

 <p>Biotechnology Regulatory Services</p>	Animal and Plant Health Inspection Service Biotechnology Regulatory Services	Document Control #: 1001 Version: 2.0
APHIS BQMS PROGRAM: AUDIT STANDARD		Effective Date: 093010

1 Purpose

The purpose of this Audit Standard is to outline the audit program requirements for the Animal and Plant Health Inspection Service (APHIS) Biotechnology Quality Management System Program (BQMS Program). It provides the requirements used for the objective evaluation of quality management systems that are submitted for verification and monitored by APHIS Biotechnology Regulatory Services (BRS). The APHIS BQMS Program is designed to provide verification of a participating organization's quality management system that addresses the management of domestic research and development of regulated genetically engineered (GE) organisms. Voluntary participants of the APHIS BQMS Program must develop, implement, and maintain a biotechnology quality management system (BQMS), following the requirements of this audit standard, for the management, containment and confinement of regulated GE organisms.

Sections 2 through 8 below contain the requirements that must be addressed in the organization's quality management system. The documentation provided for verification must be in sufficient detail that the activities performed can be audited against the requirements of this Standard.

2 Scope

The provisions of this Audit Standard are intended for the use of organizations that apply for and receive APHIS approval to introduce GE organisms regulated under Title 7 Code of Federal Regulations part 340 (7 CFR part 340).

Quality management system documentation, including the organization's BQMS critical control point procedures, are submitted by the participant to APHIS for a desk audit and on-site verification by a qualified third-party auditor of the APHIS BQMS Program. A qualified third-party auditor may be a United States Department of Agriculture (USDA) auditor (an official from USDA Marketing and Regulatory Programs) or an agent of APHIS (service provider or contractor). Qualified third-party auditors met baseline criteria and received training from APHIS officials on the audit protocols for the APHIS BQMS Program.

Participants must develop, implement, and maintain a BQMS for full participation in the APHIS BQMS Program. The extent of critical control point procedures and processes verified through audit for the APHIS BQMS Program include relevant phases of regulated GE organism introduction (Examples include, but are not limited to: shipping and handling processes from storage to field release and post-harvest monitoring). Verification also extends to the organization's management of regulated GE organism introduction (Examples include, but are not limited to: training of applicable personnel, internal and external communication of regulatory requirements, and corrective and preventive actions).

An organization receives acknowledgement of full participation in the APHIS BQMS Program when it has successfully passed a desk audit and an onsite audit, valid for a period of three years from the date of acknowledgement.

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Where any requirements within this Audit Standard cannot be applied due to the nature of an organization's scope of work and its processes, these requirements may be considered *not applicable*. The organization must provide justification for any exclusion to Clause 7 within their Quality Manual (see Clause 4.2.2a).

3 References

Title 7, Code of Federal Regulations, Part 340

ISO 9001:2008, Quality management systems--Requirements

ISO 19011:2002, Guidelines for quality and/or environmental management systems auditing

ISO 22000:2005, Food safety management systems—Requirements for any organization in the food chain

ISO/TS 22004:2005, Food safety management systems—Guidance on the application of ISO 22000:2005

ISO 22005:2007, Traceability in the feed and food chain—General principles and basic requirements for system design and implementation

USDA APHIS BRS Guidance for APHIS Permits for Field Testing of Movement of Organisms with Pharmaceutical or Industrial Intent

4 Biotechnology Quality Management System

4.1 General requirements. The organization must:

- a) Identify the processes and work instructions needed for its BQMS and their application throughout the organization and its external associates;
- b) Determine the sequence and interaction of these processes;
- c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective;
- d) Ensure the availability of resources and information necessary to support the operation and to monitor these processes;
- e) Monitor, measure, and analyze these processes;
- f) Implement actions necessary to achieve planned results and continual improvement of these processes; and
- g) Establish substantive, verifiable processes that:
 - 1) Prevent loss of confinement or containment of regulated GE organisms;
 - 2) Prevent mixing of regulated GE organisms with commercial commodities; and
 - 3) Prevent persistence in the environment of regulated GE organisms and traits.

