

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1000 Version: 1.0
APHIS BQMS PROGRAM GENERAL ADMINISTRATIVE PROCEDURE		Effective Date: 093010

1. PURPOSE

This document outlines the responsibilities and requirements for services provided under the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) Biotechnology Quality Management System Program (BQMS Program). The APHIS BQMS Program is designed to provide independent verification that processes and procedures are clearly defined and effectively implemented by an APHIS BQMS Program participant. The APHIS BQMS Program is available to organizations who voluntarily seek third-party verification of their established Biotechnology Quality Management System (BQMS).

The BQMS Program is provided by the USDA APHIS Biotechnology Regulatory Services (BRS), Regulatory Operations Program (ROP) Compliance Assistance Branch (CAB) (hereby referenced as CAB) as detailed in this procedure.

2. SCOPE

The provisions of this document apply to participants of the BQMS Program and APHIS officials providing oversight of the BQMS Program.

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.

1001 BQMS Audit Standard
ISO 19011:2002 Guidelines for quality and/or environmental management systems auditing
2000 BQMS Audit Procedure

4. DEFINITIONS

- 4.1 Participant—an entity that has submitted a *Letter for Voluntary Verification* to APHIS for independent verification that their established quality management system conforms to the requirements within the APHIS BQMS Audit Standard.
- 4.2 Significant changes—changes in any aspect of status or operation to the participant’s BQMS described in 18.2 of this document.
- 4.3 Conformity assessment— demonstration that specified requirements relating to a product, process, system, person or body are fulfilled.

 <p>Biotechnology Regulatory Services</p>	<p>Animal and Plant Health Inspection Service Biotechnology Regulatory Services</p>	<p>Document Control #: 1000 Version: 1.0</p>
<p>APHIS BQMS PROGRAM GENERAL ADMINISTRATIVE PROCEDURE</p>		<p>Effective Date: 093010</p>

4.4 Conformance/non-conformance—see Section 10.2 of this document.

5. RESPONSIBILITIES

5.1 Participants must meet applicable requirements outlined in this document.

5.2 Participants must inform the APHIS BQMS Program, without delay, of significant changes (as described in Section 18.2 of this document) relevant to program recognition.

5.3 The APHIS BQMS Program must meet applicable requirements outlined in this document.

5.4 All conformity assessment bodies and auditors providing audit services to CAB must meet all applicable requirements outlined in this document.

5.5 The APHIS BQMS Program conducts or arranges for audits in accordance with *ISO 19011:2002 Section 6 Audit Activities*. Personnel within CAB consult with participants regarding the development, implementation, and maintenance of a BQMS. Personnel that provide management consultancy may not participate on third-party audit teams for participants seeking voluntary program recognition. Audit documentation is kept by CAB in an electronic format. *Reference: 2000 BQMS Audit Procedure.*

5.6 The APHIS BQMS Program provides due notice to current and potential participants of any changes to its requirements, and verifies that participants carry out necessary adjustments.

5. CONTACT INFORMATION

Edward M. Jhee, Ph.D
Chief, Compliance Assistance Branch
Acting APHIS BQMS Program Manager
USDA APHIS BRS
4700 River Road, Unit 91
Riverdale, MD 20737
Phone: 301-734-6356
Fax: 301-734-8910
Email: BRS.BQMS@aphis.usda.gov

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1000 Version: 1.0
APHIS BQMS PROGRAM GENERAL ADMINISTRATIVE PROCEDURE		Effective Date: 093010

6. REQUEST FOR VERIFICATION SERVICE

6.1 Participants must submit a request for verification service (third party audit) to the APHIS BQMS Program Manager (see Contact Information in Section 5, above). To submit a request, the participant must complete and submit the documents outlined in Section 6.1.1, 6.1.2, and 6.1.3.

6.1.1 ***Letter for Voluntary Verification.*** This letter must be mailed, faxed or emailed to APHIS BRS CAB (see contact information in Section 5).

This letter should explicitly request verification services for the APHIS BQMS Program. The letter should include the following, as applicable:

- a) A clearly defined, requested scope of the participant's BQMS;
- b) General information concerning the participant such as its activities, human and technical resources, and its relationships in a larger corporate entity, if any;
- c) Information concerning all outsourced processes used by the participant that will affect the program; and
- d) Addresses of all physical location(s) to be covered by the scope of the participant's BQMS.

