

# Regulatory Analysis Form

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(1) Agency

Pennsylvania Milk Marketing Board

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(2) I.D. Number (Governor's Office Use)

47-15

IRRC Number: 2891

(3) Short Title

Electronic methods for testing milk for fat content

(4) PA Code Cite

7 Pa. Code Chapter 144

(5) Agency Contacts & Telephone Numbers

Primary Contact: **Tim Moyer, Acting Secretary**  
787-4194

Secondary Contact: **John Howard, Staff Attorney**  
787-4194

(6) Type of Rulemaking (check one)

- Proposed Rulemaking  
 Final Order Adopting Regulation  
 Final Order, Proposed Rulemaking Omitted

(7) Is a 120-Day Emergency Certification Attached?

- No  
 Yes: By the Attorney General  
 Yes: By the Governor

(8) Briefly explain the regulation in clear and nontechnical language.

The current regulations, last amended in 1987, specified, by manufacturer and model designation, which electronic testing instruments were approved for testing butterfat content of milk for purposes of payment to producers. Since that time, advances in testing technology and equipment, as well as changes in the way producers are paid for their milk, have made the current regulations obsolete and unworkable in practice. The purpose of the amendment is to update the regulations to reflect these changes.

After lengthy consultation with industry and other governmental entities involved in testing milk, the Board is proposing a comprehensive amendment to the regulations that will provide flexibility in adopting new technology, as well as accountability to insure that testing is well documented and performed in accordance with peer-reviewed science. The proposed amendment eliminates references to specific equipment and instead directs the regulated community to organizations that are recognized for establishing standards for equipment and methods for testing milk for the entire industry. The amendment specifies how electronic milk testing equipment must be maintained and calibrated, while still providing language that is flexible enough to accommodate foreseeable changes in technology.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

**Section 307 of the Pennsylvania Milk Marketing Law (Law) (31 P.S. § 700j-307) provides the Board with the authority to adopt and enforce regulations necessary or appropriate to carry out the provisions of the Law.**

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case, regulation, and any deadlines for action.

**Section 608 of the Law states that “It shall be unlawful for any person, including any milk dealer, to knowingly, fraudulently, or negligently weigh, measure, sample or test milk, or cause milk to be weighed, measured, sampled, or tested in such manner as to cause or tend to cause loss or injury to milk producers, stores or milk consumers, or to make any false or misleading statement with respect to the weight, measurement, sampling or testing of milk.” The existing regulation, as well as the amended regulation, establishes standards and procedures to ensure that milk is properly tested to protect producers, dealers, stores and consumers. There is no deadline for action, since there is an existing regulation in place; however due to changes in testing technology the existing regulation has become increasingly obsolete and difficult to enforce as written, necessitating the need for the amendment.**

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

**The protection of producers, dealers, stores and consumers. The Board believes it is in the public interest that all dairy producers are fairly paid for the milk they sell and that milk dealers, stores and consumers are receiving milk with the component content they are paying for.**

(12) State the public health, safety, environmental or general welfare risks associated with nonregulation.

**Dairy producers are paid for the milk they sell based upon “multiple component pricing” which uses butterfat, protein and other milk solids (such as lactose and minerals) to determine the price of that milk. Without regulation of the testing of milk components, the potential exists for dairy producers to receive less than full payment for the components in the milk they sell, and for dealers, stores and consumers to receive milk with less components than they are paying for.**

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

**Dairy producers, milk dealers, stores and consumers will benefit from accurate testing of milk components. There are approximately 7,400 dairy farmers selling milk in Pennsylvania, and approximately 126 licensed milk dealers (including cooperatives) that purchase milk from Pennsylvania producers.**

**Milk dealers, cooperatives, private laboratories and certified testers that are currently performing milk component testing for payment purposes will also benefit from this amendment because it will allow them to take advantage of newer, more efficient technology than allowed by the current regulations. These entities will also benefit by being able to maintain records in electronic form rather than on paper. There are approximately 12 laboratories testing milk for purposes of payment to Pennsylvania producers. There are currently 78 testers certified by the Board.**

## Regulatory Analysis Form

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

**No one will be adversely affected by the regulation.**

(15) List the persons, groups or entities that will be required to comply with the regulation. (Approximate the number of people who will be required to comply.)

**There are approximately 12 laboratories and 78 certified testers testing milk for purposes of payment to Pennsylvania producers who are currently required to comply with the existing regulation, and they will be required to comply with the amended regulation.**

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

**On October 12, 2006, the Board, after due notice, conducted a public hearing to receive comments on a first draft of the proposed amendment. Among the attendees were representatives of the United States Department of Agriculture Milk Marketing Order #33, QC Laboratories, Dairylea Cooperative Inc./Dairy Marketing Services LLC, Independent Regulatory Review Commission (IRRC), and Pennsylvania Milk Marketing Board staff. As a result of the discussion and comments at that public hearing, the proposed amendment was revised and a second draft was circulated among the interested parties to receive further comment.**

**A second meeting was held on November 17, 2009 to discuss the second draft. Among the attendees at this meeting were representatives of the United States Department of Agriculture Milk Marketing Order #1, the United States Department of Agriculture Milk Marketing Order #33, Eastern Lab Services, QC Laboratories, Dairylea Cooperative Inc./Dairy Marketing Services LLC, Lancaster DHIA, and Pennsylvania Milk Marketing Board staff. The parties at this meeting suggested a few minor changes which were incorporated into the amendment as proposed.**

**Regulatory Analysis Form**

(17) Provide a specific estimate of the costs and/or savings to the regulated community associated with compliance, including any legal, accounting or consulting procedures which may be required.

**The regulated community will incur no additional costs associated with compliance with the regulation.**

**The regulated community may incur some savings, which cannot be specifically estimated, by being able to maintain records in electronic form rather than on paper, and by being able to more quickly adopt newer, more cost-effective milk testing technology than is possible under the existing regulation.**

(18) Provide a specific estimate of the costs and/or savings to local governments associated with compliance, including any legal, accounting or consulting procedures which may be required.

**There will be no additional costs and/or savings to local governments associated with compliance, including legal, accounting, or consulting procedures, with this regulation.**

(19) Provide a specific estimate of the costs and/or savings to state government associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required.

**There will be no costs and/or savings to state government associated with implementation of the regulation.**

## Regulatory Analysis Form

(20) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY	FY +1	FY +2	FY +3	FY +4	FY +5
<b>SAVINGS:</b>	\$	\$	\$	\$	\$	\$
Regulated Community	\$0	\$0	\$0	\$0	\$0	\$0
Local Government	\$0	\$0	\$0	\$0	\$0	\$0
State Government	\$0	\$0	\$0	\$0	\$0	\$0
<b>Total Savings</b>	\$0	\$0	\$0	\$0	\$0	\$0
<b>COSTS:</b>						
Regulated Community	\$0	\$0	\$0	\$0	\$0	\$0
Local Government	\$0	\$0	\$0	\$0	\$0	\$0
State Government	\$0	\$0	\$0	\$0	\$0	\$0
<b>Total Costs</b>	\$0	\$0	\$0	\$0	\$0	\$0
<b>REVENUE LOSSES:</b>						
Regulated Community	\$0	\$0	\$0	\$0	\$0	\$0
Local Government	\$0	\$0	\$0	\$0	\$0	\$0
State Government	\$0	\$0	\$0	\$0	\$0	\$0
<b>Total Revenue Losses</b>	\$0	\$0	\$0	\$0	\$0	\$0

(20a) Explain how the cost estimates listed above were derived.

