

Quality Certification Services, Inc.

Auditing Policies and Procedures

*Effective January 1, 2012
Version 12.0*

The purpose of this manual is to describe the services, rates, and procedures used by Quality Certification Services Inc. (QCS) to audit service providers for the Council on Dairy Cattle Breeding (CDCB).

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QCS Organizational Structure

Code of Regulations

Quality Certification Services Inc. is organized as a corporation in the State of Ohio and is governed according to a *Code of Regulations*, the term used in Ohio as a synonym for bylaws.

Subsidiary of National DHIA

Quality Certification Services Inc. is a wholly owned subsidiary of National DHIA. Quality Certification Services Inc. policy, rates, and procedures are reviewed and approved by the National DHIA Board of Directors. The National DHIA Board of Directors considers recommendations from the QCS Advisory Committee.

QCS Advisory Committee

The eleven-member QCS Advisory Committee is composed of representatives of the following organizations:

1. National DHIA
2. National DHIA
3. National DHIA
4. National DHIA
5. National DHIA
6. National DHIA
7. At-Large Representative
8. At-Large Representative
9. Field Service Advisory Committee (FSAC)
10. Laboratory Advisory Committee (LAC)
11. Processing Center Advisory Committee (PCAC)

Auditors

All audits (on-site and off-site) and data analysis are performed by designated auditors.

1. National DHIA management provides administration of the QCS policies and procedures.
2. The Management of Quality Certification Services Inc. is responsible for the designation of certification status based on reports and findings from the respective QCS-contracted auditor(s).
3. The Manager of Quality Certification Services Inc. provides auditing (both on-site and off-site) of field service affiliates, meter centers, and meter technicians.
4. The QCS-contracted laboratory auditor provides on-site audits of laboratories and a monthly analysis of the 'Samples Unknown' data.
5. The QCS-contracted processing center auditor provides off-site audits of processing centers, monthly administration of the 'Test Herd' program, and periodic analysis of the Standard Transfer Format (STF) compliance.

QCS Advisory Committee

National DHIA Representative

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Field Service Advisory Committee (FSAC) Representative

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Laboratory Advisory Committee (LAC) Representative

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Processing Center Advisory Committee (PCAC) Representative

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QCS Auditors and Support Personnel

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Auditing Rates for Field Services

Initial Certification Audits for Field Service Providers

Quality Certification Services Inc. will perform initial certification audits for field service providers in accordance with the guidelines established by the Council on Dairy Cattle Breeding (CDCB) as described in the *CDCB Auditing Procedures for Field Services Manual*.

Renewal Audits for Field Service Providers

Quality Certification Services Inc. will perform renewal audits for field service providers in accordance with the guidelines established by the Council on Dairy Cattle Breeding (CDCB) as described in the *CDCB Auditing Procedures for Field Services Manual*.

The annual rate for initial certification and renewal is determined by the size of the field service organization. Rates are listed below.

Field services – Biennial on-site audits ^{A, B} and maximum allotted audit hours ^C

A. Annual fee for field service - <75,000 cows	[30 hours] ^C	\$4,050
C. Annual fee for field service - 75,000 – 150,000 cows	[40 hours] ^C	\$4,900
D. Annual fee for field service - 150,000 – 200,000 cows	[50 hours] ^C	\$5,750
E. Annual fee for field service - >200,000 cows	[60 hours] ^C	\$6,600

^A Service providers requiring additional time to meet audit standard submission formats, material preparation, data analysis/review or follow-up for the QC audit process in excess of the allotted audit hours will be subject to time and material charges of \$85.00 per hour.

^B Discretionary on-site audits (either requested by cooperator or required as a result of non-compliance) will be billed for all time and travel expenses. Travel time will be billed at a rate of \$400 per day or \$250 per half-day. Additional audit time will be billed at the rate of \$85.00 per hour.

^C Maximum allotted auditing hours includes, but is not limited to: audit preparation and scheduling; email/telephone exchange and support; creation of digital files (if paper documentation is submitted); data handling, analysis and review; report writing; internal and external review/validation; follow-up; and compliance enforcement.

