Quality Certification Services, Inc.

Auditing Procedures for Laboratories

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Version 26.0

The purpose of this manual is to ensure the accuracy and uniformity of all data provided by laboratories in the DHI system.

Laboratory Audits and Certification

Initial Certification Audits

Before achieving initial certification, laboratories must demonstrate acceptable machine performance by meeting the monthly proficiency test tolerances at least four consecutive months. Once this has been accomplished, the laboratory must submit to an on-site audit and demonstrate compliance with all aspects of this manual, the *Policies and Procedures,* and with the National DHIA *Code of Ethics* and *Uniform Data Collection Procedures*.

Audits

Once certification has been established, laboratories will require an every-other-year, on-site audit to renew their certification. During the audit, laboratories must allow the auditor to observe the routine analysis of samples.

Laboratories failing to address deficiencies noted in the audit report within the time frame and conditions set forth by the auditor will require additional follow-up auditing. **At any time, additional audits may be called by the auditor at the auditor's discretion or may be requested by the cooperating organization.**

Scheduling of Audits

Each laboratory will be assigned a centering month for on-site audits. Audits must be performed within 60 days of the centering period month.

Auditing Period

The auditing period will begin on the first day of the previous centering period month and end on the last day of the month prior to the current centering period month. Only data and events occurring between these dates will be used as auditing criteria.

Period of Certification

The certification period will extend through the last day of the 26th month following the centering period month. Laboratories failing to achieve certification renewal by the end of the 26th month will be classified as decertified.

If a failure to maintain standards is determined to have occurred by the auditor during the certification period, the service provider may be decertified prior to the end of the current certification period.

Audits of the Monthly PT Performance

Although the on-site audits are required for biennial laboratory certification, monthly proficiency test results must be submitted and be found within acceptable limits on a monthly basis for ongoing certification to continue. This requirement must be met for each laboratory machine used for the generation of sample results .

Data submitted late will not be included in the batch data. Late data may be accepted if the laboratory contacts the QC Program Manager prior to the submission deadline with a request for late submission accompanied by a valid reason; instrument(s) affected, and anticipated availability of results. Any laboratory submitting either late data or corrected data twice or more in the previous twelve (12) month period without a valid reason will have its respective certification status changed to provisional.

Milk Fat Analysis
All FTIR/IR analyzers must use a “B” wavelength, the “A” and “B” wavelength in a 30/70 ratio, or full spectral calibration.

Protein References
Throughout this manual, all references to protein are references to the true protein values.

Reporting False Sample Readings
Laboratories may not submit false sample analysis results in place of actual machine results for high or low sample readings.

Decertification Procedures
Decertification will only be considered when the performance of a laboratory has fallen below the minimum standards, and the organization does not take prompt action to return to compliance within the period specified by the auditor.

Centering Period Months for Laboratories – Even Years

Laboratories are subject to biennial, on-site audits. Below is a schedule of target months for the on-site audits scheduled to occur during even-numbered years.

January ..... Minnesota DHIA – Centre Labs

February .....Central Counties DHIA
..... Kings County DHIA
.....Fresno DHIA
.....Southern Counties DHIA
..... Tulare DHIA

April .....Lancaster DHIA

August .....Texas DHIA – Stephenville
..... The Dairy Authority, LLC
.....Langston DHI

September .....Alpura, Edo. de México, México, México
..... Inledesa (Alpura), Cd. Delicias, Chihuahua, México
.....Alpura, Gómez Palacio, Durango, México
.....Holstein de México, Querétaro, México

October..... Integrated Milk Testing Services – Dimmitt
.....Texas DHIA – Canyon
.....Circle H Headquarters, LLC
..... ADM Laboratories, LLC

Centering Period Months for Laboratories – Odd Years

Laboratories are subject to biennial, on-site audits. Below is a schedule of target months for the on-site audits scheduled to occur during odd-numbered years.

January .....

February ..... Dodge County DHIA
..... Eastern Wisconsin DHIC
..... CentralStar Cooperative DHI Services – Wisconsin

March ..... Eurofins - Belleview

April ..... AgSource Laboratories - Menomonie
..... Marathon County DHIA

June ..... DHI Cooperative Inc.
..... Eastern Lab Services
..... CentralStar Cooperative DHI Services - Michigan

September ..... Willamette DHIA
..... Washington State DHIA

October ..... Northwest Labs, LLC
..... High Desert Dairy Lab
..... Rocky Mountain DHIA
..... Arizona DHIA

December ..... Dairy One Cooperative Inc.

Auditing of the Continuing Education of Laboratory Managers and Leads

Continuing Education Responsibility
Laboratory managers and laboratory leads must complete additional training regularly as measured by continuing education (CE) units.