4.2 Documentation requirements

4.2.1 General. The organization's BQMS documentation must include:

- a) A quality manual;
- b) Documented statements of a quality policy and measurable quality objectives;
- c) Documented procedures required by this Audit Standard;
- d) Documents needed by the organization to ensure the effective planning, operation, and control of its processes; and
- e) Records required by this Audit Standard.

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NOTE 1: A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 2: The extent of the organization's BQMS documentation can differ from one organization to another due to: a) the size of the organization and type of activities, b) the complexity of processes and their interactions, and 3) the competence of personnel.

NOTE 3: Quality objectives must be measurable and consistent with the quality policy.

4.2.2 Quality manual. The organization must establish and maintain a quality manual that includes:

- a) The scope of the organization's processes, including details of and justifications for not addressing specific clauses or sub-clauses due to applicability;
- b) A description of its specified BQMS, including those processes from Clause 4.1g; and
- c) A description of the interaction between the processes of its BQMS.

NOTE: Where exclusions are made, claims of conformity to the BQMS Audit Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to meet applicable regulatory requirements.

4.2.3 Control of documents. Documents required for the organization's BQMS must be controlled.

A master document list must be established that shows the most current issue of procedures, work instructions, and forms.

A documented procedure must be established to define the controls needed to:

- a) Approve documents for adequacy prior to being issued;
- b) Review, update, and re-approve documents, as necessary;
- c) Ensure that changes and the current revision status of documents are identified;
- d) Ensure that applicable documents are available at points of use;
- e) Ensure that documents remain legible and readily identifiable at point of use;
- f) Ensure that documents of external origin are identified and their distribution controlled; and
- g) Prevent the unintended use of obsolete documents and identify them if they are retained for any purpose.

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- 4.2.4 Control of records.** Records must be established and maintained to provide evidence of conformity to the requirements of this Audit Standard and of the effective operation of the organization's BQMS. Records must remain legible, readily identifiable, and retrievable. A documented procedure must be established to define the controls needed for the identification, storage, protection, retrieval, and disposition of records. This documented procedure must specify the required retention time of records with the following requirements:
- a) Records that indicate the regulated GE organism(s) have arrived at the intended destinations must be controlled for a minimum of two (2) years, and
 - b) Records associated with approved field trials must be controlled for a minimum of five (5) years after relevant regulatory obligations for the permit(s) have been fulfilled.

5 Management Responsibility

- 5.1 Management commitment.** Top management must provide evidence of its commitment to the development and implementation of the organization's BQMS and continually improve its effectiveness by:
- a) Communicating to the organization the importance of meeting regulatory requirements;
 - b) Establishing a quality policy;
 - c) Ensuring that quality objectives are established;
 - d) Conducting management reviews; and
 - e) Ensuring the availability of resources.
- 5.2 Quality policy.** Top management must ensure that the quality policy:
- a) Is appropriate to the purpose of the organization;
 - b) Includes a commitment to conform with requirements and continually improve the effectiveness of the organization's BQMS;
 - c) Provides a framework for establishing and reviewing quality objectives;
 - d) Is communicated and understood within the organization; and
 - e) Is reviewed for continuing suitability.
- 5.3 Quality planning.** Top management must ensure that:
- a) Planning of the organization's BQMS conformance is carried out to meet requirements given in 4.1 as well as the objectives of the organization, and
 - b) The integrity of the organization's BQMS and compliance with applicable regulations is maintained when changes to the system are planned and implemented.
- 5.4 Responsibility and authority.** Top management must ensure that responsibilities and authorities are defined and communicated within the organization to ensure the effective operation and maintenance of the organization's BQMS.

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An organizational chart or similar document must list relevant managerial positions within the organization's BQMS. Each position must be described listing responsibilities and authorities.

Relevant personnel must be made responsible for reporting non-conformance or possible non-conformance within the organization's BQMS. The person to whom they report must be identified. Personnel responsible for initiating action and maintaining records must be identified.

