Council on Dairy Cattle Breeding

Quality Certification Requirements for Genomic Nominators

Latest Review: 2025/12/12

Effective: 2017/12/05

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Revision History

2018/05/30 – Update on the “Performance Metrics for Genotyping Laboratories” section.

2019/02/06 – Time limitation introduced for the approval process.

2019/04/03 – Update on the metric information linked to new fee schedule.

2020/03/24 – Update on Genomic Nominators Application fee and time of payment of annual fee.

2021/01/07 – Update on Service Discontinuation in “Core Requirements for Genomic Nominators section".

2021/03/08 – Update on Suspended Status in “Core Requirements for Genomic Nominators section".

2022/01/27 – Update on AI service fee communication to customers and Nominator collaboration to resolve AI service issues in “Core Requirements for Genomic Nominators section”.

2025/12/12 – Update on timelines, links and certification process. Additionally, included new “Collaborator Information Form” as well as process flow diagram.

Purpose

The guidelines for certification requirements for Genomic Nominators are established to maintain consistent standards and promote reliability across all aspects of the genomic evaluation program. These requirements serve to ensure the accuracy and uniformity of all records included in the system so that the impact of contributed resources and the overall efficiency of the program are maximized. By setting clear expectations for data quality, submission procedures, and compliance, the guidelines help safeguard the integrity of genomic information and support the generation of trustworthy evaluation results that benefit all stakeholders involved.

Background

A Genomic Nominator is a certified organization responsible for submitting and managing genomic data for inclusion into the National Cooperator Database, ensuring the accuracy, quality, and integrity of the data used in CDCB evaluations.

The performance of Genomic Nominators is tracked and assessed through CDCB's quality control system, which includes systematic checks and ongoing performance monitoring conducted by CDCB staff.

To perform effectively in this role, it is essential to have a clear understanding of the responsibilities, tasks, and requirements necessary to meet CDCB's expectations. The primary duties of CDCB Genomic Nominators include:

i) Uploading accurate information for nominated animals into the CDCB system.

ii) Identifying and resolving issues such as sampling or pedigree errors.

iii) Collaborating with laboratories, farms, and other third-party organizations to address issues that may prevent animals from receiving evaluations.

iv) Distributing evaluation results to the appropriate recipients.

v) Collecting the applicable CDCB service fees.

vi) Comply with all CDCB requirements necessary to maintain certified status.

Animal identification and pedigree errors may originate at the farm level. Although genomic testing is a powerful tool for detecting and correcting such errors, it may also introduce novel issues (e.g., sampling the wrong animal, mislabeling samples, or switching samples within the laboratory, etc.). To minimize the occurrence of these errors in the national genetic evaluation program, core requirements and performance metrics— supported by monitoring and quality reporting systems such as the *CDCB Genomic Nominator Report Card*— are essential.

Adherence to the Quality Certification Requirements will be monitored by CDCB Staff, who will conduct reviews and assess performance to determine certification status, as defined below.

Core Requirements for Genomic Nominators

Genomic Nominators Seeking Certification

Genomic Nominator candidates must undergo the CDCB certification process in order to become an Approved CDCB Genomic Nominator. Therefore, a prospective Nominator must complete the following steps[1]:

1. Submit the completed "CDCB Quality Certification for Genomic Nominators Application Form".
2. Sign the Material License Agreement (MLA) provided by CDCB, which defines the rights and obligations associated with data submission and CDCB's use of the submitted data.
3. Provide the CDCB Genomic Nominator Standard Operating Procedures (SOPs) using the designated CDCB template.
4. Pay the non-refundable Genomic Nominator Application Fee of **$1,000** to CDCB at the beginning of the certification process.
5. During the approval process, successfully provide test **Format 1/1G** files for verification by CDCB Staff.
6. Designate personnel who will be granted access to the CDCB file submission tools, web queries, CDCB-related communications, and who will receive initial training from CDCB Staff. This information must be provided using the CDCB Collaborator Information Form, which will be sent via email once the application is accepted.
7. Maintain clear and consistent communication throughout the certification process. The applicant must respond to communications from CDCB within **10 business days** during the application process. If delays are anticipated, the prospective Nominator must notify CDCB in advance to determine the next steps and avoid any penalties.
    7.1. Prospective Nominators who fail to respond to CDCB communications within the **10-business-day** period on three or more occasions during the **two-month** certification period, and who do not provide prior written notice with reasonable justification, may be moved to the end of the certification queue or have their application process terminated at CDCB's discretion.
8. Successfully complete the approval process within **two months** from the date the Genomic Nominator Application fee is received at CDCB.
9. Pay the CDCB Genomic Nominator annual fee of **$1,200**. Newly certified Genomic Nominators must submit payment immediately upon receiving official certification to begin operations. The payment will cover the remainder of the current year, prorated monthly from the date of certification approval. Upon payment confirmation, the Genomic Nominator may commence regular operations.

