQUIPMENT

21.1 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 department. 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.

21.2 MVTL controls all the equipment it uses whether it is purchased or leased. Equipment and software used is tested for accuracy and complies 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.

21.3 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 instruments 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.

21.4 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.

21.5 Personnel are authorized by management to use equipment at the completion of their training on each piece of equipment. Relevant SOPs and operator's manuals are readily available for use by the laboratory personnel to aid in training and use during analysis.

21.6 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, these instructions for safe handling, transport and storage are not applicable and will not be included in the equipment SOP, but use and maintenance will be addressed in the SOP. For equipment that is portable, the safe handling, transport, storage, use and maintenance will be covered in the SOP.

21.7 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.

21.8 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.

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

22. MEASUREMENT TRACEABILITY

22.1 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 is documented as it is performed.

22.2 Standards used for equipment calibration checks such as thermometers and weight sets, will be sent 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.

22.3 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 then 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.

23. SAMPLING

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

23.2 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 appropriate. Field analyses include, but are not limited to, pH, Eh, specific conductance, temperature, appearance, dissolved oxygen, residual chlorine and water elevations.

23.3 MVTL has policies and procedures in place for sub-sampling and/or 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.

23.4 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 of Organic, Inorganic and Micro Samples, SOP 81-63, "Sample Storage and Disposal" and this manual.

23.5 Preservation of samples should be done at the time of sampling. MVTL personnel preserve the samples on site as required for the particular analysis and matrix. This preservation is noted on the chain of custody or the sampling forms.

23.6 Sample preservation is dependent upon the matrix and analytical parameter. Required preservation can be found in the MVTL Fee Schedule 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 tables.

24. SAMPLE HANDLING

24.1 For sample receipt see MVTL SOP 10-10008, "Sample Receipt and Log-in of Organic, Inorganic and Micro Samples".

24.2 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 at 0-6°C until the analyses are completed and the holding time has expired.

24.3 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.

24.4 In addition to the assignment of a unique identification and work order number, the following information is noted in the MVTL database (LIMS):

- 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 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.

24.5 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 before being released to the customer.

24.6 Analyses are usually completed within seven to ten working days. Seasonal increase in sample load may cause an increase in turnaround time. 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.

24.7 MVTL has policies and procedures in place for sample retention and disposal. These are covered in MVTL SOP 81-63, "Sample Storage and Disposal". 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.

24.8 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.

24.9 MVTL's facilities are controlled access with environmental controls to safeguard the security and integrity of the samples.

25. ASSURING THE QUALITY OF THE TEST RESULT

25.1 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 for which the MVTL SOPs are based. Examples of QC procedures are: the use of certified reference materials, participation in proficiency testing programs, the use of replicates/duplicates as reproducibility checks in each batch, matrix spikes and matrix spike duplicates, laboratory control samples, method blanks, calibration verifications and reporting limit verifications. Each analysis has its own specific QC parameters as listed in the MVTL SOPs.

25.2 Quality control (QC) samples are evaluated with each analysis batch and when they QC samples are found to be outside the established acceptance limits, an appropriate action is taken. This action may be to re-analyze samples, re-analyze a percentage of the samples, report the samples with qualifiers or in some cases a corrective action form is issued. For a particular analysis, the appropriate action for out of control QC is listed in the MVTL SOP for that analysis.

25.3 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 stated clearly in the SOP. In the microbiology laboratory the sterility of equipment and reagent to be used must be verified before use. Certificates of sterility and/or 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. PROFICIENCY TESTING (PT)

26.1 MVTL participates in external proficiency testing (PT) programs to meet the requirements for certification programs and customers and to monitor the proficiency of MVTL's analyses. The PT programs MVTL participates in are offered at least twice per year, therefore, each analyst will be responsible for analyzing at least one of the PTs each year to show continuing capability. This schedule will be posted annually and each analyst notified when it is their responsibility to analyze the PT sample.

26.2 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. 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.

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

- For environmental programs the most common vendors used by all three MVTL locations are:

- Absolute Standards
- Environmental Resource Associated (ERA)
- Resource Technology Corporation (RTC)
- Wibby Environmental

These PTs are ordered as needed for annual and biannual acceptable result for each certified parameter.

