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**United States Department of Agriculture  
APHIS**



*BIOTECHNOLOGY PERMITS*

*ISO 9001:2008*

*QUALITY MANUAL*

October 19, 2009

Rev. 4

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The Biotechnology Permits ISO 9001:2008 Quality Manual is a controlled document and is maintained by the ISO/Management Analyst in Biotechnology Regulatory Services (BRS).

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**Core**

- C1 Receive and Review Applications
- C2a Conduct Preliminary Assessment of Notifications
- C2b Conduct Preliminary Assessment of Permits
- C3a Consult States - Notifications
- C3b Consult States - Permits
- C4a Finalize Assessment and Issue Notifications
- C4b Finalize Assessment and Issue Permits
- C5 Manage Requests for Information

**Support**

- S20 Establish and Maintain BRS Plans and Objectives
- S21 Provide Training and Knowledge
- S22a Manage Documents
- S22b Manage Records
- S23 Collect and Analyze Performance Data
- S24 Conduct Reviews of the System Performance
- S25 Conduct Internal Audits
- S26 Manage and Resolve Customer Feedback
- S27 Maintain the ePermits System
- S28 Perform Corrective and Preventive Actions
- S29 Manage Nonconformity

# Section 1 Overview

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## 1.1 Introduction

The Plant Protection Act of 2000 prevents the introduction and spread of crop and environmental pests through agricultural quarantine and inspection programs. If allowed free entry, pest invertebrates, pathogens, or noxious weeds might establish and spread, causing many millions, if not billions, of dollars annually in damage. Native plants, including endangered species, might also be harmed.

The United States Department of Agriculture (USDA) issues permits to enable the introduction (importation, interstate movement, and environmental release) of certain genetically engineered (GE) organisms for education, research, and commerce. All regulated introductions of GE organisms must be authorized by the Animal and Plant Health Inspection Service (APHIS) under either its permitting or notification procedures. The BRS Permits Team and Environmental Risk Analysis Team carefully weigh risks and benefits when evaluating applications for permits and notifications. Permits expedite trade and provide information to importers to help prevent the invasion of plant pests. A lack or abuse of permits and notifications may allow pest infested materials to move into nurseries, farms, markets, or research institutions.

This Quality Manual documents the Quality Management System (QMS) that BRS designed to consistently provide products that meet customer/stakeholder requirements, fulfill regulatory requirements, and improve the quality of the organization's services. This Quality Manual establishes compliance with the ISO 9001:2008 Quality Management System Requirements and applies to:

### Applications for Permits and Notifications for Genetically Modified Organisms

- Permit applications, using APHIS Form 2000/ePermits, provide details regarding the nature of the GE organism to be introduced and the conditions that will be used to prevent the spread and establishment of the organism in the environment.
- Notification applications are an administratively-streamlined alternative to the permit. The GE plant must meet specified eligibility criteria, and the introduction must meet certain pre-defined performance standards.

The Quality Manual describes the administrative processes that BRS uses to issue documents related to genetically engineered microorganisms. The Quality Manual documents our commitment to the following:

- Improve the quality of work.
- Maintain consistency in work processes.
- Describe current, acceptable processes for planning, conducting, evaluating, and improving the work to produce permits and notifications for genetically modified plant propagules.
- Use for training, auditing, and reviewing work processes.
- Develop a continual process improvement platform.

## 1.2 Scope

The USDA – Animal and Plant Health Inspection Service – BRS based in Riverdale, Maryland implements the coordination and administration of the review and issuance of notifications, permits, and information for genetically modified plants and microorganisms under Title 7 Code of Federal Regulations (CFR) Part 340.

Additional processes are outsourced to other parts of the U.S. Government:

- Issuing and Maintaining Scientific and Regulatory Guidance Documents – Other BRS Programs
- Facility Inspections – APHIS
- Purchasing – USDA
- Recruiting – APHIS
- Maintaining the Computer Network – APHIS
- Managing Information Security – APHIS

