

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1002 Version: 1.0
APHIS BQMS PROGRAM REVIEW COMMITTEE		Effective Date: 093010

1. PURPOSE

This document provides the method for conducting reviews by the Animal and Plant Health Inspection Service (APHIS) Biotechnology Quality Management System Program (BQMS Program) Review Committee.

2. SCOPE

The provisions of this document apply to the APHIS BQMS Program Review Committee and are limited to the APHIS BQMS Program.

The APHIS BQMS Program Review Committee conducts reviews of

- a) A participant's proposed BQMS.
- b) The ability of suitable auditors and experts with the appropriate competence to perform the audit or assessment in a timely manner.
- c) A participant's assessment results to determine the status of its recognized BQMS.
- d) A participant's request to extend the scope of its recognized BQMS.
- e) A decision to delay a participant's recognition BQMS based on the results of the assessment.

The APHIS BQMS Program Review Committee also reviews the annual surveillance documents of a participant's recognized BQMS.

3. REFERENCES

The following referenced documents are used for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

APHIS BQMS 1115A_form_Review Committee Minutes
APHIS BQMS 1115B_form_Review Committee Minutes
APHIS BQMS 1115_list_Review Committee Members
APHIS BQMS 1410 Procedure Naming Protocol for Audits, Audit Documents, and Participant Documents
BQMS 1410A List Program Identifiers
BQMS 1410B List Auditor Identifiers
APHIS BQMS Confidentiality Form
APHIS BRS Confidential Business Information Training Certificate

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4. DEFINITIONS

For the purposes of this document, the definitions outlined below apply to this document.

- 4.1 Extension of scope: Expanding the specific conformity assessment services for which program recognition is sought or has been acknowledged.

5. RESPONSIBILITIES

- 5.1 The APHIS BQMS Program Manager, or designee, is responsible for:
- a) Preparing materials for reviews,
 - b) Selecting the Committee members for each review,
 - c) Initiating the reviews of new Programs,
 - d) Initiating reviews of audit or assessment results,
 - e) Initiating reviews for extension of scope requests, and
 - f) Relaying the Committee's decisions onto participants.
- 5.2 The APHIS BQMS Program Review Committee is responsible for conducting reviews in a timely manner that are free from conflicts of interest.

6. GENERAL REQUIREMENTS

- 6.1 Reviews are held as needed to facilitate the timely review of applications, audit results, surveillance assessment results, and requests for extension of scope. Reviews should be conducted within 10 business days from receipt.
- 6.2 Reviews can be held by any means necessary (e.g., formal meetings, teleconferences, e-mail, internet meetings, etc.).
- 6.3 Recommendations are made by the Committee when the responsibility for a final decision is assigned by the APHIS BQMS Program.
- 6.4 Where the Committee uses the results of an assessment already performed by another certification body, it has assurance that the other certification body was operating in accordance with the requirements of *ISO/IEC 17021:2006*, or a mutually agreed upon agreement (i.e., Memorandum of Understanding or similar).
- 6.5 A record of each review is maintained.

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7. REVIEW OF REQUESTS FOR SERVICE AND EXTENSION OF SCOPE REQUESTS

7.1 Upon receipt of a request for service or an extension of scope request, the APHIS BQMS Program Manager, or designee, enters the applicable information into *APHIS BQMS 1115A_form*. The form is assigned a 9-digit identifier using the protocol identified in *APHIS BQMS 1410 Procedure*.

NOTE: The Julian date is the date the request for service was received by the APHIS BQMS Program; and the APHIS BQMS Program Manager's assigned 2-digit auditor identifier is used.

7.2 The APHIS BQMS Program Manager selects the Committee members and coordinates the review. A quorum of at least 3 members is used to make decisions.

NOTE: Via Memorandum of Understanding, a representative of a USDA Marketing and Regulatory Program official may participate in the Committee. Example MRP officials may include, but are not limited to: the Agricultural Marketing Service, APHIS Plant Protection and Quarantine, or APHIS Investigative and Enforcement Services.