The Board believes that that there will be no costs or revenue losses by the regulated community, local government, or state government due to this amendment. The Board believes that the regulated community may incur some savings in cost and efficiency by being able to maintain records in electronic form rather than on paper, and by being able to more quickly adopt new milk testing technology than was possible under the existing regulation, but the Board is not able to quantify any dollar value for such savings.

### Regulatory Analysis Form

(20b) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
	\$0	\$0	\$0	\$0

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

**Since no one is adversely affected by the amendments to the regulations, the benefits (i.e. savings in paperwork, cost and efficiency) clearly outweigh adverse effects.**

(22) Describe the nonregulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

**There were no nonregulatory alternatives considered. The Board believes that without regulation, the potential exists for loss or injury to milk producers, stores or milk consumers, contrary to the provisions of section 608 of the Law.**

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

**The only alternative regulatory scheme considered was to continue with the existing regulations. This was dismissed because, due to changes in technology since 1987, the existing regulations are now obsolete and difficult to enforce.**

## **Regulatory Analysis Form**

(24) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulation.

**No.**

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

**There is a large variation among states with regard to testing of milk for purposes of payment to producers. There are only eleven states with laws regarding minimum producer prices. New York's regulations are similar to this regulation; New Jersey and West Virginia have similar but less comprehensive regulations, and many other states have no regulations at all. This regulation will not put Pennsylvania at a competitive disadvantage with other states.**

(26) Will the regulation affect existing or proposed regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

**No.**

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

**No additional public hearings or informational meetings with the industry are contemplated.**



## Regulatory Analysis Form

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

**The amendment eases the reporting, record keeping and paperwork requirements somewhat. The amendment allows component test results to be reported to producers via a verbal statement, such as an automated telephone dial-in or web access, rather than a written statement, if the producer agrees. The amendment also allows for records to be maintained in electronic format rather than on paper.**

(29) Please list any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, elderly, small businesses, and farmers.

**None.**

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

**The regulation will be effective upon publication in the *Pennsylvania Bulletin*, anticipated to be no later than December 31, 2011. Compliance with the regulation will be required as of the effective date. No additional permits or licenses will be required.**

(31) Provide the schedule for continual review of the regulation.

**This regulation will be reviewed on an ongoing basis to ensure that the intent of the regulation is being met.**

FACE SHEET  
FOR FILING DOCUMENTS  
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

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Copy below is hereby approved as to  
form and legality. Attorney General

*[Signature]*

BY: \_\_\_\_\_  
(DEPUTY ATTORNEY GENERAL)

MAR 17 2011

DATE OF APPROVAL

Copy below is hereby certified to be a true and correct copy  
of a document issued, prescribed or promulgated by:

Pennsylvania Milk Marketing Board  
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 47-15

DATE OF ADOPTION 2/18/11

BY: *[Signature]*

TITLE: Acting Secretary  
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

Check if applicable  
Copy not approved. Objections  
attached.

Copy below is hereby approved as to  
form and legality. Executive or Independ-  
ent Agencies.

BY: *[Signature]*

2/18/11  
DATE OF APPROVAL

~~XXXXXXXXXXXXXXXXXXXX~~  
(Chief Counsel, Independent Agency)  
(Strike inapplicable title)

Check if applicable. No Attorney Gen-  
eral approval or objection within 30  
days after submission.

## **PENNSYLVANIA MILK MARKETING BOARD**

### **(7 Pa. Code Chapter 144)**

#### **Electronic methods for testing milk for fat content**

The Pennsylvania Milk Marketing Board (Board) proposes to amend 7 Pa. Code Chapter 144 (relating to electronic methods for testing milk for fat content) to read as set forth in Annex A.

#### ***Purpose of proposed amendment***

The current regulations, last amended in 1987, specified, by manufacturer and model designation, which electronic testing instruments were approved for testing butterfat content of milk for purposes of payment to producers. Since that time, advances in testing technology and equipment, as well as changes in the way producers are paid for their milk, have made the current regulations obsolete and unworkable in practice. The purpose of the amendment is to update the regulations to reflect these changes.

After lengthy consultation with industry and other governmental entities involved in testing milk, the Board is proposing a comprehensive amendment to the regulations that will provide flexibility in adopting new technology, as well as accountability to insure that testing is well documented and performed in accordance with peer-reviewed science. The proposed amendment eliminates references to specific equipment and instead directs the regulated community to organizations that are recognized for establishing standards for equipment and methods for testing milk for the entire industry. The amendment specifies how electronic milk testing equipment must be maintained and calibrated, while still providing language that is flexible enough to accommodate foreseeable changes in technology.

#### ***Summary of proposed amendments***

When the existing regulation was adopted, producers' milk was priced based upon its butterfat (fat) content. Now, producers are paid based upon "multiple component pricing" which uses butterfat, protein and other milk solids (such as lactose and minerals) to determine the price of milk. The amendment adds the words "and component(s)" to the Chapter heading, and replaces "fat" or "butterfat" with "component(s)" throughout the amended regulation.

Section 144.1 (7 Pa. Code § 144.1) has been amended to add a "Definitions" subsection, designated as subsection (a), to define several terms that are used throughout the regulation. Former subsection (a) has been re-designated as subsection (b) and re-worded to remove the requirement that the Board approve specific electronic instruments and reference methods, in favor of language that allows methods to be used if they have been approved by one of several organizations that are recognized authorities in the field of electronic milk testing. Former subsection (b) has been re-designated as subsection (c) and re-worded to reflect the fact that the Board will no longer require that specific instruments or testing procedures be pre-approved by the Board. Former subsection (c) has been eliminated in its entirety because the Board will no longer be designating, by manufacturer and model, which specific electronic testing instruments

may be used. Any of the record-keeping requirements in this section that have not been rendered obsolete are now contained in amended section 144.6.

Section 144.2 (7 Pa. Code § 144.2) is amended to replace the term “licensing” with “certification” to be consistent with the terminology used in section 602 of the law. Subsection (a) has been amended to include government agencies and private institutions recognized for their authority in milk testing as additional approvers of electronic testing equipment. Former subsections (b) and (d) have been eliminated because the Board will no longer be approving specific test instruments, methods, locations or facilities nor licensing persons for specific reference methods or testing instruments.

Section 144.3 (7 Pa. Code § 144.3) has been amended to remove language that was compatible with a narrow range of equipment or was superfluous because it was already required by another section. The reference to “records” has been removed because all requirements for records maintenance and retention are now contained in amended section 144.6.