Training Format
Continuing education should be in the format that best utilizes the resources available and meets the job requirements of the laboratory manager(s) and laboratory lead(s).

Continuing Education (CE) Credits
Continuing education events will be measured in CE credits accumulated between the biennial on site audits. The biennial period will begin with the centering month for audits and continue through the last day of the month preceding the next biennial on-site audit.

The CE requirements for laboratory staff are:

- Laboratory Manager(s) 10 CE per biennial period
- Laboratory Lead(s) 5 CE per biennial period

The CE will be assigned at the following levels:

Meeting Name or Type	CE Value
Laboratory Advisory Committee/NALMA Meeting	5
Instrument Manufacturer Training	4
Regional Laboratory Meeting	3
National DHIA/QCS DHI Laboratory Virtual Meeting	2
Internal Laboratory Staff Meeting	1
ELISA Technician Training School (if applicable)	1
National DHIA or DRPC Meeting	1
Other training event (as approved by the auditor)	1-3

Documentation
Documentation of the continuing education provided to each laboratory manager and laboratory lead must be furnished during an audit.

This documentation must include:

- the name of each laboratory manager and/or laboratory lead;
- a description of the training session, course, or meeting completed;
- the name(s) of individuals and organizations conducting the training; and
- a list of the topics covered during the training event(s).

Verification of Documentation
Training records should be maintained as outlined in the laboratory standard operating procedures for employee training. These records may be reviewed, or interviews held with personnel, to evaluate the continuing education completed by laboratory managers and/or laboratory leads.

Auditing of the Initial Training and Continuing Education of Laboratory Technicians

Training Responsibility and Training Personnel

Laboratories must furnish initial training and follow-up training to all new laboratory technicians. Further, all laboratory technicians must complete additional training regularly as measured by continuing education (CE) units. A qualified trainer must provide all training. In cases where new analytical equipment has been installed, it is recommended that the training be provided by the manufacturer's representative.

Minimum Initial and Follow-Up Training Requirements

The minimum requirements for laboratory technicians to analyze samples without immediate supervision include:

- FTIR/IR and SCC instrument operation,
- routine pilot sample procedures,
- required laboratory documentation, and
- ability to determine acceptable sample quality for analysis.

Continuing Education (CE) Credits

Continuing education events will be measured in CE credits accumulated between the biennial on site audits. Laboratory technicians are required to accumulate a minimum of 2 CE during the biennial period.

The CE will be assigned at the following levels:

Meeting Name or Type	CE Value
Laboratory Advisory Committee/NALMA Meeting	5
Instrument Manufacturer Training	4
Regional Laboratory Meeting	3
National DHIA/QCS DHI Laboratory Virtual Meeting	2
Internal Laboratory Staff Meeting	1
ELISA Technician Training School (if applicable)	1
National DHIA or DRPC Meeting	1
Other training event (as approved by the auditor)	1-3

Reference Documents

The laboratory manager must have a functional up-to-date Laboratory Manual, which includes standard operating procedures for procedures for laboratories. In addition, all appropriate technical documents should be available to laboratory technicians. Examples include instrument manuals, SDS sheets, etc.

Documentation

Documentation of the initial training and continuing education must be furnished during an audit. This documentation must include:

- the name of each laboratory technician,
- the name and credentials of the trainer, and
- a list of topics covered during the training.

Verification of Documentation

At the discretion of the auditor, individual training records may be reviewed or interviews held with laboratory technicians to audit the training program in place.

Calibration Check Frequency

Samples with unknown results must be analyzed and reported on a monthly basis.

Calibration Check Procedure

On a monthly basis, the laboratory must purchase duplicate sets of 12 samples from a supplier designated by the auditor. The samples must be analyzed and the following data submitted to a predetermined site by a deadline determined by the auditor.

- The sample analysis results, and
- The supplier and set number of the last calibration samples.

The auditor will compare the transmitted results to those determined via reference methods and will report the findings back to the laboratory.

Acceptable Readings for Calibration Checks for Fat and Protein

The mean difference must not exceed 0.04% and the standard deviation of differences must not exceed 0.04% in three of the previous four trials.

The rolling mean difference over the previous six trials must not exceed 0.02%.

Response to Calibration Check Failures

If an instrument fails to meet the established tolerances, it will be decertified immediately and must not be used for generating component results to be used until the problem has been identified, corrected, and recognized as such by the auditor.

In some cases, the laboratory may be required to demonstrate acceptable performance via the analysis of multiple sets of samples with unknown results.

Calibration Check Frequency

Samples with unknown results must be analyzed and reported on a monthly basis.