The number of cows reported as part of the QC audit submission will determine the fee for renewal. Payment is due upon completion of the audit. Certification will not be issued until all audit fees are paid to the auditor by the service provider.

Auditing Rates for Meter Centers & Technicians

Initial Certification Audits for Meter Centers and Meter Technicians

Quality Certification Services Inc. will perform initial certification audits for meter centers and meter technicians in accordance with the guidelines established by the Council on Dairy Cattle Breeding (CDCB) as described in the *CDCB Auditing Procedures for Meter Centers and Technicians Manual*.

Renewal Audits for Meter Centers and Meter Technicians

Quality Certification Services Inc. will perform renewal audits for meter centers in accordance with the guidelines established by the Council on Dairy Cattle Breeding (CDCB) as described in the *CDCB Auditing Procedures for Meter Centers and Technicians Manual*.

Meter Centers and Technicians – Biennial on-site audits ^{A, B}

- A. Annual fee per meter center (includes 1 technician) - with field service audit.....\$800
- B. Annual fee per meter center (includes 1 technician) - not with field service audit.....\$1,100
- C. Annual fee per additional meter technician.....\$100

^A Service providers requiring additional time to meet audit standard submission formats, material preparation, data analysis/review or follow-up for the QC audit process will be subject to time and material charges of \$85.00 per hour.

^B Discretionary on-site audits (either requested by cooperator or required as a result of non-compliance) will be billed for all time and travel expenses. Travel time will be billed at a rate of \$400 per day or \$250 per half-day. Additional audit time will be billed at the rate of \$85.00 per hour.

Payment is due upon completion of the audit. Certification will not be issued until all audit fees are paid to the auditor by the service provider.

Auditing Rates for Laboratories

Initial Certification Audits for Laboratories

Quality Certification Services Inc. will perform initial certification audits for laboratories in accordance with the guidelines established by the Council on Dairy Cattle Breeding (CDCB) as described in the *CDCB Auditing Procedures for Laboratories Manual*.

Renewal Audits for Laboratories

Quality Certification Services Inc. will perform renewal audits for laboratories in accordance with the guidelines established by the Council on Dairy Cattle Breeding (CDCB) as described in the *CDCB Auditing Procedures for Laboratories Manual*.

The annual rate for participation in the ‘Samples Unknown’ program is determined by the total number of components subject to analysis at the rate of \$150 per component per instrument. For example, the annual rate for one instrument certified to analyze for butterfat, protein, and somatic cells is \$450.

Laboratories – Biennial on-site audits ^{A, B}

A. Annual fee	\$2,400
B. Annual ‘Samples Unknown’ analysis fee (per component analyzed)	\$150

^A Service providers requiring additional time to meet audit standard submission formats, material preparation, data analysis/review or follow-up for the QC audit process will be subject to time and material charges of \$85.00 per hour.

^B Discretionary on-site audits (either requested by cooperator or required as a result of non-compliance) will be billed for all time and travel expenses. Travel time will be billed at a rate of \$400 per day or \$250 per half-day. Additional audit time will be billed at the rate of \$85.00 per hour.

Milk urea nitrogen (MUN) analysis via the ‘Samples Unknown’ program is not required for certification and is an optional service provided by QCS.

Payment is due by the last day of the centering period month. Certification will not be issued until all audit fees are paid to the auditor by the service provider.

Auditing Rates for Processing Centers

Initial Certification Audits for Processing Centers

Quality Certification Services Inc. will perform initial certification audits for processing centers in accordance with the guidelines established by the Council on Dairy Cattle Breeding (CDCB) as described in the *CDCB Auditing Procedures for Processing Centers Manual*.

Renewal Audits for Processing Centers

Quality Certification Services Inc. will perform renewal audits for processing centers in accordance with the guidelines established by the Council on Dairy Cattle Breeding (CDCB) as described in the *CDCB Auditing Procedures for Processing Centers Manual*.

Dairy Record Processing Centers – Annual audits ^{A, B}

- A. Annual fee per center for primary software platform\$9,500
- B. Annual fee for second software platform per center\$4,500

^A Service providers requiring additional time to meet audit standard submission formats, material preparation, data analysis/review or follow-up for the QC audit process will be subject to time and material charges of \$85.00 per hour.