Section 144.4 (7 Pa. Code § 144.4) has been amended to remove from subsection (a) the specific directions on production and use of control samples and replacing it with language that allows the Board to establish the standards for the production and use of control samples through Official General Orders as needed due to changes in technology. Former subsection (b) has been eliminated because the daily performance checks will accomplish the same thing. The language in the *Daily Performance* subsection, now subsection (b), has been amended to adopt the latest standards for accuracy checks and repeatability checks.

Section 144.5 (7 Pa. Code § 144.5) has been extensively amended. The definition of calibration has been moved to the definitions subsection of section 144.1. All references to the standard deviation calculation have been eliminated in recognition of the fact that standard deviations are now calculated by computer. In its place are new standards to determine whether and instrument is properly calibrated for the different components. The subsection regarding *conditions requiring calibration* has also been updated to be consistent with the other amendments to this regulation.

Section 144.6 (7 Pa. Code § 144.6) has been expanded to include all of the record-keeping requirements that were formerly contained in other sections. The amendment also allows for records to be maintained in electronic format, and further provides with more specificity exactly what must be recorded and maintained for calibration and accuracy checks.

Section 144.7 (7 Pa. Code § 144.7), formerly titled *Chronological record required*, has been replaced by a new section 144.7, titled *Summary record required*. The original regulation required a chronological record of butterfat tests using permanently bound or computer printed reports. The amended regulation recognizes the industry trend toward use of commercial laboratories and computerized records. The language used in this amendment now more closely mirrors the requirements of section 143.21 (relating to testing; notification of producer) requiring two samples be tested in each half month rather than every 15 days.

Sections 144.8 (7 Pa. Code § 144.8), 144.9 (7 Pa. Code § 144.9), and 144.10 (7 Pa. Code § 144.10) have all been repealed. These sections dealt with record-keeping requirements that are now contained in section 144.6 in the amended regulation.

Section 144.11 (7 Pa. Code § 144.11) has also been repealed because the practice of two or more licensees performing tests on a lot or group of samples is obsolete and no longer occurs in laboratories testing milk samples.

In section 144.12 (7 Pa. Code § 144.12), “patron” has been replaced by “producer” and “fat” has been replaced by “component” in both the heading and the text. The amendment allows for rechecks to occur when the next sample is taken, rather than the current 72 hour requirement. The amendment also provides specific guidance as to which component measurements will lead to a recheck requirement.

Section 144.13 (7 Pa. Code § 144.13) has been amended to add cooperatives to the list of entities that must make records available to the Board. The amendment also changes the requirement that a written statement of test results be delivered to producers “at each time a list is made” to “at least once each month,” but allows these results to be communicated to producers via a verbal statement (such as an automated telephone dial-in or web access) rather than a written statement, if the producer agrees.

Section 144.14 (7 Pa. Code § 144.14) has been amended to clarify that a certified tester at a laboratory or plant is responsible for a violation of the act or this chapter, as well as the other parties listed in the existing regulation.

### ***Statutory authority***

Section 307 of the Law (31 P.S. § 700j-307) provides the Board with the authority to adopt and enforce regulations necessary or appropriate to carry out the provisions of the Law.

### ***Public hearing***

On October 12, 2006, the Board, after due notice, conducted a public hearing to receive comments on a first draft of the proposed amendment. Among the attendees were representatives of the United States Department of Agriculture Milk Marketing Order #33, QC Laboratories, Dairylea Cooperative Inc./Dairy Marketing Services LLC, Independent Regulatory Review Commission (IRRC), and Pennsylvania Milk Marketing Board staff. As a result of the discussion and comments at that public hearing, the proposed amendment was revised and a second draft was circulated among the interested parties to receive further comment.

A second meeting was held on November 17, 2009 to discuss the second draft. Among the attendees at this meeting were representatives of the United States Department of Agriculture Milk Marketing Order #1, the United States Department of Agriculture Milk Marketing Order #33, Eastern Lab Services, QC Laboratories, Dairylea Cooperative Inc./Dairy Marketing Services LLC, Lancaster DHIA, and Pennsylvania Milk Marketing Board staff. The parties at

this meeting suggested a few minor changes which were incorporated into the amendment as proposed.

***Fiscal impact***

The proposed amendment will have no fiscal impact on the regulated entities or on the Commonwealth or its political subdivisions.

***Paperwork requirements***

The proposed amendment will require no additional paperwork by the regulated entities or by the Commonwealth or its political subdivisions.

***Effective date; sunset date***

The amendments will become effective upon publication in the *Pennsylvania Bulletin* as final rulemaking. There is no sunset date.

***Regulatory review***

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), a copy of this proposal was submitted on \_\_\_\_\_ to the Independent Regulatory Review Commission (IRRC) and to the chairpeople of the House and Senate Committees on Agriculture and Rural Affairs. In addition to submitting the proposed amendments, the Board has provided IRRC and the committees with a copy of a detailed regulatory analysis form. A copy of this material is available to the public upon request.

If IRRC has objections to any portion of the proposed amendment, it will notify the Board within 30 days of the close of the public comment period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review by the Board, the General Assembly, and the Governor of objections raised before final publication of the regulations.

***Public Comment***

Interested persons are invited to submit written comments, suggestions, or objections concerning the proposed amendments to Chief Counsel, Pennsylvania Milk Marketing Board, 2301 North Cameron Street, Harrisburg, PA 17110, within 30 days following publication in the *Pennsylvania Bulletin*.

Richard Kriebel  
*Chairman*

## ANNEX A

### CHAPTER 144. ELECTRONIC METHODS FOR TESTING MILK FOR FAT AND COMPONENT CONTENT

#### § 144.1. Electronic methods—general.

(a) [The Board will approve electronic instruments and reference methods to determine the butterfat content of milk for payment purposes. Electronic instruments and reference methods submitted to the Board for approval shall be those recognized, approved and set forth in the latest edition of either *Standard Methods for the Examination of Dairy Products*, published by American Public Health Association, Washington, D.C. or *Officials of the Association of Official Analytical Chemists (AOAC)*.

(b) A manufacturer requesting approval of an electronic butterfat testing instrument shall furnish to the Board a complete instrument operation and maintenance manual and further information as required. If, after approval of the electronic butterfat testing instrument by the Board, the manufacturer makes changes in the instrument, the testing procedure, the operating procedure or the maintenance instructions, the changes shall be submitted to the Board for approval prior to implementation of the change.

(c) Specific instructions for equipment and required reagents, testing techniques, equipment maintenance, related recordkeeping and other required procedures are as follows:

(1) *Introduction.* Some electronic fat testing instruments approved by the Board may be capable of determining the content of other components in milk, either by analysis or computation. Determination of milk components other than butterfat is outside the purview of this chapter and records of the determination are not required to be maintained. Factors which could affect the accuracy of the instrument for butterfat testing, such as certain maintenance procedures or total hours of instrument use, are subject to this chapter.

(2) *Approved electronic fat testing instruments—manufacturer and model designation.*

Milko Tester Mark II    Milko Scan 104

(Instruments with automatic    Milko Scan 203

diluent syringes only)    Milko Scan 300

Milko Tester Mark III    Milko Scan 133

Milko Tester Automatic    Milko Scan 605

Milko Tester Mark III Industrial    Multi-Spec. M

(3) *Manufacturer of instruments.* The instruments in paragraph (2) are manufactured by A/S N. Foss Electric and Berwyn Instruments.