- 5.5 Quality management representative.** Top management must appoint a Quality Management Representative (QMR) who, irrespective of other responsibilities, must have the responsibility and authority to:
- Manage the organization's BQMS;
 - Ensure relevant training and education of personnel (see **6.2.1**);
 - Ensure that the organization's BQMS is established, implemented, maintained, and updated; and
 - Report to the organization's top management on the effectiveness and suitability of their BQMS.

5.6 Communication

- 5.6.1 External communication.** The organization must establish, implement, and maintain effective arrangements for communicating with relevant external associates that may influence the effectiveness of its BQMS.

Designated personnel must have defined responsibility and authority to communicate externally any information concerning conformance to the organization's BQMS. Relevant information obtained through external communication must be included as input to system updating and management review.

Records of communications must be maintained and controlled according to **4.2.4**.

- 5.6.2 Internal communication.** The organization must establish, implement, and maintain effective arrangements for communicating with internal personnel on issues having an impact on conformance with its BQMS.

5.7 Management review

- 5.7.1 General.** Top management must review the organization's BQMS at least annually or more frequently to ensure its continuing suitability, adequacy, and effectiveness. This review must include assessing opportunities for improvement and the need for change to its BQMS, including the quality policy. Records of management reviews must be maintained according to **4.2.4**.

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5.7.2 Review input. The input to management reviews must include, but is not limited to:

- a) Results of audits (internal and third party);
- b) Process performance and conformity with established processes and procedures;
- c) Status of corrective and preventive actions to the organization's BQMS;
- d) Follow-up actions from previous management reviews;
- e) Changes that could affect the organization's BQMS; and
- f) Recommendations for improvement.

5.7.3 Review output. The management review must include any decisions and actions related to:

- a) Improvement of the effectiveness of the organization's BQMS and its processes;
- b) Improvement of processes and procedures related to regulatory compliance;
- c) Resource needs (see **6.1**); and
- d) Revisions of the organization's quality policy and related objectives (see **5.2**).

6 Resource Management

6.1 Provision of resources. The organization must determine and provide the resources needed to implement and maintain its BQMS, continually improve its effectiveness, and meet regulatory requirements.

6.2 Human resources.

6.2.1 General. Personnel performing work affecting conformance to the organization's BQMS must be competent based on appropriate education, training, skills, technical knowledge, and experience.

6.2.2 Competence, awareness, and training. The organization must document a procedure to ensure relevant personnel performing work affecting the organization's BQMS are properly trained in relevant aspects of the BQMS. The organization must:

- a) Determine the necessary competency for personnel performing work affecting regulatory compliance;
- b) Provide training or take other actions to satisfy these needs;
- c) Ensure that personnel responsible for monitoring of, corrections to, and corrective actions of its BQMS are trained;
- d) Evaluate the implementation and the effectiveness of a), b), and c); and
- e) Ensure that the personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

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Records of competency, awareness, and training must be maintained and controlled according to **4.2.4**.

- 6.3 Infrastructure.** The organization must make arrangements for, or provide the resources for, the establishment and maintenance of the infrastructure needed to achieve conformance with the organization's BQMS.

NOTE: Infrastructure includes but is not limited to: buildings, workspace, storage areas, equipment, associated utilities, and supporting services (such as transport or communication). Equipment may include those used for critical control point activities described in Clause 7 (planting, harvesting, conditioning, cleaning, processing, etc.).

7 Planning and Process Realization

- 7.1 General.** The organization must plan and develop documented procedures needed for the organization's planning and process realization. These procedures must address critical control points in the introduction of regulated GE organisms. The organization must monitor and verify the effectiveness of the planned activities and any changes to those activities. The organization must clearly identify the specific species of regulated GE organism within the documented procedure.