7.3 Each Committee member should review the request for service or request prior to the review.

7.4 The Committee reviews the participant's BQMS audit/assessment documentation.

7.4.1 The following 5 decisions may be made by the Committee:

- a) *Assign for a desk audit*. The submitted documentation for a participant's BQMS is acceptable and no information is necessary from the participant.
- b) *Assign for a desk audit and request additional information*. The submitted documentation for a participant's BQMS is acceptable; but additional information is necessary from the participant.
- c) *Hold for additional information*. Additional information is necessary from the participant before a decision can be made.
- d) *Approval*. The submitted documentation for a participant's BQMS is acceptable; and no information is necessary from the participant. Revision(s) reflect an approved program; and a desk audit is not necessary for approval.
- e) *Denied*. The participant's BQMS is not acceptable. The application or request for extension of scope can not be accepted.

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7.5 The APHIS BQMS Program Manager, or designee, notifies the participant of the decision made by the Committee as soon as possible after the review. Notification may be made by any method; and a record is maintained.

7.6 If additional information is necessary, then the APHIS BQMS Program Manager is responsible for coordinating the follow-up. Committee members review the information once it is received. Any follow-up decisions made by the Committee are recorded; and the participant is notified.

8. REVIEW OF AUDIT OR ASSESSMENT RESULTS

8.1 Upon receipt of the audit report, the APHIS BQMS Program Manager, or designee, enters the applicable information into *APHIS BQMS 1115B_Form*.
NOTE: The form is assigned the 9-digit audit identifier that was assigned by the auditor.

8.2 The APHIS BQMS Program Manager selects the Committee members and coordinates the review. A quorum of at least 3 members is used to make decisions.

8.3 Each member should review the audit report prior to the review.

8.4 Audit reports are evaluated to verify that non-conformances are applicable, within the scope of the program, and accurate.

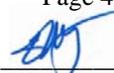
8.5 The Committee must reach a majority consensus before a decision can be made. The Committee may make decisions regarding the program's recognition status, including delay, as outlined in *APHIS BQMS Program Procedure 1000*. Additionally, the Committee may decide to hold the decision until additional information is submitted.

8.6 If program recognition is granted, the Committee schedules the anticipated surveillance assessment of the participant's program.

8.7 If an extension or reduction of scope is acknowledged, the Committee revises the plan for surveillance assessments of the participant's program, including whether additional on-site audit may be necessary.

8.8 The APHIS BQMS Program Manager, or designee, notifies the participant of the decision made by the Committee as soon as possible after the review. Notification may be by any method; and a record is maintained.

8.9 If additional information is necessary, then the APHIS BQMS Program Manager, or designee, is responsible for coordinating the follow-up. Committee members review the



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information once it is received. Any follow-up decisions made by the Committee are recorded and the participant is notified.

9. PROGRAM REVIEW COMMITTEE MEMBERS

- 9.1 Members are selected from *APHIS BQMS 1115_List* with consideration given to experience and background as they pertain to the program(s) being reviewed.
- 9.2 Members must act objectively and be free from any undue commercial, financial, and other pressures that could compromise impartiality. At no time shall a member participate in a review where he/she has a conflict of interest.
- 9.3 Members may conduct assessments or provide consultation. However, at no time shall a member participate in a review where he/she has conducted the assessment as an auditor or provided consultation to the participant within the previous 2 years.

NOTE: APHIS BRS officials may provide consultation. In the event an APHIS BRS official has provided consultation, this official must remove himself/herself from the Committee and designate another official to participate on the Committee.

- 9.4 Members must notify the APHIS BQMS Program Manager of any conflicts of interest that may occur.
- 9.5 Each member must have a signed APHIS BRS CAB *Conflict-of-Interest and Confidentiality Statement* on file prior to participating on a review.

10. RECORDS

The following records related to the APHIS BQMS Program Review Committee are maintained:

- a) A signed *APHIS BRS CAB Conflict-of-Interest and Confidentiality Statement* for each member.
- b) A list of eligible APHIS BQMS Program Review Committee members. This list is maintained using *APHIS BQMS 1115 List*.
- c) A record of each review. Reviews are documented on the appropriate form (*BQMS 1115A Form* or *BQMS 1115B Form*). The record is maintained in the participant's folder. The file naming protocol in *BQMS 1410 Procedure* should be followed. The calendar date is the date that the review was conducted.
- d) A record of the notification to the participant regarding the Committee's decision. The record is maintained in the participant's folder. The file naming protocol in *BQMS 1410 Procedure* should be followed.