[1] All application materials should be submitted to cdcb-certification-validation@uscdcb.com.

Certified Genomic Nominators

Once the Nominator has been certified, the following requirements apply.

1. Provide a unique and valid animal identification (ID) for each DNA sample using Format 1G, including sire and dam identification when available. The pedigree of the dam and/or sire should also be provided in Format 1, when available. Genomic Nominators are required to establish a data collection protocol for requesters submitting pedigree, dam and sire information, which must be recorded in Format 1.
   CDCB encourages the use of official identification (ID) systems. The system must guarantee the uniqueness of each ID.
2. Have a unique and valid animal ID associated with each tissue sample sent to the Laboratory. To minimize the risk of an animal being assigned multiple unique animal IDs, the following requirements apply:
   2.1. Genomic Nominators shall use an existing unique animal ID such as AIN, registration number or another approved form of unique ID rather than assigning an additional official ID number to the animal.
   2.2. If an animal does not yet have a unique permanent ID or registration certificate, the Genomic Nominator will advise the customer/animal owner on how to obtain a unique permanent ID for use in sample collection.
3. Report pedigree and genomic conflicts to the customer/animal owner in a timely manner. For a pedigree originating from a breed association, instruct the customer/animal owner to submit pedigree corrections to the appropriate breed association for transmission to CDCB. For herds on a DHI testing program, direct the customer/animal owner to make the corrections within their DHI data.
4. Provide the DNA Laboratory with samples that are reliably identified[2].
5. Provide DNA sample collectors that display the unique animal ID or that are linked to a unique animal ID to permit validation of the animal being sampled at the time of sample collection. For certain collection devices, it may be necessary to add a prefix to the sample ID to ensure its uniqueness within the Genomic Nominator[2].
6. Send (or direct customers to send) DNA samples to Approved CDCB Genotyping Laboratories.
7. Genotypes from non-certified Laboratories that were originally submitted to and accepted by a Recognized National Evaluation Center (NEC) may be accepted pending review and must be submitted in accordance with CDCB specifications.
8. Nominate animals before genotypes are submitted to CDCB.

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[2] For Genomic Nominators not involved in sample collection, these requirements can be met by clearly describing to customers the sample collection procedures to minimize sampling errors.

9. Deliver CDCB genomic evaluations to the appropriate recipients.

   9.1. Nominators must follow all recommendations outlined in the Mark and Logo Guidelines when distributing or publishing results.

   9.2. Failure to comply with these instructions may affect the Nominator's certification status.

   9.3. If CDCB identifies any issue related to the use of marks or logos, the Nominator shall be formally notified and required to correct the issue. Continued or repeated noncompliance may result in suspension or revocation of certification, at the sole discretion of CDCB.

10. Assign the correct fee to the nominated animals in accordance with the CDCB Fee Schedule for Genomic Evaluations Fee.

11. Collect fees on behalf of CDCB and remit them by the due date specified in the monthly invoices. Once charged, fees are non-refundable unless they were incorrectly charged due to an error resulting from CDCB's action.

12. Communicate and collaborate with CDCB and customers on key program requirements, including:

   12.1. Informing customers, at the time of receiving a request for genomic evaluation, that nominated males must enroll in the NAAB Cross Reference Program and pay the designated one-time AI Service fee if the US genomic evaluation is being used to market the bull, including multiple-herd, multiple-owner, syndicate and foreign bulls over 16 months of age (as described in page 6 of the CDCB Service Fee Schedule).