- 7.1.1 Site selection planning.** The organization must have a procedure for the planning of environmental field releases of regulated GE organisms. Roles and responsibilities must be defined. The procedure must sufficiently describe site selection, which must address:
- a) Surrounding land use and proximity to sexually compatible species;
 - b) Historical land use and topography of environmental release sites;
 - c) Provision for rights of access to land for purposes of monitoring for volunteers and/or mitigation activities, for appropriate length of time; and
 - d) Analysis of critical habitat of local threatened and endangered species.

Record of the site selection process must be maintained for each site according to 4.2.4.

NOTE: Record of site selection process may include, but is not limited to, acknowledged APHIS notifications for the introduction of regulated articles or approved APHIS permits for the introduction of regulated articles.

- 7.2 Critical control points and procedures.** The organization must develop, establish, and implement the following into their applicable BQMS:

- 7.2.1 Storage.** The organization must have a procedure for containment and storage of regulated GE organisms for environmental field release. This procedure must describe:

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- a) The method used to segregate regulated GE organisms from non-regulated GE organisms;
- b) The method used to mark or label storage areas;
- c) The type of containers used for physical storage;
- d) The method(s) of marking, labeling, and identification of storage containers; and
- e) The method used to limit access to storage areas to authorized personnel.

7.2.2 Transport, movement, and import of regulated GE organisms. The organization must have a procedure for identification of regulated GE organisms for transport, movement, and import. The procedure must describe:

- a) The physical packaging for shipment of regulated GE organisms to maintain containment;
- b) The method of tracking regulated GE organisms from shipment to receipt;
- c) The method(s) of marking, labeling, and identification of shipment packages;
- d) Verification of receipt, verification of contents according to shipping record, and inspection of physical packaging containment integrity; and
- e) The disposal or return to use of packaging material.

Records must be maintained and controlled according to **4.2.4**.

7.2.3 Environmental release planning and monitoring. The organization must have procedures for the planning and monitoring of environmental release of regulated GE organisms. Procedures must be sufficiently detailed to describe the methods the organization will use to achieve planned activities and conduct regulated activities. Roles and responsibilities must be defined. These procedures must sufficiently describe:

- a) Pre-planting handling and transfer to environmental field release sites;
- b) Preparation and cleaning of planting equipment;
- c) Use of physical markers and/or global positioning system (GPS) coordinates to identify the field release sites, including boundaries, where applicable;
- d) Documentation of environmental field release site(s). This procedure must address the development of documented environmental field release site maps indicating surrounding land uses, separation distance employed, and border rows, where applicable;
- e) Method(s) of reproductive growth control (physical separation, temporal separation, sterility, etc.);
- f) Harvest preparation and equipment cleaning which must address:
 - i. Verification of the specific environmental field release site to harvest; and
 - ii. Cleaning of relevant equipment used for harvest on the field site.
- g) Monitoring of volunteers at the environmental field release site which must address:
 - i. Communication of post-harvest land use restrictions; and

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- ii. Monitoring of the environmental field release site, including border rows, for volunteer plants.

Records of environmental field release planting, monitoring, and verification must be maintained and controlled according to **4.2.4**.

Relevant employees must have training applicable to their defined roles and responsibilities according to **6.2.2**.

- 7.2.4 Post-harvest handling and transfer.** The organization must have a procedure, which sufficiently describes post-harvest handling activities and the methods employed to maintain the identity of regulated GE organisms. This procedure must include, as applicable, the method by which:
- a) The regulated GE organisms are transferred to storage and/or further conditioning;
 - b) The regulated GE organisms are contained during transfer;
 - c) The regulated GE organisms are marked and/or labeled;
 - d) The identity of the regulated GE organisms are maintained while under use and/or conditioning;
 - e) The identity of regulated GE organisms are maintained during transfer to a subsequent facility for further evaluation and/or use;
 - f) The equipment used for conditioning, processing, or evaluating the regulated GE organisms is cleaned; and
 - g) Any misidentified regulated GE organisms are handled.

Records of post-harvest handling and transfer must be maintained and controlled according to **4.2.4**.