Calibration Check Procedure

On a monthly basis, the laboratory must purchase duplicate sets of 12 samples from a supplier designated by the auditor. The samples must be analyzed and the following data submitted to a predetermined site by a deadline determined by the auditor.

- The sample analysis results, and
- The supplier and set number of the last calibration samples.

The auditor will compare the transmitted results to those determined via reference methods and will report the findings back to the laboratory.

Acceptable Readings for Calibration Checks for SCC

The mean percent difference must not exceed 10% and the standard deviation of percent differences must not exceed 10% in three of the previous four trials.

The rolling mean percent difference over the previous six trials must not exceed 5%.

Response to Calibration Check Failures

If an instrument fails to meet the established tolerances, it will be decertified immediately and must not be used for generating component results to be used until the problem has been identified, corrected, and recognized as such by the auditor.

In some cases, the laboratory may be required to demonstrate acceptable performance via the analysis of a second set of samples with unknown results.

Auditing of MUN Instruments for Monthly PT Performance

Calibration Check Frequency
Samples with unknown results must be analyzed and reported on a monthly basis.

Calibration Check Procedure
On a monthly basis, the laboratory must purchase duplicate sets of 12 samples from a supplier designated by the auditor. The samples must be analyzed and the following data submitted to a predetermined site by a deadline determined by the auditor.

- The sample analysis results, and
- The supplier and set number of the last calibration samples.

The auditor will compare the transmitted results to those determined via reference methods and will report the findings back to the laboratory.

Acceptable Readings for Calibration Checks for MUN
The mean percent difference must not exceed 1.5 mg/dL (mg%) and the standard deviation of differences must not exceed 1.5 mg/dL (mg%) in three of the previous four trials.

The rolling mean percent difference over the previous six trials must not exceed 0.75 mg/dL (mg%).

Response to Calibration Check Failures
If an instrument fails to meet the established tolerances, it will be decertified immediately and must not be used for generating component results to be used until the problem has been identified, corrected, and recognized as such by the auditor.

In some cases, the laboratory may be required to demonstrate acceptable performance via the analysis of a second set of samples with unknown results.

Approval Protocol for New Laboratory Instrument(s) and Component(s)

DHI laboratories certified under the *Auditing Procedures for Laboratories* are required to demonstrate acceptable analytical performance on all lines of test instruments (also known as analyzers) on a routine basis. The monthly proficiency test (PT) program administered by the QC Program Manager serves this role for existing laboratory instruments.

Certified laboratories replace or add a new line(s) of instruments on a routine basis. This procedure applies to new, used, and refurbished instruments. Results from these new instruments may not be submitted until demonstration of satisfactory instrument performance is completed.

New Instrument Approval Protocol

1. As outlined in the *General Auditing Guidelines*, the new instrument(s) must be reported to QC Program Manager and subsequently enrolled in the monthly PT program. For each new instrument, the following information should be provided:

    - Manufacturer,
    - Model,
    - Condition (new, used, refurbished),
    - Serial number,
    - Components to be analyzed (fat, protein, SCC, MUN, other),
    - Fat analysis (if applicable) using "B" wavelength, the "A" wavelength and "B" wavelength in 30/70 ratio, or full spectra,
    - Instrument(s) to be replaced/taken out of service (where applicable).

2. If laboratory management and instrument technicians are not familiar with the make and/or model of the instrument, appropriate installation and training by the respective instrument manufacturer must be provided. Written evidence of this training must be forwarded to QC Program Manager.

3. The instrument must be appropriately calibrated using suitable reference controls. Sample sets with unknown results and pilot samples are not suitable reference controls for calibration of any instrument.

4. The laboratory will remain certified provided the laboratory completes one of the following options.

    a. Laboratory submits documentation to the QC Program Manager that includes the documentation listed below. Submission of data from the new instrument(s) may begin immediately when using this option.

        - Completed manufacturer's training checklist,
        - Results from one set of samples with unknown results run by the laboratory during the instrument installation,
        - Documentation of calibration check validation during the first three consecutive weeks of operation, and
        - Log files/reports for daily and hourly checks of multiple ranges of components, SCC, and zeroes during the first three consecutive weeks of instrument operation.

b. Laboratory establishes a satisfactory performance record by analysis of a minimum of three sets of samples with unknown results provided by PT sample provider. This process may be expedited by ordering and analyzing three consecutive weekly sets of samples with unknown results. The tolerances for mean difference (MD) and standard deviation of differences (SDD) as outlined in *Auditing Guidelines for Laboratories* must be met for all components analyzed. Submission of data cannot begin when using this option without approval from the QC Program Manager. The cost of these additional sample sets is the responsibility of the laboratory.

5. Laboratory management is responsible for contacting the QC Program Manager and for providing all the required information as outlined in this protocol.