   12.2. Coordinating with CDCB to detect and report cases where there is a violation of these rules.

13. Collaborate closely with CDCB and NAAB to detect and report cases in which the Artificial Insemination (AI) fee (described in page 6 of CDCB Service Fee Schedule) should be paid. In such cases, the Genomic Nominator must cooperate with CDCB to clarify and resolve the situation as soon as possible.

14. Notify CDCB staff within **30 calendar days** of any change in ownership, location, billing address, or of any issue that could interfere with regular operations or affect the quality of service.

15. Comply with the Performance Metrics for Genomic Nominators and work actively to resolve any non-compliance issues reported in monthly report cards.

16. Submit nominations regularly to facilitate performance assessment and maintain certification status.

   16.1. Genomic Nominators must submit a minimum of **one nomination per month** for at least **seven months**, totaling **1,000 nominations per year** (**applicable to new nominators only**), with no gaps exceeding **three months**.

16.2. Failure to nominate animals regularly—without notifying CDCB in advance and providing reasonable explanations—may affect the Nominator's certification status.

17. Actively participate in CDCB's quality control and certification program, which includes:

17.1. Responding to monthly Report Cards on failed metrics within **one week** of issuance (see Performance Metrics for Genomic Nominators).

17.2. Update the SOPs whenever there are changes in Genomic Nominator or CDCB processes. Submit the SOP document annually, prior to the established due date.

17.3. Participate in the Annual Review Call for Genomic Nominators.

17.3.1. Provide all the requested information and review the preliminary information provided in advance to be prepared for the Annual Review call.

17.3.2. Provide any comment, feedback or suggestions that will enhance the service or allow CDCB to improve the service.

17.3.3. Failure to participate in the Annual Review Call without prior notification will be considered a serious violation, as it demonstrates a lack of interest in the collaboration and may affect the certification status of the Nominator in question.

18. **Notify CDCB at least 90 calendar days in advance of any intent to discontinue service**. CDCB strongly recommends transferring animals to another Genomic Nominator to ensure uninterrupted service for customers. If the required transfer information is not provided at the time of discontinuation, CDCB reserves the right to manage the animals in any manner it deems appropriate.

Performance Metrics for Genomic Nominators

CDCB provides a monthly **Genomic Nominator Report Card** containing statistics on observed performance related to the quality of submitted data. Additionally, CDCB provides graphs and statistics in WebConnect under *"Performance Metrics"* within the *"Special Section"*. The monthly Genomic Nominator Report Card includes key performance metrics and flags for non-compliance[3].

Within **one week** of the report's issue date, Genomic Nominators are expected to respond to the Report Card ticket. (As stated in the monthly Report Card: *"Also note that CDCB expects your feedback on each one of these failures within a week")*. The Genomic Nominator's response should address the reasons for the non-compliance(s) and outline the intended actions to improve metric performance. Complete information on QC metrics and thresholds, can be found in the Redmine Portal.

Procedural Flow of the Certification Process

A detailed diagram outlining the systematic procedures for the Genomic Nominator Certification Process is available at https://redmine.uscdcb.com/documents/423.

[3] Failure to meet the required metrics does not automatically result in a violation or de-certification. CDCB will review the Genomic Nominator's Report Card and provide a reasonable timeframe for compliance or justification of unmet standards. If there is no evidence of improvement after the designated timeframe, the CDCB staff will formally notify the Genomic Nominator of the non-compliance.

Certification Process

Genomic Nominators may apply for certification at any time throughout the year. Upon demonstrating the capability to provide data that meets the standards outlined in this document — *Quality Certification Requirements for Genomic Nominators* — they will initially receive conditional certification status. Furthermore, CDCB staff are responsible for identifying any conditions or deficiencies to be addressed, as well as establishing the time frame for corrective action to enable the Genomic Nominator to achieve full certification.

Genomic Nominators that receive conditional certification status will be authorized to begin submitting data to the CDCB database.

Genomic Nominators will remain certified unless CDCB staff designate them as conditional, provisional, or decertified due to systematic failure to meet core requirements.