6.1.2 ***Quality Manual.*** This document should describe how the participant has met the requirements of the APHIS BQMS Audit Standard.

6.1.3 ***Required Procedures.*** These include the participant's program documentation. These procedures include quality management procedures and standard operating procedures required by the APHIS BQMS Audit Standard.

NOTE: Documents considered Confidential Business Information (CBI) must be marked as containing CBI and accompanied by a documented CBI Justification. It is not necessary to submit CBI-deleted copies of documents.

NOTE: The BQMS Program requests electronic or hard-copies of the participant's quality manual and required procedures for adequate desk audit review and preparation for the on-site audit. Receipt and review of electronic or hard-copy documents may expedite the on-site audit process.

NOTE: The ***Letter for Voluntary Verification*** will be retained on-file by CAB. The quality manual and all other supporting documentation will be returned to the participant at the conclusion of the third-party audit (see Section 8 of this document).

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1000 Version: 1.0
APHIS BQMS PROGRAM GENERAL ADMINISTRATIVE PROCEDURE		Effective Date: 093010

6.2 The participant may withdraw from the request process at any time. Participants are responsible for notifying CAB prior to withdrawing from the request process.

7. RECEIVING REQUESTS FOR VERIFICATION SERVICE

7.1 The APHIS BQMS Program notifies the participant upon receiving the Request for Service within ten (10) business days of receipt of the submitted documentation for the Request for Service.

7.2 The APHIS BQMS Program coordinates the selection of a qualified auditor for the BQMS Program with the participant within fifteen (15) business days of receipt of the submitted documentation.

7.2 The APHIS BQMS Program notifies and coordinates the BQMS Program Review Committee regarding the Request for Service within fifteen (15) business days of receipt of the submitted documentation.

7.3 The BQMS Program Review Committee determines if the participant has provided adequate information in the Request for Service to proceed with a desk (stage 1) audit. *Reference: 1002 BQMS Program Review Committee.*

7.4 If the submitted request is inadequate, the APHIS BQMS Program contacts the participant to request the additional documentation. The request for service is withheld from further processing until the necessary documentation is received.

7.5 Once the request for service is complete, the APHIS BQMS Program forwards the request for service to the qualified auditor. *Reference: 2000 BQMS Audit Procedure.*

7.6 The APHIS BQMS Program notifies the participant within ten (10) business days of the Program Review Committee's decision to proceed with a desk audit. The participant may submit written objections regarding the auditor (see Section 26 of this Procedure). Written objections must be submitted to the APHIS BQMS Program and be received within ten (10) business days after notification of assigned auditor.

8. DESK AUDIT

8.1 The participant may choose to forego a desk audit. This request must be submitted in writing to the APHIS BQMS Program. However, appropriate documents must be submitted to the APHIS BQMS Program for the third-party auditor to develop an appropriate audit plan for the on-site audit (Section 9).

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1000 Version: 1.0
APHIS BQMS PROGRAM GENERAL ADMINISTRATIVE PROCEDURE		Effective Date: 093010

8.2 The auditor conducts a desk audit of the participant's program documentation to ensure that all program requirements, as outlined in the APHIS BQMS Audit Standard, are fully addressed. The auditor uses a BQMS audit checklist to conduct the desk audit.

8.2.1 Upon completion of the desk audit, if the program documentation is adequate, the auditor notifies the APHIS BQMS Program within ten (10) business days that the initial on-site audit may be scheduled.

8.2.2 If the program documentation requires clarification or additional information, the auditor obtains the clarification or additional information. Once the program documentation is adequate and the majority of the program requirements are met, the auditor notifies the APHIS BQMS Program that the initial on-site audit may be scheduled.

8.2.3 If the participant's program documentation does not meet the majority of the program requirements or if the auditor identifies that the participant would not pass the initial on-site audit, then the auditor prepares and submits a desk audit summary to the APHIS BQMS Program. This summary is submitted to the APHIS BQMS Program. The APHIS BQMS Program sends a letter within ten (10) business days to the participant discussing the action that the participant must take before continuing the audit process. *Reference: 2000 BQMS Audit Procedure.*

9. ON-SITE AUDIT

9.1 The APHIS BQMS Program appoints the audit team to conduct the on-site audit after dialogue with the participant. The audit team consists of auditor(s) and technical expert(s). The size and composition of the audit team is determined in accordance to *ISO 19011:2002 Section 6 Audit Activities*. After the audit team is appointed, the program documentation is forwarded to the lead auditor, if necessary.