6. Failure to follow this protocol may be result in the change of the laboratory's certification status to provisional until such time satisfactory instrument performance is documented. Further, data submitted that was generated from new instrument(s) may be removed from the database if warranted.

New Component Approval Protocol

1. As with new instruments, a laboratory that desires to analyze an additional component using an existing instrument should follow a similar protocol. The additional component(s) must be reported to the QC Program Manager and subsequently enrolled in the monthly PT program.

2. The laboratory will remain certified and may submit data provided the laboratory submits documentation of instrument performance using one of the options outlined in the '*New Instrument Approval Protocol*.'

3. Laboratory management is responsible for contacting the QC Program Manager and for providing all the required information as outlined in this protocol.

4. Failure to follow this protocol may result in the change of the laboratory's certification status to provisional until such time satisfactory instrument performance is documented. Further, data submitted that was generated for the additional component(s) may be removed from the database if warranted.

Auditing of Calibration Check and Maintenance Documentation

Routine Maintenance Program

A documented, routine maintenance program must be in place for each laboratory instrument. The program must meet with the approval of the laboratory auditor.

Calibration Checks and Maintenance Documentation

All calibration checks and equipment maintenance records must be documented and provided during an audit. The documentation must include the following:

- Instrument identification,
- Name of the laboratory technician or maintenance person,
- Time and date of the calibration check or maintenance,
- Type of analytical test or maintenance performed,
- Parts used during the maintenance or repair,
- Results of the analytical test or maintenance, and
- Details of action taken to correct calibration tolerances or mechanical problems.

Record Keeping Systems

Calibration checks and maintenance records may be documented in the form of a computerized spreadsheet, manual listing, or other organized system. If manual listings are used, results should be recorded in ink.

Retention of Calibration Checks and Maintenance Documentation

Documentation of all calibration checks and maintenance records should be maintained for a minimum of two years.

Auditing of the Sample Handling and Preparation

Sample Shipping

The laboratory will not be held responsible for the condition of the samples upon arrival at the laboratory. However, samples received in poor condition should be noted and feedback furnished to the field service provider or field technician.

Sample Storage

In most situations, the laboratory should analyze all samples within 24 hours of arrival. However, if samples are routinely held for longer periods of time, it is recommended that a refrigeration system be used to maintain sample quality during storage.

Sample Preparation

Prior to analysis, samples must be heated to an optimal temperature of 104°-107° Fahrenheit or 40°-42° Celsius in a water bath. It may be necessary to set the temperature of the water bath at a slightly higher temperature to achieve the target temperature at the time of sample uptake by the instrument.

A certified, traceable thermometer must be installed in the water bath and monitored continually to ensure that the samples are heated properly. Samples should not be left in the water bath for more than 15 minutes after reaching a temperature of 40° Celsius. Non-traceable thermometers are not acceptable. Thermometer calibration certificates must be retained with expiry dates recorded and available for inspection.

Sample Analysis Results

The laboratory must have a method of capturing and storing sample analysis results electronically. It is recommended that a hardcopy be printed in real time during the analysis as a backup method for machine or power failures.

Sample Vials and Lids

Good quality vials and lids must be provided for milk sampling. Lids and vials should be routinely and randomly inspected and replaced when their condition might compromise the quality or accuracy of the sample analysis. No residue may be present on vials or lids prepared for return to the field. Cracked vials and lids must be replaced.

The laboratory should have a standard operating procedure for inspection, replacement and washing of vials when reused. It is recommended that the washing procedure for vials and lids include a sanitizing step. It is recommended that vials should be dry before microtab preservative is added to the vial.

Calibration Check Frequency

Instrument calibration must be checked weekly. It must also be checked when a problem is suspected or when major equipment maintenance is performed.

Calibration Check Procedure

At least six fresh, raw milk samples must be obtained with the butterfat percentage in the range of 2.5% to 6.0% and protein percentage in the range of 2.5% to 4.0%. The butterfat and protein percentages must have been determined by the Ether extraction fat and Kjeldahl true protein methods.

The samples must be warmed and analyzed and the instrument results compared to the chemical reference values.

Acceptable Readings for Calibration Checks

The calibration check is acceptable if the mean difference is within 0.04% and the standard deviation of differences is within 0.04%.

Response to Calibration Check Failures

If the instrument fails the calibration check, it should be recalibrated according to approved procedures.

Alternative Procedures

If the laboratory can demonstrate that the accuracy of an alternative procedure meets or exceeds that of the recommended procedure, the use of an alternative procedure is allowed. An example would be daily checks with partial sets.

Before implementation, the auditor must review a copy of the alternative procedure, and the laboratory must receive written authorization.