NOTE: Maintaining the identity of regulated GE organisms can be facilitated through effective quality control methods used for *seed quality* and/or *plant product integrity* guidelines common to the industry, as applicable.

- 7.2.5 Devitalization and final disposition.** The organization must have a procedure for devitalization and final disposition of regulated GE organisms. This procedure must include the method by which:
- a) Regulated GE organisms in the field are rendered nonviable according to relevant applicable rules, regulations, and guidance;
 - Records must be able to demonstrate that devitalization and final disposition has occurred at the field of the environmental release;
 - b) Regulated GE organisms in storage and/or other means of containment are rendered nonviable according to relevant applicable rules, regulations, and guidance.
 - Records should account for the method(s) of final disposition or disposal.

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NOTE: Final disposition is the fate of materials harvested, removed, destroyed, and/or otherwise terminated from an environmental release and/or movement. Such a fate may include various in-field methods of termination (e.g., grinding, disking, deep burial, etc.) and off-field termination (e.g., containment, landfill disposal, etc.).

Records of devitalization and final disposition must be maintained and controlled according to **4.2.4**.

7.2.6 Regulatory compliance reporting and resolution. The organization must have a procedure for the self-reporting of potential regulatory compliance incidents to appropriate regulatory authorities and for the prompt remediation and resolution of those incidents. This procedure must address:

- a) Personnel roles and responsibilities for ensuring regulatory compliance;
- b) Personnel roles and responsibilities for communicating and implementing resolution activities;
- c) The method of documenting the nature and extent of the potential regulatory compliance incident;
- d) The method of communicating internal requirements for the prompt resolution and remediation of potential regulatory compliance incidents;
- e) The method of documenting resolution activities used for the prompt remediation of potential regulatory compliance incidents;
- f) The method of reporting the potential regulatory compliance incident to appropriate regulatory authorities according to applicable rules and regulations; and
- g) Training of relevant individuals involved in regulatory compliance reporting requirements.

Records of internal and external communications regarding potential regulatory compliance incident self-reporting and actions taken must be maintained and controlled according to **4.2.4**.

NOTE: Non-conformance with planned critical control point processes and procedures may lead to a potential regulatory compliance incident that requires reporting to the appropriate regulatory authority. Examples include, but are not limited to: unauthorized release of regulated GE organisms, persistence of the regulated GE organism in the environment, mixing (co-mingling) of regulated GE organisms with non-regulated plant material, etc. The applicable regulatory authority may direct actions for the control of regulated GE organisms that are involved in a potential regulatory compliance incident. Action(s) taken to control the regulated GE organisms; authorization for use, release, or acceptance under concession; or use for another purpose may require approval from an appropriate regulatory authority.

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7.3 Management of external associates. The organization must monitor and verify the activities of relevant service providers, cooperators, and contractors that may impact conformance with BQMS procedures in Clause 7 and its sub-clauses.

Records of monitoring activities must be maintained and controlled according to **4.2.4**.

8 Monitoring, Analysis and Improvement

8.1 General. The organization must plan and implement the monitoring, measurement, analysis, and improvement processes needed to:

- a) Demonstrate conformity with the organization's BQMS and the quality policy and objectives;
- b) Ensure conformity with the requirements of the BQMS Audit Standard, as described in this document; and
- c) Continually improve the effectiveness of the organization's BQMS.

8.2 Monitoring and Measurement

8.2.1 Internal audit. The organization must conduct internal audits at least annually.

The internal audits must determine the organization's ability to meet requirements of planned arrangements, as specified in this Audit Standard, the organization's ability to meet BQMS requirements established by the organization, and whether the organization's BQMS is effectively implemented and maintained.

The organization must have a documented procedure which describes:

- a) The planning of an audit program, which must consider the status and importance of the processes and areas to be audited, as well as the results of the previous audit;
- b) The audit criteria, scope, frequency, and methods;
- c) The selection and conduct of auditors, which must ensure objectivity and impartiality of the audit process (auditors must not audit their own work);
- d) The responsibilities for planning and conducting audits;
- e) The reporting of results;
- f) The follow-up activities (follow-up activities must include the verification of the actions taken and the reporting of verification results); and
- g) The maintenance of records.