(4) *Manufacturer requirements.* The manufacturer shall submit complete instructions for the operation and maintenance of each model instrument for which approval is requested. Changes shall be submitted to the Board prior to distribution by the manufacturer.

(5) *Required records.* Records of the operation and maintenance of each electronic fat testing instrument shall be kept on forms prescribed and furnished by the Board, and shall contain the following information:

- (i) Work sheet of calibration samples showing the following:
  - (A) Individual test results by electronic method and average result.
  - (B) Individual test results by reference method and average result.
  - (C) Description of adjustments made to electronic tester.
  - (D) Laboratory name and machine identification.
  - (E) Date, signature and number of technician.
- (ii) Computation of standard deviation ( $S_D$ ) as follows:
  - (A) The results of individual samples by reference method and electronic method.
  - (B) The mathematical steps shown in computation of  $D$  and  $S_D$ .
  - (C) The name of laboratory and machine identification.
  - (D) The date of computation, name and license number of technician.
- (iii) Daily performance check showing the following:
  - (A) Name of laboratory and machine identification.
  - (B) Reference method used; sample identification, individual test results and average test.
  - (C) Electronic method used, time, sample identification, individual test results and average test results.
  - (D) Number of samples since rebuilding of homogenizer or other required maintenance procedures.
  - (E) Hours of machine operation on reporting date.



(F) Total hours of machine operation on instrument.

(G) Special maintenance. Copies of bills or service call reports for repairs or part replacements shall be kept with the maintenance records.] Definitions. The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

(1) Accuracy check – A test made at the beginning of each testing session and once per hour thereafter to determine the continued accuracy of the electronic testing apparatus.

(2) Calibration – The adjustment of an electronic instrument so that the results for a given payment component meet the comparison criteria results of an Association of Official Analytical Chemists (AOAC) or Intersociety Council on Standard Methods for the Examination of Dairy Products (ICSMEDP) approved reference method.

(3) Certified tester – A Milk Marketing Board certified technician as referenced in §144.2 (relating to certification requirements) operating electronic instruments and/or a person certified to perform specific reference methods for determining the components in raw milk.

(4) Control milk/Control sample – Samples produced by a commercial laboratory or by the United States Department of Agriculture (USDA) Market Administrator's Office or its successor agency, used for determining the calibration of an electronic instrument and also used to set the calibration of an electronic instrument.

(5) Electronic method – A method for determining the components in raw milk using an electronic testing instrument.

(6) Milk component/Component – Unique compound within milk whose relative mass within the milk may be used to determine the payment to producers. Component parts of milk include, but are not limited to, butterfat, protein, lactose, solids non-fat, other solids, and total solids.

(7) Reference method – Standard method using analytical chemistry or other approved techniques by which all other electronic methods of testing milk are compared for determining the components in milk.

(8) Repeatability check – A test run at the beginning of each testing session in order to demonstrate the ability of a given electronic testing instrument or piece of equipment to meet the requirements for repeatability in § 144.4(b)(2) (relating to repeatability check).

(b) Reference methods used to determine the component content of milk for payment purposes shall be those recognized or approved and set forth either by the ICSMEDP in the latest edition of Standard Methods for the Examination of Dairy Products, published by American Public Health Association, Washington, D.C., or by the AOAC in Official Methods of Analysis, published by AOAC International, Gaithersburg, Maryland. Only electronic instruments recognized by the USDA Dairy Division for the analysis of milk and milk components and

capable of performance standards as referenced in §144.4 (relating to routine inspection and control) shall be used to test milk for payment purposes in Pennsylvania.

(c) A manufacturer of an electronic testing instrument shall make available upon request to the Board a complete instrument operation and maintenance manual and further information as required.

**§ 144.2. [Licensing] Certification and approval requirements.**

(a) No person may use an electronic instrument or method to test milk for [butterfat] component content for payment purposes unless the instrument and [test] method have been approved by the Board[.], ICSMEDP, AOAC, or USDA Dairy Division, or their successor organizations.

(b) [No person may use an electronic instrument or method to test milk for butterfat content for payment purposes unless the specific test instrument and method, location and facilities have been approved by the Board.

(c) No person may use or employ an electronic instrument or method to test milk for [butterfat] component content for payment purposes unless [licensed] certified by the Board under [Article VI] section 602 of the act (31 P. S. [§]§ 700j-602[—700j-608]).

[ (d) A person testing milk by a reference method for the purpose of controlling the accuracy of an electronic test instrument or method shall be licensed for the method by the Board under Article VI of the act.]

**§ 144.3. Laboratory facilities[,] and supplies[ and records].**

[Laboratories and other facilities using an electronic instrument or method to test milk for butterfat content for payment purposes shall have the following supplies, facilities and records available and in proper working order:

(1) An approved electronic testing instrument, required accessories and reagents, an instruction manual for operation of the instrument and an instrument maintenance record.

(2) A complete set of equipment and reagents for testing milk by the reference method approved for the purpose of controlling the accuracy of electronic testing instruments in use.

(3) A thermostatically controlled water bath, with recording thermometer having proper temperature distribution, set to maintain samples at 95°F to 100°F or at the temperature specified by the manufacturer of the electronic testing instrument.

(4) A power supply as specified by the manufacturer of the electronic testing instrument.

(5) A means of measuring pH.

(6) A supply of distilled or deionized water.

- (7) Refrigeration at 33°—40°F for milk sample storage.
- (8) A laboratory with adequate lighting facilities and adequate counter surface to accommodate essential equipment. The laboratory shall be free from disturbing drafts, dust, noise and vibrations.
- (9) Hot and cold water, wash sinks and cleansing agents to clean equipment.
- (10) An adequate waste and sewage system to dispose of milk, acid and wash water.
- (11) Temperature and humidity controls and facilities as specified by the manufacturer of the electronic testing instrument.
- (12) An approved preservative for milk samples as specified by the manufacturer of the electronic testing instrument.] Laboratories and other facilities using an electronic instrument or method to test milk for component content for payment purposes shall have the following supplies and facilities available and in proper working order:

(1) An approved electronic testing instrument, required accessories and reagents and an instruction manual for operation of the instrument.

(2) A thermostatically controlled water (or other manufacturer-prescribed medium) bath with recording thermometer having proper temperature distribution, set to maintain samples at the temperature specified by the manufacturer of the electronic testing instrument, or other methods of obtaining the required temperature as specified by the instrument manufacturer and acceptable to the Board.

#### **§ 144.4. Routine inspection and control.**

(a) *[Preparation of control samples.*

(1) At least four control samples of natural milk of sufficient quantity shall be available to allow for performance checks and accuracy checks required by subsection (c).

(i) At least one control milk sample shall be a commingled sample of unhomogenized milk from a minimum of three herds or 100 cows, testing between 3.0% and 4.0% butterfat, and at least one control milk sample shall test between 4.5% and 6.0% butterfat. The calibration samples shall represent a variety of butterfat levels within the anticipated range of official samples to be tested.

