

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 2000 Version: 1.0
APHIS BQMS PROGRAM: AUDIT PROCEDURE		Effective Date: 093010

1. PURPOSE

This procedure provides the requirements used for the objective evaluation of a participant's Biotechnology Quality Management System (BQMS) that is voluntarily submitted for verification.

2. SCOPE

The provisions of this procedure apply to all audits of the Animal and Plant Health Inspection Service (APHIS) Biotechnology Quality Management System Program (BQMS Program).

3. REFERENCES

1000_BQMS_General Administrative Procedures
1001B_BQMS_Process Audit Checklist
1001C_BQMS_Audit Guideline
ISO 19011:2002 Guidelines for quality and/or environmental management systems auditing
2000A_BQMS_Desk Audit Response Summary_temp
2000B_BQMS_APHIS Audit Response to Participant_temp
2000C_BQMS_Audit Plan_temp
2000D_BQMS_Audit Opening and Closing Meeting Agenda_temp
2000D_BQMS_Audit Report_guideline

4. RESPONSIBILITIES

- 4.1 Auditors must meet all applicable requirements outlined in this document.
- 4.2 The APHIS BQMS Program must meet all applicable requirements outlined in this document.

5. AUDIT PROTOCOLS

- 5.1 Receiving Desk Audit Materials
 - 5.1.1 The auditor may receive desk audit files from the APHIS BQMS Program Manager, or designee. These files may contain information justified by the participant as Confidential Business Information (CBI). This information must be protected and is entitled to treatment as trade secret or proprietary data under 5 U.S.C. 552 (b)(4), Freedom of Information Act (FOIA).

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- 5.1.2 The auditor may only receive files containing CBI if the auditor has completed annual APHIS BRS CBI training.
- 5.1.3 The auditor may receive desk audit files accompanied by a “red jacket” that indicates the files contain CBI.
- 5.1.4 The auditor must follow the procedure for handling CBI as prescribed in *1000_BQMS_General_Administrative_Procedures_Appendix A*.

5.2 Desk Audit

- 5.2.1 The auditor conducts a desk audit of the participant’s BQMS program documentation to ensure that program requirements, as outlined in the APHIS BQMS Audit Standard, are fully addressed. The auditor may use an APHIS BQMS Program checklist to conduct the desk audit.
- 5.2.2 Upon completion of the desk audit, if the program documentation is adequate and the majority of the program requirements are met, the auditor notifies the APHIS BQMS Program Manager within ten (10) business days that the initial on-site audit may be scheduled.
- 5.2.3 If the program documentation requires clarification or additional information, the auditor obtains the clarification or additional information directly from the participant. Once the program documentation is adequate, the auditor notifies the APHIS BQMS Program that the initial on-site audit may be scheduled.
- 5.2.4 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 Manager (*Reference: 2000A_temp_Desk Audit Response Summary*). 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: 2000B_temp_BQMS_APHIS Audit Response to Participant*).

5.3 On-Site Audit

- 5.3.1 The APHIS BQMS Program Manager coordinates with the participant and appoints the audit team to conduct the on-site audit.
- 5.3.2 The APHIS BQMS Program Manager notifies the participant of the assigned audit team. The participant may submit written objections regarding any team member(s). Written

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objections must be submitted to the APHIS BQMS Program Manager and be received within ten (10) business days after notification of audit team members. (*Reference: 1445_BQMS_Appeals and Complaints*)

- 5.3.3 The auditor contacts the participant's quality management representative (QMR) and coordinates the date and schedule of the on-site audit and prepares an audit plan (*Reference: 2000C_temp_BQMS Audit Plan and 2000D_temp_BQMS Audit Opening and Closing Meeting Agenda*). The documents are submitted to the participant prior to the scheduled on-site audit at least five (5) business days prior to the on-site audit.
- 5.3.4 The on-site audit is conducted in accordance with *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.
- 5.3.5 The on-site audit is conducted at the premises of the participant from which regulatory compliance is managed for the interstate movement, importation, and environmental release of regulated genetically engineered organisms. 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 of the participant to gather objective evidence, which may be obtained through telephone or other correspondence.
- 5.3.6 At the conclusion of all audit activities, the auditor will return all participant documentation (Quality Manual, procedures, etc.) to the participant prior to leaving the participant's location.

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

5.4 Audit Findings and Audit Report

- 5.4.1 All audit findings, including identified non-conformances and continuous improvement points are discussed with the participant at the conclusion of the on-site audit.
- 5.4.2 After audit findings have been discussed and reviewed by the participant, the final audit report shall be delivered to the participant.
- 5.4.3 The final audit report may contain information justified by the participant as CBI (*Reference: 2000E_ BQMS Audit Report guideline*). If the audit report contains CBI, the auditor, participant, and APHIS BQMS Program officials must follow the procedural

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requirements for handling CBI as prescribed in *1000_BQMS_General Administrative Procedures Appendix A*.

- 5.4.4 If the audit team cannot reach a conclusion about an audit finding, the audit team refers to the APHIS BQMS Program for clarification. Audit findings are described in *1000_BQMS_General Administrative Procedures*.
- 5.4.5 The final audit report is submitted by the participant to the APHIS BQMS Program Manager within twenty (20) business days upon completion of the on-site audit.
- 5.4.6 The final audit report is voluntarily submitted to the APHIS BQMS Program Manager for concurrence and further review by the BQMS Program Review Committee, as necessary (*Reference: 2000E_BQMS_Audit_Report_guideline*).

NOTE: The audit report is considered the property of the participant since the report may contain CBI that is voluntarily submitted by the participant. The auditor must not retain any of the participant's documentation without prior consent of the participant.

5.5 Corrective Action Audit

- 5.5.1 If requested by the APHIS BQMS Program 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 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 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*.
- 5.5.2 The findings of the corrective action audit are outlined in an audit report. The report is submitted to participant. The participant will submit the audit report to the APHIS BQMS Program for review and concurrence. The APHIS BQMS Program Manager has the discretion to seek clarification from the audit team and/or the participant to modify the audit findings.

5.6 Auditor Recommendations

- 5.6.1 Program recognition is based upon the findings and the recommendations of the audit team.

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5.6.2 The APHIS BQMS Program Manager or the APHIS BQMS Program Review Committee will consider the recommendations to make the final decision regarding recognition status (*Reference: 1000_BQMS_General_Administrative_Procedures*).