Within the area being audited, management must ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.

The organization must review the results of internal audits during management reviews.

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The organization must maintain records of the internal audits according to **4.2.4**.

8.2.2 Monitoring of process.

The organization must apply suitable methods for monitoring and, where applicable, measurement of its BQMS processes. These methods must demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action must be taken, as appropriate.

NOTE: When determining suitable methods, it is advisable that the organization considers the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on compliance with APHIS regulations and on the effectiveness of its BQMS.

8.3 Analysis of data

The organization must determine, collect, and analyze appropriate data to demonstrate the suitability and effectiveness of its BQMS.

The organization must evaluate where continual improvement of the effectiveness of its BQMS can be made. This must include data generated as a result of monitoring and measurement and data from other relevant sources.

The analysis of data must provide information relating to:

- a) Compliance with applicable rules and regulations;
- b) Conformity to BQMS requirements; and
- c) Characteristics and trends of processes and external associate performance, including opportunities for preventive action.

8.4 Improvement

8.4.1 Continual improvement. The organization must continually improve the effectiveness of its BQMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

8.4.2 Corrective action. The organization must take corrective action to eliminate the cause of non-conformance within its BQMS in order to prevent recurrence.

Corrective actions must be appropriate to the effects of the nonconformities encountered.

The organization must establish a documented procedure, which describes the requirements for:

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- a) Reviewing nonconformities with its BQMS as well as non-compliance with regulatory requirements communicated by APHIS or other regulatory agencies;
- b) Determining the root causes of nonconformities with its established BQMS;
- c) Evaluating the need for action to ensure that nonconformities with its BQMS do not recur;
- d) Determining and implementing action(s) needed;
- e) Recording the results of action taken; and
- f) Reviewing corrective action taken to determine its effectiveness.

Records of corrective action must be maintained and controlled according to **4.2.4.**

8.5 Preventive action

The organization must determine action to eliminate the cause of potential nonconformities within its BQMS or regulatory non-compliance and their causes in order to prevent their occurrence.

Preventive actions must be appropriate to the effects of potential problems.

The organization must establish a documented procedure, which describes the requirements for:

- a) Determining potential nonconformities and their causes;
- b) Evaluating the need for action to prevent occurrence of nonconformities;
- c) Determining and implementing action needed;
- d) Recording the results of action taken; and
- e) Reviewing preventive action taken to determine its effectiveness.

Records of preventive action must be maintained and controlled according to **4.2.4.**

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Appendix A: Common Quality Management Definitions and Phrases Applicable to the APHIS BQMS Program.