(ii) An approved preservative shall be added at the required rate and mixed thoroughly if the control sample is to be used more than 24 hours after preparation. Churning shall be avoided. A sample shall be subdivided into subsamples of adequate size. The control sample shall be kept thoroughly mixed during subsampling.

(iii) A subsample of a control milk sample shall be tested in triplicate by the reference method for butterfat content. Individual determinations shall be read to at least the nearest 0.05% butterfat. The individual results and the average for a control milk sample shall be recorded.

(iv) The remaining control subsamples shall continue to be stored at 33°—40°F. until used. Subsamples more than 10 days old shall be discarded.

(v) Prior to the expiration date of the subsamples or use of the last subsample of the control milk sample, whichever comes first, preparation of a new set of control milk samples shall be completed.

(2) Standard mixtures approved by the Board may be used in lieu of the control milk samples. The mixtures shall be stored, tempered and tested in the manner prescribed by the Board.

(b) *Instrument inspection prior to daily use.* An electronic butterfat testing instrument shall be inspected prior to each day's use in accordance with the manufacturer's instructions. Deficiencies found during that inspection shall first be recorded in the instrument maintenance record and appropriate repairs or adjustments shall be made before the instrument is used to test milk.

(c) *Daily performance.*

(1) *Accuracy check.* Each day before routine testing begins, at least one subsample of control milk shall be tested in triplicate using an electronic instrument. The operator shall read the test to 0.01%. The first reading shall be disregarded. If the difference between the average of the second and third reading obtained from the electronic instrument and the average of the result obtained by the three reference methods is 0.1% butterfat or less, test three more samples of new control milk. If the difference of the additional samples exceeds 0.1% butterfat, the operator shall discontinue operation of the machine, determine the reason for the difference and correct the deficiencies before resuming operation. An accuracy check shall be performed at least once an hour during the time the electronic instrument is in operation.

(2) *Repeatability check.* Each day before routine testing begins, ten consecutive readings on a single well-mixed commingled sample of milk shall be made and recorded as a permanent record. The standard deviation of the results shall be less than 0.03% butterfat. If the standard deviation is 0.03% or greater, discontinue operation of the machine until the cause is determined and corrected. The standard deviation may be assumed to be acceptable if the range of the ten readings is .07% or less. Calculations of standard deviation are described in § 144.5 (relating to instrument calibration).] Control samples shall be prepared in accordance with methods established by the Board through Official General Order.

(b) *Daily performance.*

(1) *Accuracy check.* Each day before routine testing begins, at least once each hour during the course of the testing session, and when the testing session ends, at least one subsample of control milk shall be tested using the electronic instrument. The certified tester shall read the test to

0.01%. The result difference obtained by the reference method must be 0.05 or less than the known reference test sample result. If the difference of the samples exceeds 0.05 the certified tester shall discontinue operation of the instrument, determine the reason for the difference and correct the deficiencies before resuming operation.

(2) *Repeatability check.* Each day before routine testing begins, ten consecutive readings on a single well-mixed sample of milk that has not been homogenized shall be made and recorded as a permanent record. If more than ten consecutive readings are taken the certified tester shall use the last ten results. The repeatability check may be assumed to be acceptable if the range of the ten readings is 0.04 or less.

**§ 144.5. Instrument calibration.**

(a) [*Definitions.* Calibration means adjustment of the settings on the instrument so that the butterfat test readings obtained from the instrument match the butterfat test result obtained by using the reference method approved by the Board.

(b) *Calculation of calibration results.*

(1) A machine shall be considered to be calibrated properly when the average difference between the machine results and the reference method results, called  $D$ , and the standard deviation of difference between methods, called  $S_D$ , are less than the values described in Table 1. At least 20 samples shall be tested.

**Table 1. Maximum Allowable Difference (D) and Standard Deviation of Difference ( $S_D$ ) Between the Electronic Tester and the Reference Method.**

<i>Reference Method</i>	<i>Individual Cow Samples</i>		<i>Herd or Other Blended Samples</i>	
	$\bar{D}$ (%)	$S_D$ (%)	$\bar{D}$ (%)	$S_D$ (%)
<b>Gerber</b>	$\pm 0.04$	$\pm 0.08$	$\pm 0.04$	$\pm 0.06$
<b>Babcock</b>	$\pm 0.04$	$\pm 0.10$	$\pm 0.04$	$\pm 0.06$
<b>Roesse Gottlieb</b>	$\pm 0.04$	$\pm 0.10$	$\pm 0.02$	$\pm 0.04$

(2) The average of the results obtained by the low testing samples—3.0% to 4.0%—by the electronic method shall be compared to the average of the results obtained on the same samples by the reference method. If the difference is 0.02% butterfat or less, the calibration may be continued. If the difference is greater than 0.02% butterfat, the machine shall be adjusted and the samples retested by the adjusted electronic method until the difference is 0.02% butterfat or less.

(3) The average of the results obtained on the high testing samples—4.5% to 6.0%—by the electronic method shall be compared to the average of the results obtained on the same samples by the reference method. If the difference is 0.04% butterfat or less, the calibration procedure may be continued. If the difference is greater than 0.04% butterfat, the machine shall be adjusted and the samples retested by the electronic method until the difference is 0.04% butterfat or less.

(4) The criteria listed in paragraphs (2) and (3) shall be met simultaneously.

(5) The average difference between method, D, shall be calculated as the difference between the average of the electronic tester method on calibration samples and the average of the reference method on calibration samples. D shall be considered as the mathematical equivalent of the following formula:

$$D = \frac{1}{N} \sum_i (M_i - R_i)$$

Where N = Number of samples tested

M<sub>i</sub> = Average of electronic tester results on the i<sup>th</sup> sample

R<sub>i</sub> = Average of reference method results on the i<sup>th</sup> sample, referred to as the "true value"

Where N = Number of samples tested

M<sub>i</sub> = Average of electronic tester results on the i<sup>th</sup> sample

R<sub>i</sub> = Average of reference method results on the i<sup>th</sup> sample, referred to as the "true value"

(6) The standard deviation of difference, S<sub>D</sub> of calibration samples shall be calculated by a mathematical equivalent of the following formula:

$$S_D = \sqrt{\frac{\sum D_i^2 - \frac{(\sum D_i)^2}{N}}{N - 1}}$$

D<sub>i</sub> = Difference between the average of electronic tester results of the i<sup>th</sup> sample and the average of the reference method results for the i<sup>th</sup> sample.

D<sub>i</sub> = Difference between the average of electronic tester results of the i<sup>th</sup> sample and the average of the reference method results for the i<sup>th</sup> sample.