- For feed testing the following programs are used by the New Ulm feed laboratory:
 - National Forage Testing Association (NFTA)-six times per year
 - Association of American Feed Control Officials, Inc. (AAFCO)-monthly
 - 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 Nevada, Iowa laboratory and the New Ulm feed laboratory.
- For soil testing the Minnesota Department of Agriculture provides four sets of samples per year to the Nevada, Iowa laboratory and the New Ulm soil laboratory through North American Proficiency Testing (NAPT).
- For food testing at the New Ulm location:
 - Association of Analytical Chemists (AOAC) Food Chemistry PTs (four times per year)
 - Association of Analytical Chemists (AOAC) Food Microbiology PTs (four times per year)
 - American Oil Chemists Society (AOCS)-four times per year
 - Association of Analytical Chemists (AOAC) *Salmonella* in Eggs (two times per year)
 - FEPAS – as needed
- For food testing in the Nevada location:
 - American Proficiency Institute (API) Food Microbiology (three times per year)

26.4 For a schedule of PTs for the current year or results from past studies, contact the compliance unit.

27. LABORATORY CERTIFICATION AND ACCREDITATION

27.1 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
 - Bismarck, North Dakota Laboratory (Laboratory ID#038-999-267): Clean Water Act; Safe Drinking Water Act; Resource Recovery and Conservation .
- 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.
- Iowa Department of Natural Resources (IA DNR)
 - New Ulm, Minnesota Laboratory (Laboratory ID#132): Reciprocal certification based on the Minnesota Department of Health Certification for Clean Water Act, Safe Drinking Water Act and Resource Recovery and Conservation Program; IA DNR Underground Storage Tank Program.
 - Nevada, Iowa Laboratory (Laboratory ID#022): Clean Water Act; Safe Drinking Water Act; Resource Recovery and Conservation Program.
- Wisconsin Department of Natural Resources (WI DNR)
 - New Ulm, Minnesota Laboratory (Laboratory ID#999447680): Clean Water Act; Safe Drinking Water Act (nitrite, nitrate and fluoride only); Resource Recovery and Conservation Program.
- South Dakota Department of Environment and Natural Resources (SDDENR)
 - Bismarck, North Dakota Laboratory: Reciprocal certification based on the North Dakota Department of Health certification for the Safe Drinking Water Act.
- Iowa Department of Agriculture and Land Stewardship List of Certified Soil Testing Laboratories.
 - New Ulm, Minnesota Soil Laboratory
 - Nevada, Iowa Laboratory
- Minnesota Department of Agriculture
 - New Ulm, Minnesota Laboratory: List 1 and 2 Pesticides in water and soil
 - New Ulm, Minnesota Feed Laboratory: Manure Analysis Program (MAP)
 - Nevada, Iowa Laboratory: Manure Analysis Program (MAP)
 - New Ulm, Minnesota Soil Laboratory: Soil Testing Certification Program
 - Nevada, Iowa Laboratory: Soil Testing Certification Program
- A2LA-ISO 17025 Scopes 2459.01 and 2459.02.

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

28. REPORTING THE RESULTS

28.1 MVTL does not consider reports final until they have been signed/initialed and approved by authorized personnel. Authorized personnel have access to a password protected LIMS menu; only through this menu can reports be printed and approved. MVTL protects its company letterhead by storing

it in secure areas of each office location. Only authorized personnel are allowed direct access to these facilities and the stored letterhead. With the use of an updated LIMS system the reports can only be printed with a certain level of security, limiting the ability of unauthorized printing of reports.

28.2 The results of each test or series of tests performed by MVTL are reported accurately, clearly, unambiguously, objectively and in accordance with any specific instructions in the MVTL SOPs. The results are reported in a “Final Report” which include the following:

- Title of “Final Report”.
- 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, appears on each page of the report in order to assure that each page is recognized as part of the final report; the end of the report is indicated in the page number since the total number of pages is given for each sample.
- The name and address of the customer.
- The identification of the reference method used for each analysis.
- The description of the sample, the condition of the sample and the unique laboratory identification (number) of the sample.
- The date of receipt and 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 of the person authorizing the final report.
- As relevant, a statement to the effect that the results relate only to the item tested.

28.3 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/non-compliance with requirements and/or specifications.
- A statement of the estimated uncertainty of the measurement as requested by the customer.
- Opinions and interpretations with the documentation on which these opinions and interpretations are based.

28.4. Sampling information is also added as applicable:

- The sampling date.
- Identification of the sample.
- 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.

28.5 When the final report contains results of testing performed by subcontractors, these results are clearly identified with an “OL” in the analyst column. The specific information of the subcontract laboratory is given in a narrative on the report. When it is necessary to amend a final report; these amendments contain a statement of “AMENDMENT TO FINAL REPORT” and in some cases an explanation of what was amended.

29. CONFIDENTIALITY

29.1 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.

29.2 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 submit.

29.3 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 an effort to secure these recommendations, but current customers’ names and information will only be released upon written permission from the customer.

29.4 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. ETHICS and DATA INTEGRITY

30.1 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 any 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 customer’s confidence in the work that is performed.

30.2 Ethics and data integrity training is part of initial training and also conducted annually for employees. During the presentation employees are provided a paper copy to follow the presentation, this paper copy of the presentation is available to the employees after the presentation, as necessary. Topics

of ethics and data integrity training includes, 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.