Calibration Adjustment Frequency

Calibrations must be adjusted if the tolerances specified on the page entitled *Auditing of FTIR/IR Instruments for Calibration Checks* are not met.

Calibration Adjustment Procedure

A simple linear regression is used to recalculate the slope and intercept of the prediction equation. The instrument and reference results generated from the *Calibration Check Procedure* on the page entitled *Auditing of FTIR/IR Instruments for Calibration Checks* may be used.

Acceptable Readings for Calibration Adjustments

The calibration adjustment is valid if the resulting mean difference and standard deviation of differences are reduced to the point that the acceptance criteria outlined on the page entitled *Auditing of FTIR/IR Instruments for Calibration Checks* are met.

Response to Calibration Check Failures

If the instrument fails the calibration check, the condition of the samples should be checked and the reference tables reviewed to ensure that they are reliable. The set should be screened for outliers and the calibration adjustment procedure repeated.

If the instrument fails a second time, it should be checked for other potential problems and repaired. The instrument should be recalibrated using an alternative set of samples.

Alternative Procedures

If the laboratory can demonstrate that the accuracy of an alternative procedure meets or exceeds that of the recommended procedure, the use of an alternative procedure is allowed. Examples include:

- Zero forced regressions (i.e. no intercept),
- Adjustment of intercept only (not recommended),
- Adjustment of slope only (not recommended), or
- Adjustment of intercorrection factors with multiple linear regressions.

Before implementation, the auditor must review a copy of the alternative procedure, and the laboratory must receive written authorization.

Homogenization Check Frequency

Homogenization efficiency must be checked on a weekly basis. It must also be checked when a new homogenizer is installed or when a problem is suspected. Ideally, this check should be part of the pre-calibration routine.

Calibration Check Procedure

A sample of fresh, raw milk must be warmed and analyzed several times, and the homogenized instrument discharge collected. The discharge should be warmed again and analyzed a minimum of five times. The average of the last five test results on the original sample is compared to the average of the last five test results on the discharge.

Acceptable Readings for Calibration Checks

The absolute difference between the average of the last five test results on the original sample and the average of the last five test results on the discharge should not exceed the value calculated by multiplying the average of the last five test results on the fresh, non-homogenized sample x 0.0143.

Response to Calibration Check Failures

This calibration check will only identify a failing homogenizer. A completely defective valve will pass the check and therefore, it is essential that the guidelines regarding the minimum frequency be followed precisely.

If the instrument fails the homogenization check, the homogenizer should be repaired or replaced, and the test should be repeated. It may be necessary to recalibrate once the problem is corrected.

Alternative Procedures

If the laboratory can demonstrate that the accuracy of an alternative procedure meets or exceeds that of the recommended procedure, the use of an alternative procedure is allowed. Examples include:

- Microscopic examination of the instrument discharge,
- Particle size analysis,
- Analysis of a split sample, where one portion is homogenized externally, or
- Recorded use of a manufacturer's built-in procedures (i.e. homogenization index).

Before implementation, the auditor must review a copy of the alternative procedure, and the laboratory must receive written authorization.

Auditing of Preparation of Pilot Samples

Pilot samples should be prepared on a weekly basis or more frequently as necessary. A representative milk sample should be obtained, preserved and split accurately into individual vials.

For FTIR/IR analyzers, raw milk or whole homogenized milk may be used.

For somatic cell counters, raw milk must be used. Ideally this should be a fresh raw milk sample having a cell count of 200 to 400. (200,000 to 400,000 cells/ml).

Target values for fat, protein and SCC should be determined immediately following preparation of the samples by repeated analysis on all test lines. Ideally this should be done after the weekly calibration check/adjustment. A preparation log should be maintained. The following information should be included:

- date of collection and/or preparation;
- source of the sample;
- target value results from all lines and the calculated averages;
- identification of the technician(s) collecting/preparing the sample.

Target values should be held constant from day to day and should not differ among test lines.

Uniformity Check

Care must be taken to ensure that raw samples are well mixed while splitting. To ensure that procedures for splitting are acceptable, a periodic check of the uniformity of pilot samples should be conducted. It is recommended that this be done twice yearly and whenever procedures for splitting the sample are changed. The uniformity check is conducted as follows:

- While dispensing the raw milk, select a minimum of 10% of the total number of vials prepared. Ensure that the samples are selected at equal intervals during the dispensing process. For example, if a total of 100 vials are being filled, select every tenth vial for the homogeneity check.
- Analyze each of the selected samples for fat, protein and somatic cell count.
- If procedures for splitting are acceptable, the total range for fat and protein should not exceed 0.03%. For somatic cell count, all values should fall within 5% of the average count.
- If these tolerances are exceeded, the procedure for dispensing the samples must be modified to provide more uniform splitting.