^B Discretionary on-site audits (either requested by cooperator or required as a result of non-compliance) will be billed for all time and travel expenses. Travel time will be billed at a rate of \$400 per day or \$250 per half-day. Additional audit time will be billed at the rate of \$85.00 per hour.

Payment is due by the last day of the centering period month. Certification will not be issued until all audit fees are paid to the auditor by the service provider.

Auditing Procedure for Field Services

Quality Certification Services Inc. conducts field service audits as stipulated in the CDCB contract. Below is a summary of the planned routine for the program:

1. The Quality Certification Services Inc. Manager conducts both on-site and off-site field service audits.
2. Approximately 30-60 days prior to the centering period month, the auditor contacts the field service and sends an audit preparation guide that specifies the documents and files needed for the audit. If the audit is to be scheduled on-site, the auditor identifies potential date(s) to be selected for the on-site audit. The field service provider is asked to electronically submit data prior to the audit date for review by the auditor prior to the on-site audit. If the audit is to be conducted off-site, the auditor will specify a mutually agreeable date (not to exceed 30 days from the last day of the audit period) by which all electronic and hard-copy data submission must be completed. A secure FTP site is available for the convenience of all field service providers.
3. During the visit, the auditor reviews the documentation, analyzes the data, and enters the results in a standard field service audit report format. The report describes deficiencies and makes recommendations for improvements.
 - A. In cases where minor deficiencies are identified, the auditor provides instructions for correction and allows the field service the opportunity to address the deficiencies prior to the next audit.
 - B. In cases where the deficiencies are deemed critical to certification, the auditor provides a detailed list of tasks that must be completed before certification will be issued.
4. At the completion of the on-site audit, the auditor reviews the findings to the field service management.
5. Once the Quality Certification Services Inc. Manager has returned to the QCS office, the final report and a cover letter are written that confirms the renewal certification or describes the steps required for certification. The appropriate number of copies are made, bound, and mailed as described in the audit report.
 - A. If certification has been attained and the auditing fees paid, a certificate is mailed to the field service provider.
 - B. If additional documentation is required, the certificate is withheld until the field service has addressed deficiencies as described in the audit report.
6. The off-site audit will be conducted at the QCS office, with a final report, cover letter, and certification notification handled in the same manner as the on-site audit.
7. When the audit process has been completed and certification has been issued, QCS management will update the listing of certified field service providers on the QCS website.

Auditing Procedure for Meter Centers

Quality Certification Services Inc. conducts meter center audits as stipulated in the CDCB contract. Below is a summary of the planned routine for the program:

1. The Quality Certification Services Inc. Manager conducts the meter center audits.
2. Approximately 30-60 days prior to the centering period month, the auditor contacts the meter center and schedules a time for the on-site audit.
3. During the visit, the auditor reviews the operation of the meter center equipment and enters the results in a standard meter center audit report format. The report describes deficiencies and makes recommendations for improvements.
 - A. In cases where minor deficiencies are identified, the auditor provides instructions for correction and allows the meter center the opportunity to address the deficiencies prior to the next audit.
 - B. In cases where the deficiencies are deemed critical to certification, the auditor provides a detailed list of tasks that must be completed before certification will be issued.
4. At the completion of the on-site audit, the auditor reviews the findings of the audit with the meter center personnel and/or manager.
5. Once the Quality Certification Services Inc. Manager has returned to the QCS office, the final report and a cover letter are written that confirms the renewal certification or describes the steps required for certification. The appropriate number of copies are made, bound, and mailed as described in the audit report.
 - A. If certification has been attained and the auditing fees paid, a certificate is mailed to the meter center.
 - B. If additional documentation is required, the certificate is withheld until the meter center has addressed deficiencies as described in the audit report.
6. When the audit process has been completed and certification has been issued, QCS management will update the listing of certified meter centers on the QCS website.

