

 <p>Biotechnology Regulatory Services</p>	<b>Animal and Plant Health Inspection Service</b> <b>Biotechnology Regulatory Services</b>	Document Control #: <b>1445</b> Version: <b>1.0</b>
<b>APHIS BQMS PROGRAM PROCEDURE:  APPEALS AND COMPLIANTS</b>		<b>Effective Date:  093010</b>

## 1. PURPOSE

This document sets forth the responsibilities and requirements for the documentation and resolution of appeals and complaints that are received by the Animal and Health Inspection Service (APHIS) Biotechnology Quality Management System Program (BQMS Program).

## 2. SCOPE

The appeals process outlined in this document applies to the APHIS BQMS Program. The complaint process outlined in this document applies to all services applied by the APHIS 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.

*BQMS 1445A\_Form\_Appeals*  
*BQMS 1445B\_Form\_Complaints*  
*BQMS 1445\_LogA\_Appeals*  
*BQMS 1445\_LogB\_Complaints*  
*BQMS 1410A\_List, Program Identifiers*  
*BQMS 1410B\_List, Auditor Identifiers*  
*BQMS Program Procedure 1412, Control of Documents and Records*

## 4. DEFINITIONS

- 4.1** Appeal: a request from the participant for reconsideration of any adverse findings, assessment findings, or decisions issued by the APHIS BQMS Program or BQMS Program Review Committee related to the participant's BQMS.
- 4.2** Complaint: an objection to the policies, procedures, and/or performance of the APHIS BQMS Program. A complaint may also be an objection to the performance or activities of an approved Biotechnology Quality Management System (BQMS) submitted to the APHIS BQMS Program by a third party.
- 4.3** The APHIS BQMS Program Manager is responsible for evaluating non-conformances and implementing sufficient corrective and preventive actions. The APHIS BQMS

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Program Manager is also responsible for notifying the Compliance Assistance Branch (CAB) Chief of the actions.

## 5. RESPONSIBILITIES

The CAB Chief is responsible for ensuring that appeals and complaints are addressed by the APHIS BQMS Program.

## 6. APPEALS

- 6.1 Participants have the right to appeal any adverse audit findings, assessment findings, or decisions.
- 6.2 Appeals must be submitted in writing to the CAB Chief within 30 days of the date of the official report or letter rendering the findings or decisions. This timeframe may be adjusted as referenced in other procedures.
- 6.3 The appeal must include the basis for the appeal and the requested alternative decision or actions.
- 6.4 Upon receipt, the CAB Chief, or designee, logs the appeal into the 1445\_Log\_Appeals. The CAB Chief, or designee, also documents the organization's appeal using BQMS 1445\_Form\_Appeals. Sections 1, 2 and 3 of 1445\_Form\_Appeals must be completed at this time.
- 6.5 The CAB Chief reviews all appeals. If necessary, the CAB Chief appoints a person, or group of persons, to investigate the appeal. The person(s) must be competent and independent of the subject of the appeal. Sections 4 and 5 of 1445\_Form\_Appeals must be completed. The resolution activities should include the dates and activities taken.
- 6.6 The CAB Chief decides the validity of the appeal, using the findings of the investigative team, if applicable.
- 6.7 The CAB Chief provides written notification to the participant of the final decision(s) of the APHIS BQMS Program. The final decision must be provided within 30 days from receipt of the appeal. Section 6 of 1445\_Form\_Appeals must be completed. The CAB Chief completes the log entry into the 1445\_Log\_Appeals.

NOTE: If the final decision cannot be reached within this timeframe, the participant is provided with a progress report.

- 6.8 When necessary, the CAB Chief takes follow-up action where required.