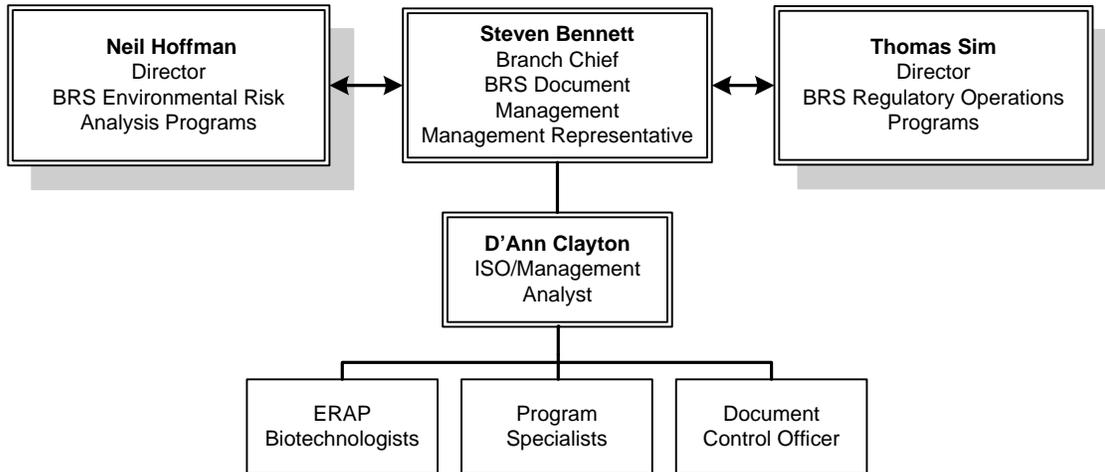
## 1.3 Application

BRS' quality management system satisfies the requirements of the ISO 9001:2008 Standard. Due to the nature of BRS activities, product, and the scope of the QMS, the ISO 9001:2008 requirements that can not be applied will be considered for exclusion. The following ISO 9001:2008 requirements are excluded from compliance.

- 7.3 Design and Development. BRS Regulatory Operations Programs (ROP) and Environmental Risk Analysis Programs (ERAP) do not have design capabilities. Therefore clause 7.3 of the ISO 9001:2008 Standard does not apply to the QMS described by this manual.
- 7.4 Purchasing. BRS ROP and ERAP do not have purchasing facilities or functions. BRS uses the USDA-wide Purchasing Function to qualify vendors and issue purchase orders. Therefore clause 7.4 of the ISO 9001:2008 Standard does not apply to the QMS described by this manual.
- 7.5.2 Validation of Processes for Production and Service Provision. BRS ROP and ERAP operate service processes where product characteristics are transparent to interested parties and verifiable by BRS Regulatory Operations and the applicants. Therefore clause 7.5.2 of the ISO 9001:2008 Standard does not apply to the QMS described by this manual.
- 7.6 Control of Monitoring and Measuring Devices. BRS ROP and ERAP do not use measuring or monitoring devices to create its products that meet customer or regulatory requirements. Therefore, clause 7.6 of the ISO 9001:2008 Standard does not apply to the QMS described by this manual.

## 1.4 Organization

The relationship of BRS personnel who manage, perform, and verify work affecting quality is defined in Figure 1. BRS Permits and Environmental Risk Analysis Teams. Section 5.5.1 presents the details regarding responsibilities and authorities.



**FIGURE 1. BRS Permits and Environmental Risk Analysis Teams**

## Section 2 Quality Policy

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### 2.1 Policy Statement

BRS Regulatory Operations Managers initially approved the following Quality Policy. Copies of the Quality Policy are available in the Quality Management System Folder in the Document Warehouse on the I-drive network server.



#### QUALITY POLICY

We provide regulatory oversight and customer satisfaction through continual improvement.

Our commitment is to establish and meet objectives and other requirements that will protect American plant resources and provide our customers with permits, authorizations, and information that meet their needs. To achieve this, we conduct our business in an environment of continual improvement. This means we use our QMS to:

- Provide training so we have the skills to meet our job responsibilities.
- Maintain documented procedures for our key processes so they remain transparent to us and the public.
- Control our key processes so they are effective and efficient in meeting our stated obligations.
- Measure important aspects of our key processes and take timely action to improve performance.
- Continually improve customer satisfaction and the effectiveness of our QMS.

Steven M. Bennett  
Chief, Document Management Branch  
Biotechnology Regulatory Services

Date: October 3, 2007

## Section 3 Definitions and Acronyms

---

### 3.1 Definitions

**Animal and Plant Health Inspection Service (APHIS):** USDA Agency responsible for protecting and promoting U.S. agricultural health, administering the Animal Welfare Act, and carrying out wildlife damage management activities.

**Biotechnology Regulatory Services (BRS):** BRS implements the APHIS regulations for certain genetically engineered (GE) organisms that may pose a risk to plant health, in order to protect plant health. In the regulation of genetically engineered organisms, BRS is part of a science-based federal regulatory framework to protect America's agricultural resources and the broader environment.