Auditing Procedure for Meter Technicians

Quality Certification Services Inc. conducts meter technician audits as stipulated in the CDCB contract. Below is a summary of the planned routine for the program:

1. The Quality Certification Services Inc. Manager conducts the meter technician audits.
2. Approximately 30-60 days prior to the centering period month, the auditor contacts the meter technician and schedules a time for the on-site audit.
3. During the visit, the auditor reviews the meter technician knowledge and operation of the meter center equipment and enters the results in a standard meter technician audit report format. The report describes deficiencies and makes recommendations for improvements.
 - A. In cases where minor deficiencies are identified, the auditor provides instructions for correction and allows the meter technician the opportunity to address the deficiencies prior to the next audit.
 - B. In cases where the deficiencies are deemed critical to certification, the auditor provides a detailed list of tasks that must be completed before certification will be issued.
4. At the completion of the on-site audit, the auditor reviews the findings of the audit with the meter technician.
5. Once the Quality Certification Services Inc. Manager has returned to the QCS office, the final report and a cover letter are written that confirms the renewal certification or describes the steps required for certification. The appropriate number of copies are made, bound, and mailed as described in the audit report.
 - A. If certification has been attained and the auditing fees paid, a certificate is mailed to the meter technician.
 - B. If additional documentation is required; the certificate is withheld until the meter technician has followed up as described.
6. When the audit process has been completed and certification has been issued, QCS management will update the listing of certified meter technicians on the QCS website.

Auditing Procedure for Laboratories

Quality Certification Services Inc. conducts laboratory audits as stipulated in the CDCB contract. Below is a summary of the planned routine for the program:

1. Under normal circumstances, the laboratory auditor conducts the laboratory audits. Under particular circumstances though, other auditors may be assigned to conduct audits in place of the laboratory auditor.
2. Approximately 60 days prior to the centering period month, the auditor contacts the laboratory and schedules a time for the on-site audit.
3. During the visit, the auditor reviews the operation of the laboratory and enters the results in a standard laboratory audit report format. The report describes deficiencies and makes recommendations for improvements.
 - A. In cases where minor deficiencies are identified, the auditor provides instructions for correction and allows the laboratory the opportunity to address the deficiencies prior to the next audit.
 - B. In cases where the deficiencies are deemed critical to certification, the auditor provides a detailed list of tasks that must be completed before certification will be issued.
4. At the completion of the on-site audit, the auditor reviews the findings of the audit with the laboratory manager.
5. A complete audit report in copy-ready format is then forwarded to the QCS management for review.
6. Once the report has been received, the QCS manager writes a cover letter that confirms the renewal certification or describes the steps required to attain certification. The appropriate number of copies are made, bound, and mailed as described in the audit report.
 - A. If certification has been attained and the auditing fees paid, a certificate is mailed to the laboratory provider.
 - B. If additional documentation is required, the certificate is withheld until the laboratory has addressed deficiencies as described in the audit report.
7. When the audit process has been completed and certification has been issued, QCS management will update the listing of certified laboratories on the QCS website.

Auditing Procedure for the Samples Unknown Program

Quality Certification Services Inc. administers a ‘Samples Unknown’ program as stipulated in the CDCB contract. Below is a summary of the planned routine for the program:

1. On Monday of the second full week of each month (subject to change for holidays, etc.), the ‘Samples Unknown’ supplier sends two duplicate sets of 12 samples to each certified laboratory via one or two-day air shipments. Additional sets are provided to equipment manufacturers and other specific laboratories as deemed necessary.
2. Laboratories are required to analyze the samples using routine operating procedures and submit the results to the ‘Samples Unknown’ website by midnight EST on the Friday following the shipment.
3. After a laboratory has entered or uploaded their data, a ***Batch Entry Confirmation Report*** verifying that the data entered can be printed from the website. The report shows the actual data included.
4. On or by the following Monday, the laboratory auditor downloads the raw ‘Samples Unknown’ data and analyzes it for accuracy and consistency.
5. Once the laboratory auditor has analyzed the data and made any adjustments deemed necessary, the corrected data is uploaded into the ‘Samples Unknown’ website.
6. The laboratory auditor then prompts the web site to email the ***Batch Certification Report*** to the laboratories and submits a summary report to QCS management. The QCS-contracted laboratory auditor will copy QCS management on all communications related to the ‘Samples Unknown’ program.
7. QCS management reviews the summary report and follows up directly with laboratories having machines outside of the CDCB approved tolerances.

