Council on Dairy Cattle Breeding

Quality Certification Requirements for Genomic Nominators

Latest review: 01/27/2022
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Contents

Revision History

20180530 – Update on the "Performance Metrics for Genotyping Laboratories" section.

20190206 – Time limitation introduced for the approval process.

20190403 – Update on the metric information linked to new fee schedule.

20200324 – Update on Genomic Nominators Application fee and time of payment of annual fee.

20210107 – Update on Service Discontinuation in "Core Requirements for Genomic Nominators section".

20210308 – Update on Suspended Status in "Core Requirements for Genomic Nominators section".

20220127 – Update on AI service fee communication to customers and Nominator collaboration to resolve AI service issues in "Core Requirements for Genomic Nominators section".

Purpose

These requirements serve to ensure the accuracy and uniformity of all records included in the national genomic evaluation program so that the impact of contributed resources and efficiency of the system are maximized.

Background

A nominator is a certified organization that provides and monitors genomic data that is going to the CDCB evaluation system in order to ensure quality of data that is used for CDCB evaluations. Nominators' performance is also recorded and evaluated by CDCB's quality control system. In order to be a successful nominator, it is essential to know the responsibilities, tasks and requirements to satisfy our expectations. Main tasks and responsibilities of CDCB Genomic Nominators are: i) Upload information for nominated animals into the CDCB system; ii) Resolve errors such as sampling errors and pedigree errors; iii) Work with laboratory and farms to resolve problems so animals get evaluations; iv) Distribute the evaluation results to the appropriate recipients; v) Collect the appropriate CDCB service fee.

Animal identification and pedigree errors can occur on the farm. Although genomic testing is a powerful tool for resolving pedigree errors, it may also introduce additional errors (for example, sampling the wrong animal, mislabeling samples, swapping samples within the laboratory, etc.). Core requirements and performance metrics that are supported by available monitoring and quality reporting systems such as the CDCB Genomic Nominator Report Card are needed to help minimize the introduction of such errors into the national genetic evaluation program.

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

Core Requirements for Genomic Nominators

The genomic nominator has to be able to perform the tasks required to submit nomination information to the CDCB database and agree to comply with all the following requirements:

1. Provide the CDCB Quality Certification for Genomic Nominators application form (https://redmine.uscdcb.com/documents/7).
2. Pay the CDCB Genomic Nominator application fee ($1000).
3. Sign a Material License Agreement (MLA) proposed by the CDCB which describes the respective rights and obligations regarding how data are provided to CDCB and how CDCB is allowed to use the data (https://redmine.uscdcb.com/documents/75)
4. Provide CDCB Genomic Nominator Standard Operating Procedures (SOPs) following the template available at https://redmine.uscdcb.com/documents/12.
5. During the approval process, successfully submit test format 1/1G files for verification by the CDCB staff
6. Successfully conclude the approval process within 2 months from the application date.
7. Pay the CDCB Genomic Nominator annual fee ($1000). Newly certified Nominators should pay immediately after receiving the official certification for start operating. This payment will cover the rest of the year, from the time the certification is approved, and the amount will be prorated monthly. After confirmation of payment, the Nominator will be able to start operating regularly. This policy will only affect applications received after the date of implementation (2020-03-24).
8. Provide a unique animal identification (ID) for each DNA sample using Format 1 (https://redmine.uscdcb.com/projects/cdcb-customer-service/wiki/Format_1), including sire and dam if available. A Format 1 for the dam and/or sire should be provided if available and her/his pedigree is not in the CDCB database. Genomic nominators are required to establish a data collection protocol for requesters submitting pedigree, and dam and sire information to be transcribed in the Format 1.
9. Have a unique animal ID associated with each tissue sample sent to the laboratory. To reduce the potential of an animal with more than one unique animal ID:
    a. 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.
    b. If an animal does not have a unique permanent ID or registration certificate yet, the genomic nominator will advise the customer/animal

owner on how to obtain a unique permanent ID for use in sample collection.