Accreditation	Formal recognition of competence to issue a certificate.
Adequacy	The ability to satisfy a requirement.
Audit	A systematic, independent, and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.
Certified	Audited and approved by USDA or a USDA accredited certifying body
Clause/sub-clause	The numbered sections in the BQMS Audit Standard that define specific requirements which must be met.
Commercial commodity	Viable or non-viable plant material that is intended for commerce including, but not limited to: seeds, seedlings, tissues.
Commingle	To blend, mix, or combine different, but similar products.
Competence	Demonstrated knowledge, skills, and abilities.
Compliance	Adherence to regulatory requirements.
Confinement	The control of viable regulated material released into the environment in a manner that mitigates the spread of reproductive material or other propagative parts out of the confined area authorized by regulatory authorities.
Conformance	Fulfillment of a requirement of the BQMS Audit Standard.
Conforming process	Process which can be verified as meeting the specified requirements of an organization's BQMS.
Containment	The control of regulated GE organisms in a matter that mitigates the release outside of controlled storage or packaging during movement, handling, or transfer.
Continual improvement	Recurring process to increase the ability to fulfill requirements and objectives.
Contractor	An organization or individual that signs a formal agreement to conduct activities. See External associates.
Control	An act or instance of controlling; also power or authority to guide or manage (example: control of documents means to properly manage the issuance, revision, and storage of documents).
Cooperator	A person or organization who enters a cooperative agreement (via legal agreement) for services directly related to BQMS processes. A service provider that is directly or indirectly involved with the introduction of regulated GE organisms under APHIS rules and regulations. Similarly, any person who grants permission to a permittee or a permittee's designated participant for the use of an experimental use pesticide at an application site owned or controlled by the cooperator.
Correction	Action to eliminate a detected nonconformance.
Corrective action	Action to eliminate the cause of a detected non-conformance.
Critical control points	The activities or processes where a vulnerability to non-compliance with APHIS regulations exists during an introduction of regulated GE organisms.
Design protocol	A documented procedure that a permit or notification holder uses to meet the performance standards governing a notification or to meet the conditions and other requirements of a permit.
Devitalization	Rendering regulated GE organisms nonviable (e.g., autoclaving, herbicide treatment, disking, deep burial, etc.). Removal or deprivation of vitality or of vital properties required to sustain life or reproduce.
Disposition	The transfer and fates of viable material produced from an environmental release.
Document	Information and its supporting medium (hard copy or electronic).
Document control	Ability to store, retrieve, and secure documents and records related to the quality

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	management system.
Documented procedure	A procedure that must be established, documented, implemented, and maintained.
Effectiveness	The extent to which planned activities are realized and planned results achieved. A voluntary participant of the BQMS Program defines their own effectiveness through its internal processes for monitoring, verification activities, corrective and preventive actions, continual improvement activities, and management reviews.
External	Refers to the parties involved in regulated activities including, but not limited to, suppliers and contractors, statutory and regulatory authorities, or other organizations that have an impact on, or will be affected by, the effectiveness or updating a BQMS.
External associates	Any individual, university, or business entity, external to the organization that is involved in activities of handling or managing regulated GE organisms, including service providers, cooperators, contractors, or sub-contractors.
Handling	Refers to the handling, transfer, and distribution of regulated GE organisms.
Identification	The ability to identify regulated GE organisms from movement, transfer, and pre-planting activities to devitalization and final disposition. A carefully controlled production and distribution system that maintains identification of regulated GE organisms from non-regulated or commercial products.
Introduction	An interstate movement, importation, or environmental field release of a genetically engineered organism regulated under 7 CFR Part 340.
Marking	The act of labeling, color coding, or other actions for identification and tracking purposes.
Monitor	To watch, verify, or check an activity for an intended purpose.
Must	Commanded or requested to do something; to be compelled; a requirement that must be completed (e.g., processes listed in the BQMS Audit Standard must be documented to conform to the requirement for program recognition).
Objective	An outcome toward which effort is directed; an aim, goal or end of action; a strategic position to be attained or a purpose to be achieved by a program such as BQMS.
Organization	In reference to the APHIS permit applicant and BQMS Program participant. The unit (company, entity, division, etc.) to which the BQMS Audit Standard applies.
Outsource	To procure services (as services needed by a business or organization) from a supplier not related to the business (e.g., outsourcing the production of regulated GE crops through cooperative or contract agreements).
Permitted organization	An organization that applies for and receives approval for an APHIS permit to move or release GE organisms into the environment.
Preventive action	Action to eliminate the cause of a potential non-conformance.
Procedure	Specified way to perform an activity.
Process	A set of interrelated or interacting activities which transforms inputs into outputs. A documented process means that a process must be established, documented, implemented and maintained.
Process realization	Developing documented procedures after analyzing critical control points for the introduction of regulated GE organisms.
Program	A plan or system under which actions may be taken toward a goal (e.g., The BQMS Program is an integrated management system for regulatory compliance).
Quality objective(s)	Written statements from Top Management (see definition) that are consistent and measurable with respect to the Quality Policy, which state a commitment to continual improvement.
Quality policy	The overall Quality Objectives. Intentions and direction of an organization regarding quality, as formally expressed by top management.
Quality Manual	A collection of quality management system documentation.