NOTE: the technical expert's primary role is to ensure the audit adheres to the scope of the participant's BQMS.

9.2 The APHIS BQMS Program notifies the participant of the assigned audit team. The participant may submit written objections regarding any team member(s). Written objections must be submitted to the APHIS BQMS Program and be received within ten (10) business days after notification of audit team members.

9.3 The APHIS BQMS Program, the lead auditor, and the participant establish and agree upon the scope of the audit plan and date(s).

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1000 Version: 1.0
APHIS BQMS PROGRAM GENERAL ADMINISTRATIVE PROCEDURE		Effective Date: 093010

- 9.4 Once the date and schedule is arranged between the participant and the audit team, the audit team leader prepares an audit plan. The audit plan is submitted to the participant at least five (5) days prior to the on-site audit.
- 9.5 The on-site audit is conducted in accordance to *ISO 19011:2002 Section 6 Audit Activities*. The objective of an on-site audit is to verify the participant's conformance to the audit criteria.
- 9.6 The on-site audit is conducted at the premises of the participant from which one or more key activities are performed. Where relevant, the on-site audit includes other selected locations where the participant operates, to gather objective evidence that the participant is competent and conforms to the requirements of the APHIS BQMS Audit Standard. Additionally, the audit team may interview a representative number of staff (sample) of the participant to gather objective evidence, which may be obtained through telephone or other means of communication.

NOTE: When the audit team interviews representatives of the participant, the participant's quality management representative, or designee, should be present during the interview.

10. AUDIT FINDINGS AND AUDIT REPORT

- 10.1 All audit findings, including identified non-conformances and continuous improvement points are discussed with the participant at the conclusion of the on-site audit. If the audit team cannot reach a conclusion about an audit finding, the audit team refers to the APHIS BQMS Program Manager, or designee, for clarification.
- 10.2 Audit findings may consist of the following:
- a) *Major non-conformance:* A non-conformance that compromises the integrity of the participant's BQMS to the extent that BQMS Program recognition should be denied, delayed, or withdrawn until corrective action is completed. Any absence or complete breakdown of a BQMS requirement is considered a major non-conformance.
 - b) *Minor non-conformance:* A non-conformance that does not compromise the integrity of the participant's BQMS. Isolated incidences of non-conformance are considered a minor non-conformance. Minor non-conformances not corrected or addressed in a timely manner may be upgraded to a major non-conformance.
 - c) *Continuous improvement point (CIP):* Observations or areas identified as opportunities for improvement. Although not identified as non-conformances, CIPs have the potential to become non-conformances if not corrected or addressed.

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1000 Version: 1.0
APHIS BQMS PROGRAM GENERAL ADMINISTRATIVE PROCEDURE		Effective Date: 093010

- 10.3 The audit findings, *excluding* CIPs, are outlined in the audit report, which is submitted to the participant. A qualified third-party BQMS auditor is responsible for the content of the audit report.
- 10.4 CIPs are provided in writing to the participant during the closing meeting and are *not* outlined in the audit report.
- 10.5 The final audit report is submitted to the APHIS BQMS Program by the participant for program recognition and further review by the BQMS Program Review Committee, as necessary.

11. CORRECTING IDENTIFIED NON-CONFORMANCES

- 11.1 Participants must address all identified non-conformances and respond to all requests for corrective actions¹ and corrections, as applicable, within the time frame specified in the audit report.
- 11.2 Participants must identify the cause(s) of the non-conformance, determine the necessary corrective action, and implement the corrective actions as specified on the corrective action report. Written corrective action responses must be submitted in hard copy or electronic form to the auditor.
- 11.3 After the corrective actions have been submitted and accepted by the auditor, the auditor submits the final audit report to the participant.
- 11.4 The following actions must be taken by the participant, when applicable:
- a) *Corrective Action*: Action to eliminate the cause of a detected non-conformance of the organization's BQMS. Corrective action is taken to prevent recurrence.
 - b) *Correction*: Action to eliminate a detected non-conformance of the organization's BQMS. Correction does not address the cause of the non-conformance but rather the specific non-conforming process and/or outcome.
 - c) *Preventive Action*: Action to eliminate the cause of a potential non-conformance of the organization's BQMS. Preventive action is taken to prevent occurrence.