10. Report pedigree and genomic conflicts to customer/animal owner in a timely manner. For a pedigree originating from a breed association, direct customer/animal owner to submit pedigree corrections to the appropriate breed association for transmission to the CDCB. For herds on a DHI testing program, direct the customer/animal owner to make the corrections in their DHI data.
11. Provide the DNA laboratory with samples that are reliably identified[1]
12. 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 some collection devices, it may be necessary to add a prefix to the sample ID to make it unique within nominator[1].
13. Send (or direct customers to send) DNA samples to CDCB-certified laboratories. For a list of CDCB-certified laboratories check the CDCB website at: https://redmine.uscdcb.com/projects/cdcb-customer-service/wiki/Approved_CDCB_Genotyping_Laboratories
14. Genotypes from noncertified laboratories that were originally submitted and accepted by another national genomic evaluation system may be acceptable pending review and will be submitted as specified by the CDCB Staff.
15. Nominate animals before genotypes are received by CDCB.
16. Deliver genomic evaluations to customers.
17. Identify the appropriate fee class, collect fees on behalf of CDCB according to the fee structure and herd class supplied by CDCB, and remit fees to CDCB by the due date. Fees, once charged, are non-refundable unless they were wrongly charged due to an error caused CDCB/CDCB Staff.
18. Communicate to 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 sell semen of the animal (as described in page 6 of CDCB Service Fee Schedule).
19. Collaborate closely with CDCB and NAAB to detect and report cases in which the Artificial Insemination fee (described in page 6 of CDCB Service Fee Schedule) should have been paid. In those cases, the Nominator must cooperate and work with the CDCB to clarify and resolve the situation as soon as possible.
20. Notify CDCB staff of changes in ownership, location address, billing address, and any issue that could affect quality of service within 30 days of occurrence.
21. Comply with the Performance Metrics for Genomic Nominators defined in these guidelines. During monthly reviews of the Quality Metrics resolve any non-compliance identified by CDCB Staff.
22. Notify the CDCB 90 days in advance, if the Nominator decides to discontinue the service. We strongly recommend that the Nominator "transfer' their animals to another Nominator/s so the service for current customers will not be affected. In case the Nominator does not provide the information required for the transfer

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

at the time of service interruption; the CDCB has the right to deal with such animals in the manner it deems most appropriate and without any restrictions.

Performance Metrics for Genomic Nominators

The CDCB provides a Genomic Nominator Report Card on a monthly basis with statistics on the observed performance regarding the quality of the submitted data. In addition, CDCB provides graphs and statistics in the "affiliate specific genotype reports" section, in the Lab/Nominator Queries. The monthly Laboratory Report Card has the following performance metrics including a flag for non-compliances[2]: Nominators are expected to report what actions they intend to take to improve results for the metrics with a non-compliance.

Full QC metrics and thresholds information can be found in: https://redmine.uscdcb.com/projects/cdcb-customer-service/wiki/QC_Metrics_for_Genomic_Nominators

Detailed information on procedures for genomic nominators can be found in: https://redmine.uscdcb.com/documents/39

Certification Process

Genomic Nominators can apply for certification at any time throughout the year. Upon demonstration, through review, of the capability to provide data meeting the standards outlined in the *Quality Certification Requirements for Genomic Nominators*, they will initially achieve conditional certification status. Further, the CDCB Staff is responsible for identifying both the conditions or deficiencies to be addressed and the timeframe for action so that the laboratory may achieve full certification.
Genomic Nominators that receive conditional certification status will be authorized to start providing data to the CDCB database.
Genomic Nominators will remain certified unless the CDCB staff renders them decertified or provisional because of systematic failure to meet core requirements.

Certification Status

Conditional

Conditional certification status may be assigned to both new and existing genomic nominators. A new genomic nominator may be assigned conditional status if the CDCB Staff believes that the nominator has demonstrated competency to perform necessary procedures meeting Quality Certification Requirements for Genomic

[2] Failure to comply with the required metrics will not automatically result in de-certification of a genomic nominator. CDCB will evaluate the nominator's report and give a reasonable time for the nominator to comply or justify why the standard could not be achieved. The CDCB staff will formally notify the genomic nominator of the non-compliance if there is no evidence of improvement after the period of time indicated in the non-compliance letter.