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

- Fabrication, falsification or misrepresentation of 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 step to make it appear that holding times were met.
- Unwarranted manipulation of samples, software or analytical conditions. 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; manipulation of software so that operational codes are deleted, calibrations 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 spiking, 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.
- Improper calibrations 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; failure 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.

30.4 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.

31. CONFLICT OF INTEREST

31.1 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 and/or senior management for a decision. Correspondence and contact with customers are handled by management and customer service so that personnel generating results are not burdened with undue pressure and influences from the customer. MVTL works very hard not only to assure there is no conflict of interest, but also to assure there is no perceived conflict of interest.

31.2 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 and family members are 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.

32. INTERNAL INVESTIGATIONS OF BREACH OF POLICIES

32.1 Upon discovery of inappropriate activity with regard to MVTL policies 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 are protected; it is equally important for the respect of the employee being investigated.

REVISION DETAILS

30 September 2010 revision:

- Replaced “client” with “customer” throughout this Quality Manual.
- Numbered each paragraph throughout this Quality Manual.
- Page 2: Addition of Wisconsin Sales Office
- Page 5: Clarified and expanded the policies and objectives by changing the wording.
- Page 6: In 1.6 added “All locations are under the scope of this quality manual”.
- Page 7: In Table 1, Method 8021B was indicated to be for soil only to reflect the work we do; deletion of OA-1 and OA-2 since these have been replaced with 8015B and 8015C.
- Page 9: Added ISO 17025, NELAC, OECD and WI LUST to the glossary.
- Page 10: Addition of review process and external audits to paragraph 2.2.
- Page 10: Addition of job descriptions for the executive committee (2.4.1).
- Page 11-12: Addition of job description for laboratory management (2.4.2), compliance director (2.4.3), logistics department (2.4.4) and accounting and IT services (2.4.6).
- Page 12: In 2.6 clarification that non-conformances maybe be from both analytical and support service.
- Page 13: Updated organization chart by deleting marketing Vice President and Sales Director.
- Page 14: Addition of 3.3 and parts of 3.4, explaining the online SOPs maintenance.
- Page 15: Addition of 3.7.1 and 3.8.
- Page 15: Addition of section 4. CONTROL OF RECORDS (removed from page 23).
- Page 16: Additon of “This includes state certification requirements.” to 5.2, first bullet.
- Page 16: Addition of 5.3 and 5.5.
- Page 17: Addition of the last sentence in 6.1, addition of 6.4.
- Page 18: Addition of the Customer Special Request Policy under Service to the Customer (8.2 and 8.3).
- Page 19: Deleted SOP 10-10016 in 10.1 since this SOP is not effective.
- Page 20: Addition of 12.3 and 12.4.
- Page 20: Replacement of ISO/IEC 17025 with management system and addition of the Minnesota Department of Health accreditation in 14.1.
- Page 21: Addition of 15.3.
- Page 22: Addition of uncertainty SOP 40-10011 to 16.2.
- Page 22: Corrected typographic error in 17.2; added “and integrity” to ethics training.,
- Page 23: Addition of sentence “Each CV also has the employee’s signature and initials to serve as the person’s identity when signing/initials records”; addition of 17.6.
- Page 25: Subsection “Standard Operating Procedures” changed to its own section (20)
- Page 25: Addition of last sentence in 19.3.
- Page 26-27: Addition of 21.9; deletion of sections Balances, Temperature Controls, Temperature Controlled Environments, Timing Devices, Volumetric Devices, Microscopes, pH Meters, Spectrophotometers, Fume Hoods, Autoclaves, and Deionized Water and Reverse Osmosis System. This information is found in the individual SOPs.
- Page 27-28: Changed “field service personnel” to “MVTL personnel” since it is not always field service personnel doing the sampling.

Page 28: Made subsection "Sample Preservation" a part of section 23. Sampling; made subsection "Sample Handling" its own section (24); removed the portion of sample handling that is covered in MVTL SOP 10-10008 and referenced this SOP.

Page 29: Removed "and in this manual" from sample retention and disposal since it is covered in SOP 81-63 only.

Page 30: Included subsection "Reagents" in the section 23.

Page 30: Made subsection "Proficiency Testing" into its own section (26).

Page 30: Removed second sentence in 26.1 since we do more than one PT study for all analytes.

Page 31: Made subsection "Laboratory Certification and Accreditation" into its own section (27).

Page 32: Addition of API PT program for Nevada laboratory.

Page 32: Addition of 27.2.

Page 32: Addition of security of new LIMS system.

Page 33-36: The last section dealing with confidentiality, ethics and conflict of interest was divided into sections 29, 30, 31; addition of 29.4; addition of data integrity to ethics topic; addition of 30.2, 30.3 and 30.4; addition of 31.2.

Page 36: Addition of 32. INTERNAL INVESTIGATIONS OF BREACH OF POLICIES.