Note this is NOT the same as the daily repeatability check of the instruments. This procedure is used to ensure the method used to split the raw pilot sample is acceptable. It is important to conduct a regular repeatability check prior to conducting this test to ensure instrument precision is acceptable.

A record of the uniformity checks should be maintained.

Auditing of FTIR/IR Instruments for Pilot Samples

Pilot Sample Check Frequency

Pilot sample checks must be performed on an hourly basis during routine operation of instruments. A pilot sample should also be tested at start-up, when the instrument has been idle or shut down, or when a problem is suspected.

Laboratories that do not retain milk samples until the analysis of an hourly check must run a pilot sample at least every 300 samples during the course of the hour.

Calibration Check Procedure

A new set of pilot samples must be prepared on a weekly basis. This is accomplished by taking a supply of fresh, raw milk or homogenized, whole milk and dividing it into a set of individual sample vials.

The individual sample vials should be tested several times and the results averaged to determine the "target" values for the set. Ideally, this should be done immediately following the calibration check or adjustment.

During the week, a pilot sample must be warmed but not remain in the water bath for more than 15 minutes after reaching a temperature of 40° Celsius and analyzed as specified during normal operation of the instruments. The instrument results must be compared to the target values.

Acceptable Readings for Calibration Checks

The difference between instrument results and the target value should not exceed 0.04% for butterfat or protein.

Response to Calibration Check Failures

If the instrument fails the pilot sample check,

- A second sample should be analyzed to confirm or refute the result.
- If the second sample confirms that there is a discrepancy in the pilot sample result, the instrument should be cleaned, zeroed, and a pilot check performed.
- If the problem continues, the instrument should be shut down and repaired.
- Upon repair and start-up, a pilot check should be performed.

Alternative Procedures

If the laboratory can demonstrate that the accuracy of an alternative procedure meets or exceeds that of the recommended procedure, the use of an alternative procedure is allowed. Examples include:

- The use of reference samples (i.e. with chemical test results),
- The use of UHT (sterilized) milk samples for longer period than one week, or

Before implementation, the auditor must review a copy of the alternative procedure, and the laboratory must receive written authorization.

Purging Check Frequency

Purging efficiency must be checked on a weekly basis. It must also be checked when a problem is suspected. Ideally, this check should be part of the pre-calibration routine.

Calibration Check Procedure

A sample of homogenized, pasteurized whole milk must be obtained and split into ten separate vials. A sample of distilled water, deionized water, or detergent solution must also be obtained and split into ten separate vials.

The twenty vials must be placed in a sample rack in an alternating sequence of two waters, two milks, etc. The samples should be warmed and analyzed using automatic stirring and sampling equipment.

Acceptable Readings for Calibration Checks

The purging efficiencies for butterfat and protein are calculated as follows and all purging efficiencies should be 99-101%.

- The sum of the first water samples w1 = #1 + #5 + #9 + #13 + #17
- The sum of the second water samples w2 = #2 + #6 + #10 + #14 + #18
- The sum of the first milk samples m1 = #3 + #7 + #11 + #15 + #19
- The sum of the second milk samples m2 = #4 + #8 + #12 + #16 + #20
- The water to milk purging efficiency = (m1 - w2) / (m2 - w2) x 100
- The milk to water purging efficiency = (w1 - m2) / (w2 - m2) x 100

Response to Calibration Check Failures

If an instrument fails the purging efficiency test, repeat the procedure while wiping the stirrer and pipette between each two-sample cycle.

If the instrument passes the purging efficiency test when the stirrer and pipette are wiped, the problem is related to the automatic sampling equipment. Ensure the stirrer motor is operating properly and that both stirrer and pipette are clean. Repeat the procedure to ensure that the purging efficiency check passes consistently.

If the instrument fails the purging efficiency test when the stirrer and pipette are wiped, the problem is related to the flow system. Check for leaks in the flow system. Check the pump operation and the purge stroke settings. Adjust the carry-over compensation factors, if necessary. Repeat the procedure to ensure that the purging efficiency check passes consistently.

Alternative Procedures

If the laboratory can demonstrate that the accuracy of an alternative procedure meets or exceeds that of the recommended procedure, the use of an alternative procedure is allowed. Examples include (1) the purge volume measurements, (2) the hourly water / milk checks, or (3) the milk to milk (high - low) procedures.

Before implementation, the auditor must review a copy of the alternative procedure, and the laboratory must receive written authorization.

Repeatability Check Frequency
Repeatability must be checked on a daily basis. It must also be checked when a problem is suspected.