12. CORRECTIVE ACTION AUDIT

- 12.1 The audit team leader conducts a corrective action audit to ensure that the participant's responses are sufficient in addressing the non-conformance(s) to their BQMS. If the responses are found not to be sufficient, further information is requested. Evidence of

¹ The definitions of "corrective action" and "correction" apply to the participant's BQMS.

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1000 Version: 1.0
APHIS BQMS PROGRAM GENERAL ADMINISTRATIVE PROCEDURE		Effective Date: 093010

effective implementation of actions taken may be requested. Corrective action audits are normally conducted via a document review. However, an on-site corrective action audit may be conducted to verify effective implementation of the corrective actions. Corrective action audits and any other post on-site audit activities are conducted in accordance to *ISO 19011:2002 Section 6 Audit Activities*.

- 12.2 The findings of the corrective action audit are outlined in an audit report. The report is submitted by the participant to the APHIS BQMS Program for final review and disposition. The APHIS BQMS Program has the discretion to seek clarification from the audit team and/or the participant if necessary.

13. PROGRAM RECOGNITION

- 13.1 Program recognition is based upon the findings and the recommendations of the audit team. The recognition is issued for three (3) years. The APHIS BQMS Program Review Committee makes the final recommendation regarding recognition status. APHIS BRS makes the final decision regarding recognition status.

- 13.2 Program recognition status may be one of the following:

- a) *Full Program Recognition*: No non-conformances were identified during the audit. No actions are necessary by the participant.
- b) *Full Program Recognition with Conditions*: Non-conformances were identified during the audit. Participants must submit corrective actions and corrections as applicable within the time frame specified in the audit report. Additional desk audits and/or on-site audits may be conducted at the participant's expense. Full Program Recognition with Conditions may be changed to Full Program Recognition once non-conformances have been cleared by the third-party auditor and validated by the APHIS BQMS Program.
- c) *Delayed Program Recognition*: Delayed program recognition may be issued prior to the initial program recognition for any of the following reasons:
 1. Failure to adequately address a APHIS BQMS Audit Standard requirement resulting in a major non-conformance.
 2. Failure to demonstrate capability to meet a APHIS BQMS Audit Standard requirement resulting in a major non-conformance.
 3. Finding of objective evidence of a major non-conformance within the scope of the BQMS.
 4. An accumulation of minor non-conformances that result in the assignment of a major non-conformance for the BQMS.
 5. Presenting false or misleading information to any USDA official or an auditor.

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1000 Version: 1.0
APHIS BQMS PROGRAM GENERAL ADMINISTRATIVE PROCEDURE		Effective Date: 093010

6. Denying access to participant's facilities and records within the scope of the BQMS.

Participants must submit corrective actions and corrections to the auditor, as applicable, to address any identified non-conformances before full program recognition may be issued. Additional desk audits and/or on-site audits may be conducted at the participant's expense.

- 13.3 Upon reaching a decision, the APHIS BQMS Program returns to the participant the audit report and any additional documentation that is the property of the participant. The audit report includes the "Notification of Audit Results" section, which details the approval status and any terms and conditions as appropriate.

14. PROGRAM DELAYED RECOGNITION

- 14.1 Program delay is the temporary delay of a participant's recognized BQMS on the official listing (on the APHIS BRS website), or a portion of it, pending corrective action by the participant or formal program withdrawal.
- 14.2 The APHIS BQMS Program makes the final decision regarding program recognition delay. When appropriate, the APHIS BQMS Program Review Committee may make the recommendation regarding program delay, in accordance to APHIS BQMS Program Recognition Procedure found in *1002 BQMS Program Review Committee*.
- 14.3 Program delay may occur for any of the following reasons:
- a) Failure to adequately address any BQMS requirement.
 - b) Failure to demonstrate capability to meet any BQMS requirement.
 - c) Failure to follow the participant's recognized BQMS.
 - d) Failure to maintain the participant's recognized BQMS.
 - e) Failure to provide corrective actions and correction as applicable in the timeframe specified.
 - f) Persistently failing to meet the requirements of the program or to abide by APHIS BQMS Program policies and procedures.
 - g) Implementing significant changes to an approved BQMS without prior written notification to and approval by the APHIS BQMS Program (see section 18.2 of this document).