(7) An example of the calculations required in paragraphs (5) and (6) is provided as follows:

**Table 2**  
**Sample Work Sheet for Determining Standard Deviation**  
*Column No.*

1	2	3	4	5
<i>Sample Average</i>	<i>Average</i>	<i>Difference (D)</i>	<i>Difference</i>	

No.	Duplicate	Triplicate Babcock		Squared (D) <sup>2</sup>
		Babcock	4a 4b	
1	3.53	3.55	-.02	.0004
2	3.61	3.60	.01	.0001
3	3.69	3.65	.04	.0016
4	3.40	3.30	.10	.0100
5	3.47	3.45	.02	.0004
6	3.85	3.80	.05	.0025
7	3.62	3.60	.02	.0004
8	3.71	3.75	-.04	.0016
9	3.91	3.85	.06	.0036
10	3.62	3.60	.02	.0004
11	6.12	6.15	-.03	.0009
12	6.39	6.40	-.01	.0001
13	6.75	6.80	-.05	.0025
14	6.39	6.35	.04	.0016
15	6.77	6.70	.07	.0049
16	6.42	6.45	-.03	.0009
17	6.71	6.75	-.04	.0016
18	6.68	6.70	-.02	.0004
19	6.71	6.70	.01	.0001
20	6.43	6.45	-.02	.0004
		Sub total	4a .44 4b -.26	.0344

Step 4— $\sum D$  (4a - 4b) + 0.18 (if step 4 is negative, it does not affect results)

Step 5— $\sum D^2 = .0344$

Step 6— $\bar{D} = \frac{\sum D}{N} = \frac{.18}{20} = .009$

Step 7— $\bar{D} \times \sum D = .009 \times .18 = .00162$

Step 8— $\sum D^2 - (\bar{D} \times \sum D) = .0344 - .00162 = .03278$

Step 9— $\frac{\sum D^2 - (\bar{D} \times \sum D)}{(N - 1)} = \frac{.03278}{19} = S_D^2 = .0017$

Step 10—Find  $S_D$  from  $S_D^2$  in Table 3.

(8) The data in Table 3 provides sufficiently accurate estimate of  $S_D$ .

**Table 3**

If $S_D^2$ is:	The $S_D$ is:
.0001	.01
.0004	.02
.0009	.03
.0016	.04
.0025	.05
.0036	.06
.0049	.07
.0064	.08
.0081	.09
.0100	.10

(i) In the example in Table 3,  $S_D^2$  was 0.0017, so the  $S_D$  would fall between 0.04 and 0.05. To estimate that it was 0.04 is sufficient. If the value for  $S_D^2$  exceeds .0036 on blended milk or .01 on an individual cow's milk, the instrument shall be recalibrated.

(ii) The average difference ( $\bar{D}$ ) in the example is 0.009 and the standard deviation ( $S_D$ ) is 0.04, so the instrument is in proper calibration because these values are less than the values shown in Table 1 for the Babcock method for individual cow samples.

(iii) If either the mean difference or the standard deviation of difference, determined as outlined, exceed the values shown in Table 3, the instrument shall be adjusted as provided in subsection (b), and the calibration procedure repeated by retesting the same samples with the instrument.

*(c) Conditions requiring calibration.*

- (1) The instrument shall be calibrated when initially installed.
- (2) The instrument shall be calibrated when the performance check fails or the accuracy check fails.
- (3) The instrument shall be calibrated if a part which may affect proper operation of the instrument is replaced, rebuilt or adjusted.
- (4) The instrument shall be calibrated upon the occurrence of the specific circumstances which require calibration for that instrument, as set forth in this section.] Calculation of calibration results. An instrument shall be considered to be calibrated properly when the average difference between the instrument results for butterfat and protein and the reference method results for at least ten different control samples, called mean average, is +/-0.04 and the standard deviation of the difference between the instrument and reference methods, called standard deviation, are 0.04 or less. For all solids the mean average is +/-0.09 and the standard deviation of the differences between the instrument and reference methods are 0.12 or less for those same ten samples.

(b) Conditions requiring calibration.



- (1) The instrument shall be calibrated when initially installed.
- (2) The instrument shall be calibrated when the accuracy check is confirmed to have failed.
- (3) The instrument shall be calibrated if a part which may affect proper operation of the instrument is replaced, rebuilt or adjusted.
- (4) The instrument shall be calibrated upon the occurrence of the specific circumstances which require calibration for that instrument, as determined by the manufacturer.

**§ 144.6. Required records.**

- (a) [Records of butterfat tests shall conform to section 602 of the act (31 P. S. § 700j-602).
- (b) Records of calibrations, performance checks, D and S<sub>D</sub> computations and other instrument use shall be maintained for 1 year under § 144.1 (relating to electronic methods—general).
- (c) An instrument record shall be maintained for each test instrument in use under § 144.1.] The certified tester(s) and testing facilities or laboratories shall maintain all records required by this section for a period of at least one year. Records may be maintained in paper or electronic formats. In all cases records must denote the record date and the name and license number of the Certified Tester who created or maintained the record(s).
- (b) Records of calibrations, accuracy checks, mean average and standard deviation computations and other instrument use.
- (c) Records of the operation and maintenance of each electronic testing instrument and records of all test results by electronic method.
- (d) Certified testers shall record standard deviation of the calibration verification as follows:
  - (i) The results of individual samples by reference method (average only for reference method) and electronic method.
  - (ii) The date of computation, name and license number of certified tester.
- (e) Certified testers operating all electronic testing equipment shall perform a daily accuracy check and record the following:
  - (i) Reference method used, sample identification, individual test results and average test.
  - (ii) Electronic method used, time, sample identification, individual test results and average test results.

**§ 144.7. [Chronological] Summary record required.**

[A record of butterfat tests shall be kept in chronological order either in a permanently bound record or in computer printed reports made at least once every 15 days. The record shall contain the farm sampling date, the lab testing date and the test result for each sample. The record shall be known as the original record or laboratory record. If bottles are numbered, the samples in each set shall be arranged for testing in numerical order, so that they may be reported in the same numerical order in the record book or printed report.] (a) The certified tester and the testing facility or laboratory shall compile summary records of all component tests performed for all producers for the first and second half of each month containing results for at least two evenly spaced representative samples in each half month for each producer. The record shall contain the farm sampling date, the laboratory testing date, the laboratory or testing site, the tester identification, the producer identification and the test result for each sample. The record shall be known as the original record or laboratory record and shall be maintained by the tester for at least one year. If the tests are performed by a milk dealer licensed by the Board, the milk dealer shall maintain the records of the component content of producers' milk samples for at least one year.

(b) If tests are performed in a commercial laboratory which is not an integral part of the milk plant where the samples were delivered, that licensed dealer or plant must make available to the Board a copy of the final laboratory records of the component tests in computerized or written form for at least one year.

**§ 144.8. [Date, sign, keep record 1 year.**

(a) Original records containing information with respect to the fat content of a producer's sample, whether the record is for 1 day or for more than 1 day, shall be dated and subscribed to by the person making the determination or by the technician or supervisor responsible for testing during the testing period for which the entry is made, and preserved for at least 1 year, regardless of the fact that the milk dealer may copy the record for the purpose of making a more permanent record for personal use.