In addition to establishing a normal routine for the ‘Samples Unknown’ program, QCS has set the following policies in place as supplements to the program:

1. The website is programmed to disable the data entry function once the deadline has been reached. After that time, all data must be forwarded to the QCS Manager in order to be included in the batch. The laboratory auditor may be copied on this data, but cannot enter late data for a laboratory.
2. Data submitted late will not be included in the batch data. Late data may be accepted if the laboratory contacts the QCS 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 that submits data late more than twice in the previous twelve (12) month period without a valid reason will have its respective certification status changed to provisional.
3. Summaries of the ‘Samples Unknown’ results, including late data entries, will be included in the audit reports and will contribute to the overall pass/fail decision for laboratory certification.
4. Current and historical ***Batch Certification and Comparison Reports*** can also be downloaded directly from the website.

Auditing Procedure for Processing Centers

Quality Certification Services Inc. conducts processing center audits as stipulated in the CDCB contract. Below is a summary of the planned routine for the program:

The processing center auditor conducts the processing center audits.

1. Prior to the centering period month, the auditor sends the processing center a list specifying the documents and files needed for the audit.
2. Once the data has been received, the auditor reviews the documentation, analyzes the data, and enters the results in a standard processing center audit report format. The report describes deficiencies and makes recommendations for improvements.
 - A. In cases where minor deficiencies are identified, the auditor provides instructions for correction and allows the meter center the opportunity to address the deficiencies prior to the next audit.
 - B. In cases where the deficiencies are deemed critical to certification, the auditor provides a detailed list of tasks that must be completed before certification will be issued.
3. At the completion of the off-site audit, the auditor provides a complete audit report in copy-ready format to QCS management for review.
4. Once the report has been received, the QCS manager writes a cover letter that confirms the renewal certification or describes the steps required for certification. The appropriate number of copies are made, bound, and mailed as described in the audit report.
 - A. If certification has been attained and the auditing fees paid, a certificate is mailed to the processing center.
 - B. If additional documentation is required, the certificate is withheld until the processing center has addressed deficiencies as described in the audit report.
5. When the audit process has been completed and certification has been issued, QCS management will update the listing of certified dairy records processing centers on the QCS website.

Auditing Procedure for the Test Herd Program

Quality Certification Services Inc. administers a 'Test Herd' program as stipulated in the CDCB contract. Below is a summary of the planned routine for the program:

1. On a monthly basis, the processing center auditor creates a new set of data for two test herds and distributes the data to the processing centers.
2. Processing centers are required to enter the data using routine operating procedures and process the herds as noted in the corresponding test plans. The results are then submitted to AIPL.
3. Once the data has been entered into an AIPL comparison database and the records are compared, the processing center auditor views the comparison report for individual records from each processing center and performs an analysis.
4. Several times a year the processing center auditor requests Standard Transfer Files for the test herds from the processing centers. The files are comparatively analyzed.
5. The results are summarized and distributed by the processing center auditor as deemed necessary.

Auditing Procedure for the Handling of Complaints

In order to ensure that complaints regarding deficiencies are legitimate and handled consistently, the following procedure has been established:

1. Only complaints submitted in writing and signed by the allegedly damaged party will be investigated.
2. The complaint should accurately describe a violation or deficiency of the *Code of Ethics or Uniform Data Collection Procedures* and provide reasonable cause for the matter to be investigated.
3. Upon receipt of a properly documented complaint, the Quality Certification Services Inc. staff will provide copies of the complaint to all parties involved.
4. The Quality Certification Services Inc. staff will then investigate the complaint in a timely manner and prepare a report of the facts. The report will include a list of recommended sanctions, remedies, and/or deadlines if needed to resolve the complaint.
5. The report will be sent to the all parties involved in the dispute.
6. If any party finds the recommended Quality Certification Services Inc. staff solution unacceptable, the matter will be turned over to the QCS Advisory Committee for deliberation.
7. If any party finds the recommended QCS Advisory Committee solution unacceptable, the matter will be turned over to the CDCB for review.
8. The decision of the CDCB will be considered final.