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Quality management system	A documented and implemented BQMS.
Records	Document stating results achieved or evidence of process.
Registered	An organization that has been acknowledged as meeting all BQMS requirements set forth in this document by an independent third-party audit. The organization becomes recognized by APHIS based on acceptance of the certification recommendation by the third-party auditor. (Recognition).
Regulated article/Regulated GE organism	See 7 CFR part 340 for Regulated Article. Any organism which has been altered or produced through genetic engineering, including any plant parts capable of propagation.
Requirements	Includes, but is not limited to, the requirements of the BQMS Audit Standard, the requirements outlined in the organization's Quality Manual, and applicable regulatory requirements.
Scope	Intention, object; extent of treatment, activity, or influence; the range of operation (e.g., the scope of our BQMS will include corn, soybean, and cotton programs).
Segregation	The act of separation or isolation of a crop variety or grain of a specific quality from others in the same class, intended to maintain its unique identity; the separation for special treatment or observation.
Separation	In reference to environmental release, refers to the distance required from other fields of sexually compatible species to minimize mixing (e.g., separation distance to minimize cross-pollination or gene-flow).
Service provider	For Clause 7.3, refers to suppliers, cooperators, contractors, and subcontractors that conduct activities under the scope of the BQMS.
Standard operating procedure	A controlled document that describes the standard methods and work instructions for a particular activity. Instructions for completing a task.
Supplier	Provides an organization with services regarding the regulated introduction of GE organisms. Services include, but are not limited to, transportation, storage, handling, and environmental release activities.
Top management	Person or group of people who directs and controls an organization.
Topography	Landscape, geography, and layout of natural and artificial surface features including, but not limited to: mountains, water bodies, and floodplains.
Validation	Confirmation, through the provision of objective evidence, that requirements have been fulfilled.
Verification	Confirmation by examination and documented objective evidence that specified requirements have been fulfilled.

Appendix B: List of Acronyms and Abbreviations

APHIS	Animal and Plant Health Inspection Service
BRS	Biotechnology Regulatory Services
BQMS	Biotechnology Quality Management System
CFR	Code of Federal Regulations
GE	Genetically Engineered
ISO	International Organization of Standardization
USDA	United States Department of Agriculture

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Appendix C: Documented Procedures, Objectives and Records Required by the BQMS Standard

Procedures	
Clause	Description
4.2.3	Management of documents
4.2.4	Management of records
6.2.2	Personnel training procedures
7.1.1	Site selection planning
7.2.1	Storage
7.2.2	Transport, movement, and import of regulated GE organisms
7.2.3(a)	Pre-planting handling and transfer
7.2.3(b)	Planting equipment preparation/cleaning
7.2.3(c)	Environmental field release site boundary identification and/or marking
7.2.3(d)	Documentation of environmental field release site
7.2.3(e)	Method(s) of reproductive growth control
7.2.3(f)	Harvest preparation and equipment cleaning
7.2.3(g)	Volunteer monitoring
7.2.4	Post-harvest handling and transfer
7.2.5	Devitalization and final disposition of regulated GE organisms
7.2.6	Regulatory compliance reporting and resolution
8.2.1	Internal Audit
8.4.2	Corrective Action
8.5	Preventive Action
Documented Statements, Lists, Charts and Objectives	
Clause	Description
4.2.1(b)	Policies and objectives
4.2.3	Master document list
5.4	Organizational chart
Records	
Clause	Description
5.6.1	External communication
5.7.1	Management reviews
6.2.2	Competency, awareness, and training
7.2.2	Transport, movement, and import of regulated GE organisms
7.2.3	Environmental release planning and monitoring
7.2.4	Post-harvest handling and transfer
7.2.5	Devitalization and final disposition
7.2.6	Regulatory compliance reporting and resolution
7.3	Management of external associates
8.2.1	Internal audit
8.4.2	Corrective action
8.5	Preventive action