**Biotechnology Notifications:** Documents issued by APHIS-BRS to allow a genetically modified plant material to move into the U.S., through the U.S., or between states. Materials eligible for this process are typically of lower risk as compared to regulated items that receive a permit. The types of notifications are described below.

**Notification for Movement from State to State (Interstate Movement):** Documents issued by APHIS-BRS to allow a genetically modified plant material to move within the U.S. from containment in one state to containment in another state. Regulation 7 CFR 340 requires this notification to be issued or denied within 10 days.

**Notification for Import Movement:** Documents issued by APHIS-BRS to allow a genetically modified plant material to move within the U.S. from containment in one state to containment in another state. Regulation 7 CFR 340 requires this notification to be issued or denied within 30 days.

**Notification for a Release into the Environment:** Documents issued by APHIS-BRS to allow genetically modified plant material to be released outside the constraints of physical confinement that are found in a laboratory, containment greenhouse fermented, or other contained structure. Regulation 7 CFR 340 requires this notification to be issued or denied within 30 days.

**Notification for Interstate Movement and Release into the Environment:** Documents issued by APHIS-BRS to allow genetically modified plant material to be released outside the constraints of physical confinement that are found in a laboratory, containment greenhouse fermented, or other contained structure. Regulation 7 CFR 340 requires this notification to be issued or denied within 30 days.

### 3.1 Definitions, cont.

**Biotechnology Permit:** Documents issued by APHIS-BRS to allow a single genetically modified plant material to move into the U.S., through the U.S, or between states. Types of permits are described below.

**Interstate Movement Permit:** Documents issued by APHIS-BRS to allow a single genetically modified plant material to move within the U.S. from containment in one state to containment in another state Regulation 7 CFR 340 requires this permit to be issued or denied within 60 days.

**Import Permit:** Documents issued by APHIS-BRS to allow a single genetically modified plant material to move from a foreign country to specific locations(s) within the United States. These locations must possess approved facilities capable of containing any risk. Regulation 7 CFR 340 requires this permit to be issued or denied within 60 days.

**Release into the Environment Permit:** Documents issued by APHIS-BRS to allow a single genetically modified plant material to be released outside the constraints of physical confinement that are found in a laboratory, containment greenhouse fermented, or other contained structure. Regulation 7 CFR 340 requires this permit to be issued or denied within 120 days.

**CBI:** Confidential Business Information. Information protected from disclosure under section 5 U.S.C. § 552(b)(4), of the Freedom of Information Act (FOIA). CBI includes 'Trade Secrets', commercial information, and financial information for which substantial competitive harm could result if information was disclosed. CBI is similar to Sensitive Secure Information (SSI) and Sensitive Business Unclassified (SBU) information.

**Compliance and Inspection Branch (CIB):** Compliance specialists and APHIS inspectors ensure compliance with all relevant provisions of the regulations, including authorizations under the permitting and notification procedures by performing targeted inspections of field tests and thoroughly evaluating all potential noncompliance incidents. CIB also evaluates facilities, equipment, records of developers, and potential incidents reported by permittees.

### 3.1 Definitions, cont.

**Containment Facility:** Prior to issuing a Permit for Import and/or Interstate Movement, BRS needs proof that the facility that will house the material is capable of containing it to prevent release into the environment. The Program Specialist checks a database look-up table for evidence that the containment facility was inspected. If the facility has not been inspected, current policy dictates whether or not to initiate a facility inspection. If one is needed, the Program Specialist notifies the Compliance and Inspection Branch. The Compliance and Inspection Branch contacts the regional representative to arrange for an inspection of the facility.

**Endangered Species Act (ESA):** Federal legislation intended to provide a means whereby the ecosystems upon which endangered and threatened species depend may be conserved, and provide programs for the conservation of those endangered species and threatened species, thus preventing extinction of native plants and animals.

**Environmental Risk Analysis Programs (ERAP):** The Environmental Risk Analysis Programs include the Plants Branch and the Plant Pests and Protectants Branch. These branches address potential environmental impacts of genetically engineered organisms on the environment by conducting risk assessments of these products. ERAP has experts in scientific fields (e.g., plant pathology, botany, animal science, entomology, virology, ecology, environmental science, molecular biology, and biochemistry) who review permit applications, petitions for deregulation, permit concerns, and proposed regulatory changes.