Certification Status

Certified

A certified Genomic Nominator meets or exceeds the *Quality Certification Requirements for Genomic Nominators.*

Conditional

Conditional certification status may be assigned to both new and existing Genomic Nominators. A new Genomic Nominator may be assigned conditional certification status if CDCB Staff determine that the Genomic Nominator has demonstrated the competence to perform the necessary procedures meeting the *Quality Certification Requirements for Genomic Nominators* but has not yet undergone a comprehensive review.

An existing provisional Genomic Nominator may be assigned conditional certification status if CDCB staff determine that the Nominator has met all conditions and corrected the deficiencies identified in a previous review but has not yet undergone a subsequent review. Alternatively, if a fully certified Genomic Nominator fails to meet the requirements outlined above, it may be demoted to conditional certification status.

Conditional certification status can be granted a maximum of two times within a **five-year period**. If a Genomic Nominator receives conditional certification status for a **third time** within **10 years** (following the first review), or exceeds the **two-time** limit within **five years**, CDCB reserves the right to decertify the Genomic Nominator.

Provisional

A conditionally certified Genomic Nominator that fails to meet the core requirements for Genomic Nominators will be assigned provisional certification status on a temporary basis.

Following further evaluation and review by CDCB staff, a Genomic Nominator with temporary provisional status may maintain that status until an Annual Review Call is conducted. After the call, the Genomic Nominator will either:

i) Be upgraded to conditional certification status if it meets the core requirements for certified Genomic Nominators.
ii) Be decertified if non-compliances persist.

For a provisionally certified Genomic Nominator to regain conditional certification status, the Genomic Nominator must comply with the following requirements:

i) A **three-month** Corrective and Preventive Action (CAPA) plan with measurable outcomes and due dates must be submitted to the CDCB team within **10 business days** of being assigned provisional certification status.
    a. The CAPA plan should include an action plan to, where applicable, increase the number of nominations, implement preventative actions, and outline a comprehensive strategy for improving current services.
    b. Additional corrective actions may include, but are not limited to, the following: providing complete responses to monthly Report Cards within **one week**; maintaining proactive communication with CDCB; and implementing changes to business or marketing approaches, if necessary.
ii) A **monthly** meeting will be held between CDCB and the Genomic Nominator to assess progress against the CAPA plan.

Upon successful completion of the CAPA plan milestones, demonstration of consistent and proactive communication, and fulfillment of the core requirements for Genomic Nominators, the Genomic Nominator will be granted conditional certification status. In the event of limited progress against the CAPA plan, poor communication or an unsuccessful Annual Review, CDCB reserves the right to decertify the Genomic Nominator.

Provisional certification is a temporary status that may be granted **only once** within a **five-year period**. If a Genomic Nominator receives provisional certification a **second time** within **10 years**, or exceeds this **one-time limit** within **five years**, CDCB reserves the right to immediately decertify the Genomic Nominator.

Suspended

CDCB reserves the right to temporarily suspend services at its discretion when immediate action is required and deferral to the Annual Review Call is not feasible. This status applies only in urgent or emergency circumstances. Upon notification of suspension, the Genomic Nominator must promptly contact CDCB to address and resolve the issue that led to the suspension. Failure to do so within one week of the suspension may result in

immediate decertification. A reinstatement fee of **$500** must be paid to resume services.

Decertified

A Genomic Nominator that fails to meet the *Quality Certification Requirements for Genomic Nominators*, even after a period of provisional certification and review, will be decertified by CDCB. A decertified Genomic Nominator will not be permitted to submit data to the CDCB collaborator database. Notification of decertification will be sent by CDCB via email and/or postal mail to the decertified Genomic Nominator.

Decertification will be considered only when:

i) The performance of the Genomic Nominator has fallen below the minimum standards established by CDCB;

ii) The Genomic Nominator fails to take prompt action to return to compliance within the time period specified by CDCB; or

iii) The Genomic Nominator fails to pay fees due to CDCB.