NOTE: The participant may request delay.

- 14.4 Upon reaching a decision, the APHIS BQMS Program notifies the participant in writing of the delay and the details of actions required to achieve full recognition. The details of actions do not include specific remedies.

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1000 Version: 1.0
APHIS BQMS PROGRAM GENERAL ADMINISTRATIVE PROCEDURE		Effective Date: 093010

- 14.5 The official listing of recognized participants on the applicable APHIS BRS website is updated to reflect the status of the participant's program.
- 14.6 Recurring delay of a participant's program recognition may result in program withdrawal, or a reduction in the scope of the approval to exclude those parts where the participant has persistently failed to meet the requirements of the APHIS BQMS Program.

15. RECOGNITION OF A DELAYED PROGRAM

- 15.1 Final decisions regarding recognition of a delayed program is at the discretion of the APHIS BQMS Program. When appropriate, the APHIS BQMS Program Review Committee may make the final decision regarding recognition, in accordance with *1002 BQMS Program Review Committee*.
- 15.1.1 A program delayed due to any of the reasons in 14.3 is recognized immediately upon receipt of appropriate corrective actions and corrections, as applicable. Additional desk audits and/or on-site audits may be conducted at the participant's expense.

16. PROGRAM WITHDRAWAL

- 16.1 Program withdrawal is the removal of a participant's recognized BQMS, or a portion of it. Partial withdrawal may apply where a participant is approved for multiple scopes that may be treated individually for approved purposes.

NOTE: Permanent withdrawal may apply if a participant deliberately used program recognition in a manner as to bring APHIS into disrepute. APHIS BRS will not provide service to the participant during the timeframe that the permanent withdrawal is in effect.

- 16.2 The participant may request withdrawal from the BQMS Program.
- 16.3 The quality management representative (QMR) of the participant contacts, in writing, the BQMS Program indicating withdrawal from the program.
- 16.4 The BQMS Program communicates to the BQMS Program Review Committee the withdrawal of the participant.
- 16.5 The official listing on the APHIS BRS website is updated to reflect the status of the participant's program. Reference to the participant's program is removed from the official listing after a period of 60 days.

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1000 Version: 1.0
APHIS BQMS PROGRAM GENERAL ADMINISTRATIVE PROCEDURE		Effective Date: 093010

17. REINSTATEMENT OF A WITHDRAWN PROGRAM

- 17.1 Final decisions regarding reinstatement of a withdrawn program is at the discretion of the APHIS BQMS Program. When appropriate, and for programs that are in permanent withdrawal status, the BQMS Program Review Committee may make the final decision regarding reinstatement, in accordance with *1002 BQMS Program Review Committee*.
- 17.2 Following withdrawal, reinstatement may be granted only after the participant has successfully completed an onsite audit. In addition:
- 17.2.1 A program withdrawn due to the audit findings must provide corrective actions and correction, as applicable, which specifically address the audit findings that resulted in the program withdrawal.
- 17.2.2 A program withdrawn due to deliberate misrepresentation must provide corrective actions and correction, as applicable, which specifically address the deliberate misrepresentation.
- 17.2.3 A program withdrawn due to the denial of access must provide access.

18. MAINTAINING PROGRAMS

- 18.1 Participants are required to maintain their BQMS as described in their program documentation.
- 18.2 Any significant changes in any aspect of status or operation to the participant's recognized BQMS, which would impact the scope of the officially recognized BQMS, must be submitted in writing to the APHIS BQMS Program. Such changes may include the following:
- a) Legal, commercial, ownership, or organizational status;
 - b) Organization, BQMS top management, and key personnel;
 - c) Main policies;
 - d) Resources and premises;
 - e) Scope of BQMS; and
 - f) Other matters that may affect the ability of the participant to fulfill requirements for the BQMS.

Depending on the nature and extent of the changes, the APHIS BQMS Program Manager may require a complete or partial on-site audit of the program prior to recognition. In situations where an additional on-site audit is required, a new letter of recognition is issued by APHIS BRS for an appropriate time period based on the findings of the audit.