(b) If tests are performed in a commercial laboratory which is not an integral part of the milk plant where the samples were taken, a carbon copy of the original laboratory records of the fat tests shall be prepared for transmittal to the plant where the samples were taken for filing purposes for at least 1 year.] **Reserved.**

**§ 144.9. [Identify samples/tests.**

If fat tests for different sets of samples or for samples representing different periods of time or different days are recorded on a single page in the original record book, ample space shall be used for the correct, clear and legible identity of a sample or sets of samples, to be followed immediately on the same page by the record of the fat tests thereon. The name and license number of the tester who made the tests or the technician or supervisor responsible for testing when the tests are made shall appear immediately following the fat-test record on a set of samples requiring a separate identity. The identification of a set of samples shall show the dates the fresh samples were taken or the limiting dates of the period which the composite samples represent. If there is more than one sample in a set, a sample as received at the laboratory shall

be identified to distinguish it from others in the set. Show other available pertinent information to identify and characterize the sample.] Reserved.

**§ 144.10. [Identify test with patron's number.**

The percentage of milk fat found in the patron's sample shall be recorded opposite the distinctive number or mark assigned to a patron. Entries in the laboratory record book shall be made with an indelible pencil, with a pen and permanent ink or by a computer printed line of letters and numbers. If it is necessary to correct errors, corrections shall be made by drawing a line across the incorrect figure and placing the correct value nearby on the same line, or by adding an additional computer printed line clearly signifying the correcting information.]

Reserved.

**§ 144.11. [Two or more licensees.**

If two or more licensees are performing tests on a lot of samples, each licensee shall work independently of the other to the extent of preparing a selected group of samples, including the measurement of the fat columns, and recording the results of the tests in the laboratory record book. The testing does not necessarily prohibit the common use of apparatus by the different licensees successively or simultaneously, such as the joint operation of the centrifuge, the joint use of the tempering bath, the use of the same balance and weights and the like. If two or more licensees are testing, the records as reported in the laboratory record book shall indicate the tests made by each licensee-name and license number subscribed to each series of tests and the completed tests shall be subscribed to—name and license number—by the responsible licensee in charge of the laboratory at the time the tests are made.] Reserved.

**§ 144.12. Credit [patrons] producers with actual [fat] component test.**

(a) No [patrons] individual producers delivering milk or cream, or both, to a milk or cream-receiving or purchasing plant, where the milk or cream is purchased on the basis of the milk [fat] components contained therein, may be credited with a greater or lesser percentage or average percentage of milk [fat] components than is actually contained in the milk or cream delivered.

(b) No report on a test to determine the milk [fat] component content of milk or cream may be of a greater or lesser percentage of milk [fat] components than is actually contained in the milk or cream from which the sample was taken. In order to be a basis of payment to [the patron] an individual producer, a recheck of a [patron's] producer's milk [fat] component test shall be made from [a] the next available sample taken [no later than 72 hours] after the original test. Rechecks of a producer's milk component test shall be made when the butterfat varies 0.5% or more or the protein varies 0.3% or more from the most recent test.

**§ 144.13. Availability of records.**

Laboratory, cooperative, or plant records shall be open to examination by the Board or its authorized representative. Upon request of a producer, the purchaser or receiver of milk or cream, or both, shall permit the producer to examine the part of the record containing

information concerning the samples of milk or cream representing the milk or cream delivered by the producer. A purchaser or receiver of milk or cream from the producer thereof shall, on written request, at least once each month mail or deliver to the producer[, at each time a list is made,] a written statement, unless the producer agrees to accept a verbal statement, of the percentage of milk [fat] components found to have been contained in the sample or samples representing the milk or cream delivered by the producer.

**§ 144.14. Responsibility for violations.**

A certified tester at a laboratory or plant shall be responsible for a violation of the act or this chapter, including the keeping of the reports and records required by the act and this chapter. Additionally, [T]the purchaser or receiver, or both, of the milk or cream, or both, or the licensed manager of a milk-gathering station, manufactory or plant receiving or purchasing milk or cream from producers for sale or resale or for manufacture, where the payment or settlement for the milk or cream is based in whole or in part on the milk [fat] component content thereof, [is] shall be responsible for a violation of the act or this chapter by a person working under his direction or subject to his orders or the act or this chapter, including the keeping of the reports and records [of the milk fat-tests] required by the act and this chapter.

## ANNEX A

### CHAPTER 144. ELECTRONIC METHODS FOR TESTING MILK FOR FAT AND COMPONENT CONTENT

#### § 144.1. Electronic methods—general.

(a) *Definitions.* The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

(1) *Accuracy check* – A test made at the beginning of each testing session and once per hour thereafter to determine the continued accuracy of the electronic testing apparatus.

(2) *Calibration* – The adjustment of an electronic instrument so that the results for a given payment component meet the comparison criteria results of an Association of Official Analytical Chemists (AOAC) or Intersociety Council on Standard Methods for the Examination of Dairy Products (ICSMEDP) approved reference method.

(3) *Certified tester* – A Milk Marketing Board certified technician as referenced in §144.2 (relating to certification requirements) operating electronic instruments and/or a person certified to perform specific reference methods for determining the components in raw milk.

(4) *Control milk/Control sample* – Samples produced by a commercial laboratory or by the United States Department of Agriculture (USDA) Market Administrator's Office or its successor agency, used for determining the calibration of an electronic instrument and also used to set the calibration of an electronic instrument.

(5) *Electronic method* – A method for determining the components in raw milk using an electronic testing instrument.

(6) *Milk component/Component* – Unique compound within milk whose relative mass within the milk may be used to determine the payment to producers. Component parts of milk include, but are not limited to, butterfat, protein, lactose, solids non-fat, other solids, and total solids.

(7) *Reference method* – Standard method using analytical chemistry or other approved techniques by which all other electronic methods of testing milk are compared for determining the components in milk.

(8) *Repeatability check* – A test run at the beginning of each testing session in order to demonstrate the ability of a given electronic testing instrument or piece of equipment to meet the requirements for repeatability in § 144.4(b)(2) (relating to repeatability check).

(b) Reference methods used to determine the component content of milk for payment purposes shall be those recognized or approved and set forth either by the ICSMEDP in the latest edition of Standard Methods for the Examination of Dairy Products, published by American Public Health Association, Washington, D.C., or by the AOAC in Official Methods of Analysis,

published by AOAC International, Gaithersburg, Maryland. Only electronic instruments recognized by the USDA Dairy Division for the analysis of milk and milk components and capable of performance standards as referenced in §144.4 (relating to routine inspection and control) shall be used to test milk for payment purposes in Pennsylvania.

(c) A manufacturer of an electronic testing instrument shall make available upon request to the Board a complete instrument operation and maintenance manual and further information as required.

#### **§ 144.2. Certification and approval requirements.**

(a) No person may use an electronic instrument or method to test milk for component content for payment purposes unless the instrument and method have been approved by the Board, ICSMEDP, AOAC, or USDA Dairy Division, or their successor organizations.

(b) No person may use or employ an electronic instrument or method to test milk for component content for payment purposes unless certified by the Board under section 602 of the act (31 P. S. § 700j-602).

#### **§ 144.3. Laboratory facilities and supplies.**

Laboratories and other facilities using an electronic instrument or method to test milk for component content for payment purposes shall have the following supplies and facilities available and in proper working order:

(1) An approved electronic testing instrument, required accessories and reagents and an instruction manual for operation of the instrument.