Course of Action upon Decertification:

i) If no appeal process is initiated, the **"in"** directory in SFTP will be disabled **10 business days** after the Notice of Decertification is sent.

ii) The Genomic Nominator must suspend nominations no later than **10 business days** after the Notice of Decertification is issued. Failure to comply will result in full decertification by CDCB, causing the Nominator to lose the opportunity to appeal.

iii) The **"out"** directory in SFTP will be unavailable **90 calendar days** after the Letter of Decertification is sent.

iv) The Genomic Nominator must confirm, at least **10 business days** prior to SFTP shut down, whether it will transfer its animals. Should the Genomic Nominator decline or fail to provide the necessary transfer information, CDCB reserves the right to manage the transfer as it deems appropriate and without restriction. The **10-business-day notice period** falls within the overall **90-calendar-day timeline**.

v) The Genomic Nominator will be ineligible to apply for CDCB Genomic Nominator certification for a period of **two years** from the date of the Final Decertification Letter.

Decertification Appeals

Any Genomic Nominator that is decertified by CDCB has the right to appeal the decision within **10 business days** from the date the Notice of Decertification is issued. However, decertification may only be appealed if the Genomic Nominator was decertified after receiving its first provisional certification status.

The appeal must consist of a written report submitted to the CDCB certification team by the decertified Genomic Nominator. The report must explain why the reviewer's decision should be reconsidered and include a Corrective and Preventive Action (CAPA) plan to

address the identified issues over the following **three months**.

The matter will be reviewed by CDCB within **30 calendar days** of receiving the report, and CDCB's decision will be final. If CDCB upholds the findings of its staff, no additional data will be accepted from the Genomic Nominator after **30 calendar days** from the date CDCB notifies the appealing entity of its decision.

If no appeal is submitted, no further data will be accepted from the Genomic Nominator after the appeal deadline. Genomic Nominators that are no longer certified but are interested in reapplying for certification following the **two-year suspension period**, must meet the same requirements and conditions as new prospective entities seeking to offer certified services.

Review of Genomic Nominators

The performance of Genomic Nominators will be monitored continuously to ensure that service delivery, data processing, and data quality continue to meet the standards outlined in the *Quality Certification Requirements for Genomic Nominators.*

CDCB staff may request submission of electronic or hard-copy data or documents at any time it is considered necessary to determine whether the Genomic Nominator is fulfilling the requirements. The submitted material will be used solely for evaluation purposes and will be assessed based on a pass/fail criteria.

Review Types

Reviews of Genomic Nominators are classified as either mandatory or discretionary:

1. Mandatory Review

   A mandatory review is defined as the Annual Review of a Genomic Nominator. CDCB staff schedule these reviews toward the end of the year and into the beginning of the following year to determine whether the Genomic Nominator remains eligible to submit data to the CDCB collaborator database and to assign the appropriate certification status.

   During the review, CDCB requires:

   i) Submission of an updated Standard Operating Procedures (SOP) document from the previous year.

   ii) Participation in the Annual Review Call.

2. Discretionary Review

   A discretionary review is defined as a review deemed necessary by either CDCB staff or the Genomic Nominator and is scheduled on an **as-needed** basis when:

   i) Changes in facilities, procedures, or staffing have occurred.

   ii) Certain aspects of the Genomic Nominator's performance are out of compliance with *Quality Certification Requirements for Genomic Nominators*.

iii) The Genomic Nominator seeks to attain full certification from a conditional certification status.

iv) The Genomic Nominator would like to move out of provisional certification status; or

v) The Genomic Nominator aspires to regain provisional certification following decertification (typically during the appeal process).

CDCB Staff Responsibilities

The CDCB staff are responsible for ensuring that all certified Genomic Nominators meet the *CDCB Quality Certification Requirements for Genomic Nominators.*

CDCB staff responsibilities include, but are not limited to, the following:

1. Ensuring trained personnel are available to perform the Annual Review.
2. Reviewing the Genomic Nominator's monthly Report Cards, assessing responses to non-compliances and communicating with Genomic Nominators to ensure that data are supplied according to the specifications outlined in the *Quality Certification Requirements for Genomic Nominators.*
3. Assigning a certification status to each Genomic Nominator reviewed.
4. Including the certified Genomic Nominators into the official list of Approved CDCB Genomic Nominators.
5. Submitting the Final Report within **45 calendar days** of the Annual Review Call to the Genomic Nominator, identifying any missing or deficient data or procedure and providing options for addressing the deficiencies.