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1000 Version: 1.0
APHIS BQMS PROGRAM GENERAL ADMINISTRATIVE PROCEDURE		Effective Date: 093010

19. SURVEILLANCE

- 19.1 All participants that have voluntarily adopted a BQMS and have received recognition for the development and implementation of a BQMS will receive acknowledgement for their participation in the BQMS Program for a period of three years subject to the conditions of this Section.
- 19.2 Participants of the BQMS Program must voluntarily participate in third-party surveillance reviews on an annual basis to maintain recognition by the APHIS BQMS Program. The surveillance reviews for year 2 and year 3 of program recognition may include, but is not limited to:
- a) Results of internal audit (as specified in Section 8.2.1 of the BQMS Audit Standard)
 - b) Management review meeting(s);
 - c) Review of Clause 7 processes and procedures; and
 - d) The status of corrective and preventive actions for the participant's BQMS (as they relate to Sections 8.4.2 and 8.3 of the BQMS Audit Standard).

Surveillance audit plans will be coordinated with the voluntary participants.

NOTE: Surveillance reviews will typically be conducted on or before the anniversary date of initial recognition.

20. EXTENSION OF SCOPE

- 20.1 A participant with a recognized BQMS may extend the scope of their program at any time by submitting a Request for Service to the APHIS BQMS Program Manager (as described in Section 6 of this document). When a request is received, the APHIS BQMS Program Review Committee undertakes the necessary activities to determine whether or not the extension of scope may require additional verification. These activities are outlined in Section 8 through 15 of this Procedure. The APHIS BQMS Program Review Committee may make the final acceptance of an extension in scope and confer full program recognition, in accordance to APHIS BQMS Program Procedure 1002.

21. REDUCTION IN SCOPE

- 21.1 Participants with a recognized BQMS may reduce the scope of their programs at any time by submitting a written notice to the APHIS BQMS Program Manager. Upon receipt and review by the APHIS BQMS Program Review Committee, the official listing is updated on the APHIS BRS website to reflect the reduced scope, when applicable.

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1000 Version: 1.0
APHIS BQMS PROGRAM GENERAL ADMINISTRATIVE PROCEDURE		Effective Date: 093010

22. CANCELLATION

- 22.1 Participants with a recognized BQMS may cancel service at any time by submitting a written notification to the APHIS BQMS Program Manager. When applicable, participants who cancel service are removed from the listing on the APHIS BQMS Program website.

Participants who cancel service must resubmit a request for service to regain full program recognition. When a request for service is received, the APHIS BQMS Program undertakes the necessary activities, as outlined in Sections 8 through Section 15 of this Procedure before program recognition may be acknowledged.

23. REFERENCE TO FULL BQMS PROGRAM RECOGNITION

- 23.1 Participants with a recognized BQMS may make reference to their full program recognition in the APHIS BQMS Program in communication media, such as the internet, documents, brochures, or advertising.
- 23.2 Participants must ensure that references to BQMS participation are not misleading or ambiguous.
- 23.3 If a recognized program is cancelled, the participant must discontinue its use of all communication media that contains any reference to the recognized BQMS.
- 23.4 The following statement will be used by APHIS to recognize a participant for full BQMS Program recognition:

“The following organizations have voluntarily established a Biotechnology Quality Management System (BQMS) to manage their domestic research and development of regulated genetically-engineered organisms. Each organization’s BQMS has been verified by independent third-party audits as conforming to the USDA APHIS BQMS Program audit standard.”

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1000 Version: 1.0
APHIS BQMS PROGRAM GENERAL ADMINISTRATIVE PROCEDURE		Effective Date: 093010

Example table from the APHIS BRS website listing organizations that receive recognition for full participation in the BQMS Program:

Organization	Scope of BQMS
Organization A	Regulatory compliance monitoring of field trials regulated by 7 CFR part 340
University A	Interstate movement, importation and environmental release of regulated genetically engineered organisms under 7 CFR part 340
Organization B	Management and oversight of activities associated with the introduction of regulated genetically engineered organisms.