Calibration Check Procedure
A sample of fresh, raw milk must be warmed and analyzed at least ten times in succession.

Acceptable Readings for Calibration Checks
Discard the first result to eliminate potential carry-over effects. The range between the highest result and the lowest result should be determined and must not exceed 0.04% for butterfat or protein.

Response to Calibration Check Failures
If an instrument fails the repeatability test, check to ensure that the sample is in good condition, that the instrument is properly warmed up, and that the desiccant is not saturated. Then repeat the procedure.

If the instrument fails the repeatability test again, check homogenization and purging efficiency and duplicate the procedure until the repeatability test passes consistently.

Alternative Procedures
If the laboratory can demonstrate the accuracy of an alternative procedure meets or exceeds that of the recommended procedure, the use of an alternative procedure is allowed. An example would be the use of fewer replicates with increased frequency (i.e. hourly).

Before implementation, the auditor must review a copy of the alternative procedure, and the laboratory must receive written authorization.

Zero Drift Check Frequency

Zero drift must be checked hourly during routine operation of instruments. Drift figures should be documented each time the zero is reset.

Calibration Check Procedure

A distilled water, deionized water, or a detergent solution sample must be warmed and analyzed.

Acceptable Readings for Calibration Checks

The zero drift must be reset if either the butterfat or protein reading exceeds 0.03%.

Response to Calibration Check Failures

If an instrument fails the zero-drift check, the cell should be cleaned and the zero-drift checked again.

If the instrument fails the zero-drift check again, the zero value should be reset.

Alternative Procedures

If the laboratory can demonstrate the accuracy of an alternative procedure meets or exceeds that of the recommended procedure, the use of an alternative procedure is allowed.

Before implementation, the auditor must review a copy of the alternative procedure, and the laboratory must receive written authorization.

Auditing of SCC Instruments for Calibration Checks

Calibration Check Frequency

Instrument calibration must be checked weekly. It must also be checked when a problem is suspected or when major equipment maintenance is performed.

Calibration Check Procedure

At least four fresh, raw milk samples must be obtained from an approved source. The SCC's must have been determined by direct microscopic SCC and must be in the range of 100,000 to 1,200,000 cells/ml.

The samples must be warmed and analyzed at least four times, and the instrument results compared to the reference values.

Acceptable Readings for Calibration Checks

The calibration check is acceptable if the mean percent difference is within 5% and the standard deviation of percent differences is within 10%.

Response to Calibration Check Failures

If the instrument fails the calibration check, it should be recalibrated according to approved procedures.

Alternative Procedures

If the laboratory can demonstrate that the accuracy of an alternative procedure meets or exceeds that of the recommended procedure, the use of an alternative procedure is allowed.

Before implementation, the auditor must review a copy of the alternative procedure, and the laboratory must receive written authorization.

Calibration Adjustment Frequency

Calibrations must be adjusted if the tolerances specified on the page entitled *Auditing of SCC Instruments for Calibration Checks* are not met.

Calibration Adjustment Procedure

Several different adjustment procedures are utilized for somatic cell counters. These adjustments range from physical adjustments (sample volume, nozzle height) to statistical procedures (slope / intercept adjustments via simple linear regression).

Generally, the manufacturer's recommendations should be followed. It is essential that specific adjustment procedures in each laboratory be documented and enforced.

Acceptable Readings for Calibration Adjustments

The calibration adjustment is valid if the resulting mean percent difference and standard deviation of percent differences are reduced to the point that the acceptance criteria outlined on the page entitled *Auditing of SCC Instruments for Calibration Checks* are met.

Response to Calibration Check Failures

If the instrument fails the calibration check, the condition of the samples should be checked and the reference tables reviewed to ensure that they are reliable. The set should be screened for outliers and the calibration adjustment procedure repeated.

If the instrument fails a second time, it should be checked for other potential problems and repaired. The instrument should be recalibrated using an alternative set of samples.

Alternative Procedures

If the laboratory can demonstrate that the accuracy of an alternative procedure meets or exceeds that of the recommended procedure, the use of an alternative procedure is allowed.

Before implementation, the auditor must review a copy of the alternative procedure, and the laboratory must receive written authorization.

Pilot Sample Check Frequency

Pilot sample checks must be performed on an hourly basis during routine operation of instruments. A pilot sample should also be tested at start-up, when the instrument has been idle or shut down, or when a problem is suspected.

Laboratories that do not retain milk samples until the analysis of an hourly check must run a pilot sample at least every 300 samples during the course of the hour.

Calibration Check Procedure

A new set of pilot samples must be prepared on a weekly basis. This is accomplished by taking a supply of fresh, raw milk or homogenized, whole milk and dividing it into a set of individual sample vials. The SCC range should be between 200,000 and 400,000 cells/ml.