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## 7. COMPLAINTS

- 7.1** Participants have the right to submit a complaint regarding the APHIS BQMS Program’s activities, including processes or decisions, APHIS BQMS Program officials and auditors.
- 7.2** 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.
- 7.3** The person receiving the complaint must log the complaint into 1445\_Log\_Complaints, and must document the complaint using BQMS 1445\_Form\_Complaints. Sections 1, 2 and 3 must be completed at this time.
- 7.4** Once the complaint is documented, it is delivered to the CAB Chief.
- 7.5** The CAB Chief, or designee, is assigned to investigate the complaint. The complaint may be assigned to another member of the management team or to a member of the Program Review Committee if necessary to avoid a conflict-of-interest and to maintain impartiality. Additionally, any person directly involved in a complaint must not assist in the investigation.
- 7.6** The APHIS BQMS Program Manager decides the validity of the complaint based on the findings of the investigation.
- 7.7** The APHIS BQMS Program Manager takes appropriate actions to resolve the complaint, and assess the effectiveness of the actions.
- 7.7.1** When the complaint concerns another participant, that participant is responsible for first addressing the complaint.
- 7.7.2** When the complaint concerns another USDA Agency, a copy of the complaint is sent to the Agency.
- 7.8** The BQMS Program Manager provides the complainant with progress reports as necessary. Section 4 and 5 of the complaint record must be completed. The resolution activities should include the dates and activities taken.
- 7.9** The BQMS Program Manager provides written notification of the final outcome to the participant. Section 6 of the complaint record must be completed. Additionally, the

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CAB Chief is notified of the final outcome of the complaint. The BQMS Program Manager completes the log entry into the 1445\_Log\_Complaints.

NOTE: Complaints are considered outstanding until final resolution is achieved.

## 8. APPEAL RECORDS

**8.1** Records of appeals, final decisions, and follow-up actions are maintained in accordance with *BQMS Program Procedure 1412*.

**8.2** Appeal records, including the written request, are maintained electronically on the APHIS BRS server.

- a) Working records are maintained in a secure network server.
- b) Completed records are maintained in the participant folder.

**8.3** Each written request for an appeal is identified using a 9-digit identifier which consists of the following:

- a) “AE” (The assigned 2-digit program identifier as outlined in *BQMS 1410A\_List*);
- b) The last digit of the calendar year;
- c) The Julian date that the request was received;
- d) The Chief’s assigned 2-digit identifier (*BQMS 1410B\_List*); and
- e) The applicable letter (A, B, C...). This letter identifies how many appeals were received during one day.

**8.4** The file name of the record related to an appeal consists of the following:

- a) The 9-digit appeal identifier;
- b) The organization’s name;
- c) The organization’s location (city and state abbreviation); and
- d) The calendar date (MM DD YY) that the record was completed.

**8.5** Records associated with the appeal are identified using the same file naming system, including a brief description of the record, and the calendar date (MM DD YY) that the record was received.

## 9. COMPLAINT RECORDS

**9.1** Records of complaints and actions taken are maintained in accordance with *BQMS Program Procedure 1412*.

 <p>Biotechnology Regulatory Services</p>	<b>Animal and Plant Health Inspection Service</b> <b>Biotechnology Regulatory Services</b>	Document Control #: <b>1445</b> Version: <b>1.0</b>
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- 9.2** Complaint records are maintained electronically by APHIS BRS.
- a) Working records are maintained in a secure network server.
  - b) Completed records about a participant are maintained in the participant folder.
  - c) Completed records about APHIS BQMS are maintained in a secure network server.
  - d) Completed records about an APHIS BQMS Program official are maintained in the official's personnel folder in a secure network server.
- 9.3** Each complaint record is identified using a 9-digit complaint identifier which consists of the following:
- a) "CD" (The assigned 2-digit program identifier as outlined in BQMS 1410A\_List);
  - b) The last digit of the calendar year;
  - c) The Julian date that the request was received;
  - d) The Chief's assigned 2-digit auditor identifier (BQMS 1410B\_List); and
  - e) The applicable letter (A, B, C...). This letter identifies how many complaints were received during one day.
- 9.4** The file name of each complaint consists of the following:
- a) The 9-digit complaint identifier;
  - b) The associated BQMS Program referenced in the complaint (workshop, baseline assessment, consultation, internal audit assistance, recognition audit);
  - c) The organization's name;
  - d) The organization's location (city and state abbreviation); and
  - e) The calendar date (MM DD YY) that the record was completed, as appropriate.
- 9.5** Records associated with the complaint are identified using the same file naming system, including a brief description of the record, and the calendar date (MM DD YY) that the record was received.