## Purpose of State of Montana Central Milk Laboratory

The State Central Milk Laboratory in the Montana Veterinary Diagnostic Laboratory is a state owned and operated Official Laboratory with analysts employed by the State working in conjunction with the State Regulatory Agency designated as the primary State laboratory for the examination of producer samples of Grade 'A' raw and commingled raw milk for pasteurization, pasteurized milk and milk products, and dairy waters, as necessary. This laboratory follows the guidelines of the National Conference on Interstate Milk Shipments, a cooperative program between FDA, the states, and the dairy industry. It was established to promote reciprocity and uniformity among states, dairy farms, and plant inspection programs.

The Grade 'A' Pasteurized Milk Ordinance, FDA ver. 2013, Standard Methods for the Examination of Dairy Products, 17<sup>th</sup> ed., 2004, The Handbook for Evaluation of Milk Laboratories, FDA rev. 2011, FDA/NCIMS 2400 Series and Appendix N Survey forms are key reference sources and are considered valuable aids in regulating the dairy industry. These are well-defined rules that give processors the guidelines they need to ensure product safety and give regulators the guidelines to inspect facilities. The rules also help ensure consistency and uniformity for state inspectors and dairy processors. No matter where the dairy products are shipped, the requirements are the same.

The State Central Milk Laboratory performs a variety of microbiological and chemical tests to guide the sanitarians in their farm and plant inspections. A summary of the testing procedures provided are: standard methods plate count (general bacteria), coliform count (fecal coliform in milk and water), inhibitors (antibiotic residues), BRT ring test (Brucellosis), Somatic Cell Count (detect mastitis), phosphatase (proper pasteurization), fat, lactose, protein, total solids, moisture, and yeast and mold. Additional testing procedures may include Added Water and Pesticide Residues. Any one *type* of testing procedure mentioned above may include knowledge of multiple testing procedures. (example: the central laboratory now performs 9 different antibiotic testing procedures.) The required testing procedures for samples are listed in the *Grade 'A' Pasteurized Milk Ordinance*, FDA ver. 2013 and more succinctly detailed in FDA memorandum M-a-98, FDA Validated Laboratory Methods, 3-1-13.

To retain certification/accreditation, a large portion of a central laboratory's daily function is maintaining a Quality Assurance/Quality Control program in their laboratory. Records are kept on all aspects of the testing criteria performed. (note: all required milk program qa/qc details are listed in the 2400 forms as well as MVDL requirements for NAHLN accreditation)

A state milk analyst is responsible for meeting the requirements for FDA/NCIMS Dairy Analyst Certification by:

- 1) successfully participating in the Annual Proficiency Testing Program provided by FDA/LPET and,
- 2) demonstrating satisfactory competence of milk laboratory analytical methods during the triennial onsite survey conducted by an FDA Laboratory Proficiency and Evaluation Team Officer.

FDA/LPET must certify all Microbiologists before they may analyze any **official** samples for the state milk program.

The State Laboratory Evaluation Officer (LEO) must meet the following criteria:

- 1) Must be a state government employee and demonstrate continued satisfactory competence in evaluating milk laboratory test methods of analysts during a check evaluation with a FDA Laboratory Proficiency and Evaluation Officer.
- 2) The State LEO must submit written evaluation reports of the plant milk laboratories in the state to the FDA/CFSAN/OFS/DFPST Laboratory Proficiency and Evaluation Team.
- 3) The State LEO must keep all laboratory evaluations, proficiency test examinations and reports current.

- 4) The State LEO must maintain a list of certified and approved analysts and procedures by laboratory to the state milk sanitation rating agency and the FDA/CFSAN/OFS/DFPST Laboratory Proficiency and Evaluation Team.
- 5) The State LEO is responsible for conducting the training of Appendix N supervisors and certified industry analysts. The LEO is also responsible for training all screening laboratory analysts, any new analysts that may request training, and any analysts seeking retraining in any of the multitude of official testing procedures a plant laboratory may want to be certified/approved for.
- 6) The State LEO must attend the Milk Evaluation Officers Workshop (FDA Course #373) once every three years.
- 7) The State LEO must not fail, without just cause, to attend the FDA Regional Milk Seminar, once every two years.