Nominators, but has not undergone a comprehensive review. An existing provisional genomic nominator may be assigned conditional status if the CDCB Staff believes that the genomic nominator has met all conditions or corrected the deficiencies outlined as part of a previous review but has not undergone a subsequent review.

Provisional
A previously certified genomic nominator that fails to meet 1 or more aspects of the CDCB guidelines will be deemed as having provisional status. Upon further action and review by the CDCB Staff, the genomic nominator may be:

- Restored to full certification;
- Designated conditional until an annual review is conducted;
- Designated provisional for an additional period of review; or
- Decertified.

Certified
A certified genomic nominator meets or exceeds the Quality Certification Requirements for Genomic nominator.

Suspended
The CDCB has the authority to temporarily suspend service when deemed necessary. This status is reserved for emergency situations that require immediate action and cannot be delayed until the annual review. During this period, the genomic nominator should immediately contact the CDCB to clarify and resolve the situation that caused the suspension. Otherwise, the CDCB will proceed to decertify the nominator in question. The suspended nominator must pay a fine of $500 to resume normal service.

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 the CDCB. A decertified genomic nominator will not be allowed to submit data to the Cooperator database. Notification of the decertification will be sent via email and via mail by CDCB to the decertified genomic nominator.
Decertification will only be considered when:

- The performance of the genomic nominator has fallen below the minimum standards established by CDCB; and
- The genomic nominator does not take prompt action to return to compliance within the time period specified by CDCB.
- The genomic nominator fails to pay fees by due to CDCB.

Decertification Appeals
Any provisional genomic nominator that fails to obtain certification from the CDCB Staff will have the right to appeal that decision to CDCB within 10 business days of receipt of the first notification received. The appeal will consist of a written report that must be submitted to the CDCB CEO by the genomic nominator and must explain why the decision of the reviewer was incorrect.

The matter will be reviewed by CDCB within 30 calendar days of receipt of the report, and CDCB's decision will be final. If CDCB upholds the findings of the CDCB Staff, no more data will be accepted from the genomic nominator after 30 calendar days from the time that CDCB notifies the appealing entity of its decision.
If no appeal is forthcoming, no more data will be accepted from that genomic nominator after the deadline for the appeal. genomic nominators that are no longer certified but wish to reapply for certification must meet the same costs and conditions as a new entity wishing to offer certified services.

Review of Genomic Nominators

Performance of genomic nominators will be monitored continuously to assure that the quality of data provided by the genomic nominator continues to meet the standards outlined in the Quality Certification Requirements for Genomic Nominators. The CDCB Staff may request submission of electronic or hard copy data to determine if the genomic nominator is fulfilling the requirements. The material submitted will be evaluated using pass/fail criteria.

Review Classes

Reviews of genomic nominators are classified as either mandatory or discretionary:

1. A mandatory review is defined as a regularly scheduled review of the genomic nominator. CDCB staff will schedule these reviews towards the end of the year to determine if the nominator is eligible to continue to submit data to the cooperator database.
2. A discretionary review is defined as a review deemed necessary by either the CDCB staff or the genomic nominator and will be scheduled on an as needed basis when:
   2.1. Changes in facilities, procedures, or staffing have occurred;
   2.2. Certain aspects of the nominator's performance are out of compliance with Quality Certification Requirements for Genomic Nominators;
   2.3. The laboratory wishes to attain full certification from a conditional status;
   2.4. The laboratory wishes to regain full certification from a provisional status; or
   2.5. The laboratory wishes to regain provisional certification from a decertified status.

CDCB Staff Responsibilities

The CDCB Staff has the responsibility to ensure that all certified genomic nominators are meeting the CDCB Quality Certification Requirements for genomic nominators.
Specific responsibilities are to:

1. Assure trained staff is available to perform the review.
2. Review the nominator monthly report cards and the nominator replies on deficiencies and communicate with nominators to ensure that data is supplied according to the specifications documented in the Quality Certification Requirements for Genomic Nominators.

3. Designate a certification status for each nominator reviewed.
4. Post certification status of certified nominators on CDCB website.
5. Submit a printed report within 30 days of a review to the genomic nominator and to the CDCB CEO that will identify missing or deficient data and options for addressing the deficiencies prior to expiration of certification.