http://www.aphis.usda.gov/biotechnology/news_bqms_orgpart.shtml

24. APPEALS

- 24.1 An appeal is a request from the participant for reconsideration of any adverse audit findings, assessment findings, or decisions issued by the APHIS BQMS Program related to the participant's program. *Reference: 1445 BQMS Appeals and Complaints.*
- 24.2 Participants have the right to appeal any adverse audit findings, assessment findings, or decisions issued by the APHIS BQMS Program. (Refer to Section 26 of this document for Objections of Audit Team Members.)
- 24.3 Appeals must be submitted in writing to the APHIS BQMS Program within 30 days of the date of receipt of the official report or letter rendering the findings or decisions.
- 24.4 Appeals must include:
- a) The basis for the appeal, and
 - b) The requested alternative decision or actions.
- 24.5 The APHIS BQMS Program reviews any appeal and notifies the participant of the final decision within 30 business days from receipt of the appeal. If the final decision cannot be determined within this timeframe, the participant is provided with a progress report.
- 24.6 Delays and/or denied approvals remain in effect pending the outcome of the appeal.

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1000 Version: 1.0
APHIS BQMS PROGRAM GENERAL ADMINISTRATIVE PROCEDURE		Effective Date: 093010

25. COMPLAINTS

- 25.1 A complaint is an objection to the policies, procedures and/or performance of the APHIS BQMS Program staff.
- 25.2 Participants have the right to submit a complaint regarding APHIS BQMS Program policies, procedure and/or performance, including performance of APHIS officials and auditors. Any third party also has the right to submit a complaint regarding the performance or activities of participants with a recognized BQMS.
- 25.3 Complaints may be submitted in any format to the APHIS BQMS Program. Complaints should provide enough information to allow the APHIS BQMS Program to investigate the complaint.
- 25.4 The APHIS BQMS Program provides the complainant with progress reports and the outcome, as applicable. *Reference: 1445 BQMS Appeals and Complaints.*

26. OBJECTIONS TO AUDITOR OR AUDIT TEAM MEMBERS

- 26.1 Participants have the right to object to any audit team member(s).
- 26.2 Objections must be submitted in writing to the APHIS BQMS Program within ten (10) business days after notification of the audit team.
- 26.3 Objections must include:
- a) The basis for the objection, and
 - b) The requested alternative decision or actions.
- 26.4 The APHIS BQMS Program reviews any objections and notifies the participant of the final decision within ten (10) business days from receipt of the appeal.
- 26.5 The participant has the right to appeal the decision issued by the APHIS BQMS Program.
- 26.6 The appeal must be submitted in writing to the APHIS BQMS Program within ten (10) business days of the date of receipt of the official report or letter rendering the decision.
- 26.7 Appeals must include:
- a) The basis for the appeal, and
 - b) The requested alternative decision or actions.

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1000 Version: 1.0
APHIS BQMS PROGRAM GENERAL ADMINISTRATIVE PROCEDURE		Effective Date: 093010

26.8 The APHIS BQMS Program reviews the appeal and notifies the participant of the final decision within ten (10) business days from receipt of the appeal.

27. AUDIT/ASSESSMENT SERVICES COSTS

27.1 Cost of third-party audit services is subject to available funds by APHIS.

28. CONFIDENTIALITY

28.1 Documentation submitted by participants and maintained by the APHIS BQMS Program is subject to disclosure under the Freedom of Information Act (FOIA) (5 USC § 552). FOIA applies to documents that are in the control of or maintained by a government agency. Documents which contain information submitted voluntarily by participants of the APHIS BQMS Program that are considered to be confidential business information will be withheld based on Exemption 4 of FOIA.

28.2 Any portion of the program documentation that the participant considers proprietary must be identified to the APHIS BQMS Program at the time the information is submitted. The APHIS BQMS Program makes appropriate provisions to protect the information from disclosure to the extent possible under existing federal laws.

28.3 APHIS BQMS Program officials must have a signed *Confidential Business Information* certificate of training and a signed *Conflict-of-Interest and Confidentiality Statement*, and appropriate disclosure agreement on file prior to assignment to provide APHIS BQMS Program audit service to participants.

29. APHIS BRS WEB SITE

29.1 APHIS BRS' web site provides information on the APHIS BQMS Program.

29.2 The APHIS BRS *Newsroom* web site provides the latest news and information.

29.3 The *Questions and Answers* web site provides answers to frequently asked questions regarding program requirements.