The individual sample vials should be tested several times and the results averaged to determine the "target" values for the set. Ideally, this should be done immediately following the calibration check or adjustment.

During the week, a pilot sample must be warmed but not remain in the water bath for more than 15 minutes after reaching a temperature of 40° Celsius and analyzed as specified during normal operation of the instruments. The instrument results must be compared to the target values.

Acceptable Readings for Calibration Checks

The difference between instrument results and the target value should not exceed 10%.

Response to Calibration Check Failures

If the instrument fails the pilot sample check,

- A second sample should be analyzed to confirm or refute the result.
- If the second sample confirms that there is a discrepancy in the pilot sample result, the instrument should be cleaned, zeroed, and a pilot check performed.
- If the problem continues, the instrument should be shut down and repaired.
- Upon repair and start-up, a pilot check should be performed.

Alternative Procedures

If the laboratory can demonstrate that the accuracy of an alternative procedure meets or exceeds that of the recommended procedure, the use of an alternative procedure is allowed. Examples include:

- The use of direct microscopic cell counts, or
- The alternating between multiple levels (low and high).

Before implementation, the auditor must review a copy of the alternative procedure, and the laboratory must receive written authorization.

Repeatability Check Frequency
Repeatability must be checked on a daily basis. It must also be checked when a problem is suspected.

Calibration Check Procedure
A sample of fresh, raw milk with a SCC of 200,000 to 800,000 cells/ml must be warmed and analyzed at least six times in succession.

Acceptable Readings for Calibration Checks
The average of the readings should be determined, and each sample must be within 7% of that figure.

Response to Calibration Check Failures
If an instrument fails the repeatability test, check to ensure that the sample is in good condition and that the instrument is properly warmed up, and then repeat the procedure.

If the instrument fails the repeatability test again, check the condition of the sample. Once rectified, duplicate the procedure until the repeatability test passes consistently.

Alternative Procedures
If the laboratory can demonstrate that the accuracy of an alternative procedure meets or exceeds that of the recommended procedure, the use of an alternative procedure is allowed. An example would be the use of fewer replicates with increased frequency (i.e. hourly).

Before implementation, the auditor must review a copy of the alternative procedure, and the laboratory must receive written authorization.

Zero Drift Check Frequency

Zero drift must be checked at start up during routine operation of instruments. It must also be checked when pilot sample results are out of tolerance. Drift figures should be documented each time the zero is reset.

Calibration Check Procedure

A distilled water, deionized water, or a detergent solution sample must be warmed and analyzed.

Acceptable Readings for Calibration Checks

The zero drift tolerances must meet or exceed the manufacturer's recommendation for the instrument brand and model number.

Response to Calibration Check Failures

If an instrument fails the zero-drift check, the instrument should be cleaned and the zero-drift checked again.

If the instrument fails the zero-drift check again, the zero value should be reset.

Alternative Procedures

If the laboratory can demonstrate that the accuracy of an alternative procedure meets or exceeds that of the recommended procedure, the use of an alternative procedure is allowed.

Before implementation, the auditor must review a copy of the alternative procedure, and the laboratory must receive written authorization.

Auditing of Records Related to Working Solutions

Records of preparation of key solutions and reagents should be maintained. Of particular importance are records associated with preparation of lots of dye used in somatic cell counters.

Key working solutions include, but are not limited to:

- Dye & buffer solutions
- Rinse solutions
- Other solutions, where applicable

Records should include:

- date prepared
- technician
- lot or batch number of any stock solutions or chemicals
- quantity prepared
- expiration date (if applicable)
- date, time and instrument when batch put into service

The auditor should be able to identify the batch used during the analysis of any routine sample processed in the laboratory.

On-Site Backups

Each laboratory must demonstrate the ability to back up herd and laboratory records using an electronic method and store media on-site.

Off-Site Backups

Each laboratory must demonstrate the ability to back up herd and laboratory records using an electronic method and store media in a secured off-site location or in a cloud-based environment.

Short-Term or Disrupted Operations Plan

Each laboratory must demonstrate a short-term operations plan in the event of disruptions including equipment failure, delayed sample arrival at the respective laboratory, and/or inadequate staffing. The plan should detail the following:

- if the samples are held until the equipment is repaired and conforming with quality certification guidelines.
- analyzed at another laboratory; and/or
- discarded with no results reported.

Further, the plan should detail notification protocols for any delays or non-delivery of sample analysis results.

Disaster Recovery Plan

Each laboratory must demonstrate the ability to restore herd and laboratory records from a variety of hazards such as equipment failures, software viruses, natural disasters, malicious employees, and other occurrences.