(2) A thermostatically controlled water (or other manufacturer-prescribed medium) bath with recording thermometer having proper temperature distribution, set to maintain samples at the temperature specified by the manufacturer of the electronic testing instrument, or other methods of obtaining the required temperature as specified by the instrument manufacturer and acceptable to the Board.

#### **§ 144.4. Routine inspection and control.**

(a) Control samples shall be prepared in accordance with methods established by the Board through Official General Order.

(b) *Daily performance.*

(1) *Accuracy check.* Each day before routine testing begins, at least once each hour during the course of the testing session, and when the testing session ends, at least one subsample of control milk shall be tested using the electronic instrument. The certified tester shall read the test to 0.01%. The result difference obtained by the reference method must be 0.05 or less than the known reference test sample result. If the difference of the samples exceeds 0.05 the certified

tester shall discontinue operation of the instrument, determine the reason for the difference and correct the deficiencies before resuming operation.

(2) *Repeatability check.* Each day before routine testing begins, ten consecutive readings on a single well-mixed sample of milk that has not been homogenized shall be made and recorded as a permanent record. If more than ten consecutive readings are taken the certified tester shall use the last ten results. The repeatability check may be assumed to be acceptable if the range of the ten readings is 0.04 or less.

#### **§ 144.5. Instrument calibration.**

(a) *Calculation of calibration results.* An instrument shall be considered to be calibrated properly when the average difference between the instrument results for butterfat and protein and the reference method results for at least ten different control samples, called mean average, is +/- 0.04 and the standard deviation of the difference between the instrument and reference methods, called standard deviation, are 0.04 or less. For all solids the mean average is +/-0.09 and the standard deviation of the differences between the instrument and reference methods are 0.12 or less for those same ten samples.

(b) *Conditions requiring calibration.*

- (1) The instrument shall be calibrated when initially installed.
- (2) The instrument shall be calibrated when the accuracy check is confirmed to have failed.
- (3) The instrument shall be calibrated if a part which may affect proper operation of the instrument is replaced, rebuilt or adjusted.
- (4) The instrument shall be calibrated upon the occurrence of the specific circumstances which require calibration for that instrument, as determined by the manufacturer.

#### **§ 144.6. Required records.**

(a) The certified tester(s) and testing facilities or laboratories shall maintain all records required by this section for a period of at least one year. Records may be maintained in paper or electronic formats. In all cases records must denote the record date and the name and license number of the Certified Tester who created or maintained the record(s).

(b) Records of calibrations, accuracy checks, mean average and standard deviation computations and other instrument use.

(c) Records of the operation and maintenance of each electronic testing instrument and records of all test results by electronic method.

(d) Certified testers shall record standard deviation of the calibration verification as follows:

(i) The results of individual samples by reference method (average only for reference method) and electronic method.

(ii) The date of computation, name and license number of certified tester.

(e) Certified testers operating all electronic testing equipment shall perform a daily accuracy check and record the following:

(i) Reference method used, sample identification, individual test results and average test.

(ii) Electronic method used, time, sample identification, individual test results and average test results.

#### **§ 144.7. Summary record required.**

(a) The certified tester and the testing facility or laboratory shall compile summary records of all component tests performed for all producers for the first and second half of each month containing results for at least two evenly spaced representative samples in each half month for each producer. The record shall contain the farm sampling date, the laboratory testing date, the laboratory or testing site, the tester identification, the producer identification and the test result for each sample. The record shall be known as the original record or laboratory record and shall be maintained by the tester for at least one year. If the tests are performed by a milk dealer licensed by the Board, the milk dealer shall maintain the records of the component content of producers' milk samples for at least one year.

(b) If tests are performed in a commercial laboratory which is not an integral part of the milk plant where the samples were delivered, that licensed dealer or plant must make available to the Board a copy of the final laboratory records of the component tests in computerized or written form for at least one year.

**§ 144.8. [Reserved].**

**§ 144.9. [Reserved].**

**§ 144.10. [Reserved].**

**§ 144.11. [Reserved].**

#### **§ 144.12. Credit producers with actual component test.**

(a) No individual producers delivering milk or cream, or both, to a milk or cream-receiving or purchasing plant, where the milk or cream is purchased on the basis of the milk components



contained therein, may be credited with a greater or lesser percentage or average percentage of milk components than is actually contained in the milk or cream delivered.

(b) No report on a test to determine the milk component content of milk or cream may be of a greater or lesser percentage of milk components than is actually contained in the milk or cream from which the sample was taken. In order to be a basis of payment to an individual producer, a recheck of a producer's milk component test shall be made from the next available sample taken after the original test. Rechecks of a producer's milk component test shall be made when the butterfat varies 0.5% or more or the protein varies 0.3% or more from the most recent test.

#### **§ 144.13. Availability of records.**

Laboratory, cooperative, or plant records shall be open to examination by the Board or its authorized representative. Upon request of a producer, the purchaser or receiver of milk or cream, or both, shall permit the producer to examine the part of the record containing information concerning the samples of milk or cream representing the milk or cream delivered by the producer. A purchaser or receiver of milk or cream from the producer thereof shall, on written request, at least once each month mail or deliver to the producer a written statement, unless the producer agrees to accept a verbal statement, of the percentage of milk components found to have been contained in the sample or samples representing the milk or cream delivered by the producer.

#### **§ 144.14. Responsibility for violations.**

A certified tester at a laboratory or plant shall be responsible for a violation of the act or this chapter, including the keeping of the reports and records required by the act and this chapter. Additionally, the purchaser or receiver, or both, of the milk or cream, or both, or the licensed manager of a milk-gathering station, manufactory or plant receiving or purchasing milk or cream from producers for sale or resale or for manufacture, where the payment or settlement for the milk or cream is based in whole or in part on the milk component content thereof, shall be responsible for a violation of the act or this chapter by a person working under his direction or subject to his orders or the act or this chapter, including the keeping of the reports and records required by the act and this chapter.

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE  
REGULATORY REVIEW ACT**

LD. NUMBER: 47-15

SUBJECT: Electronic methods for testing milk for fat content

AGENCY: Pennsylvania Milk Marketing Board

**TYPE OF REGULATION**

Proposed Regulation

Final Regulation

Final Regulation with Notice of Proposed Rulemaking Omitted

120-day Emergency Certification of the Attorney General

120-day Emergency Certification of the Governor

Delivery of Tolled Regulation

a.  With Revisions

b.

Without Revisions

RECEIVED  
IRRC  
2011 MAR 24 P 3:21

**FILING OF REGULATION**

DATE	SIGNATURE	DESIGNATION
3/24/11	Mary Seiger	HOUSE COMMITTEE ON Agriculture & Rural Affairs
3/24/11	J. K. [Signature]	
3/24	J. [Signature]	SENATE COMMITTEE ON Agriculture & Rural Affairs
3/24/11	K. Cooper	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
3/24	n. [Signature]	LEGISLATIVE REFERENCE BUREAU

April 20, 2001