**ePermits:** A secured web-based tool that provides customers with the ability to apply for a notification or permit, check the status of an application, and view the application online. ePermits also enables BRS and Federal regulatory officials to issue, track, and verify the validity of import permits, thus reducing data-entry, processing, delivery time, and expense.

**Genetically Engineered Organism:** The genetic modification of organisms by recombinant DNA techniques.

**National Environmental Policy Act:** The National Environmental Policy Act (NEPA) declares a national policy, which promotes efforts that prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man; to enrich the understanding of the ecological systems and natural resources important to the Nation; and to establish a Council on Environmental Quality. The NEPA process is intended to assist public officials in making decisions that are based on an understanding of environmental consequences. Establishes policy, sets goals, and provides means for carrying out the policy. Declares a national policy which will encourage productive and enjoyable harmony between man and his environment; to promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man; to enrich the understanding of the ecological systems and natural resources important to the Nation; and to establish a Council on Environmental Quality.

**Organism:** Any active, infective, or dormant stage or life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids, viruses, or any entity characterized as living, related to the foregoing.

**Petition:** Request for the deregulation of genetically modified plant material. This process is not included in ISO certification at this time (future enhancement).

**Policy Statement:** A declaration of a standard operating procedure.

**Regulatory Operations Programs:** The Regulatory Operations Programs includes the Compliance and Inspection Branch and the Document Management Branch. These branches manage the administrative portion of notification acknowledgement and permit issuance for all introductions of genetically engineered organisms, direct compliance inspections, respond to noncompliance incidents, and maintain records of notifications and permits, which can include field reports and compliance inspections.

**Risk Assessment:** The process of identifying hazards and evaluating the consequences and likelihood of specific hazards in qualitative or quantitative terms. This process should include estimates of uncertainty and should be objective, repeatable, and science-based.

**Stakeholder/Customer:** A person or organization with valid interests in a given situation or action and who is affected, or can be affected, by the USDA's actions. The term applies to:

- Permit applicants (academic or commercial entity)
- USDA Field Officers (e.g., Plant Protection and Quarantine Officers)
- Cooperating local, State (e.g., State Plant Regulatory Officials) and Federal (e.g., Department of Homeland Security, Custom and Border Control) agencies
- The Biotechnology Industry
- BRS Employees

**Territories or Possessions:** These locations fall within USDA's regulatory authority; Guam, the Northern Mariana Islands, Puerto Rico, and the Virgin Islands of the United States.

**7 CFR:** The Code of Federal Regulations (CFR) is published in the Federal Register by the Executive departments and agencies of the Federal Government. Title 7 contains the regulations of the Department of Agriculture, Animal and Plant Health Inspection Service Parts 300 to 399 – Agriculture.

## 3.2 Acronyms

<b>Acronym</b>	<b>Definition</b>
APHIS	Animal and Plant Health Inspection Service
BRS	Biotechnology Regulatory Services
CAR	Corrective Action Request
CFR	Code of Federal Regulations
CIB	Compliance and Inspection Branch
DCO	Document Control Officer
DMBC	Branch Chief, BRS Document Management Branch
ERAP	Environmental Risk Analysis Programs
ESA	Endangered Species Act
FOIA	Freedom of Information Act
GE	Genetically Engineered
MRP	Marketing and Regulatory Programs
NEPA	National Environmental Policy Act
PAR	Preventive Action Request
PPQ	Plant Protection and Quarantine
QMS	Quality Management System
ROP	Regulatory Operations Programs
PS	Program Specialist
SPHD	State Plant Health Director
SPRO	State Plant Regulatory Officials
USDA	United States Department of Agriculture

## Section 4 Quality Management System

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### 4.1 General Requirements

BRS established, documented, implemented, and maintains a Quality Management System in accordance with the ISO 9001:2008 Quality Management System Requirements and Standards, and U.S. regulatory policies and standards. BRS continually improves the effectiveness of its QMS by:

- a) Identifying the processes needed for its operations and the application of our processes throughout the organization;
- b) Determining the sequence and interaction of these primary processes;
- c) Determining criteria and methods needed to ensure that both the operation and management of these processes are effective;
- d) Ensuring the availability of resources and information necessary to support the operation and monitoring of these processes;
- e) Monitoring, measuring, and analyzing these processes; and
- f) Ensuring the implementation of actions necessary to achieve planned results and continual improvement of these processes.

The key processes within the BRS QMS include processes for management activities, provision of resources, product realization, and measurement and are presented in Figure 2 through Figure 4.

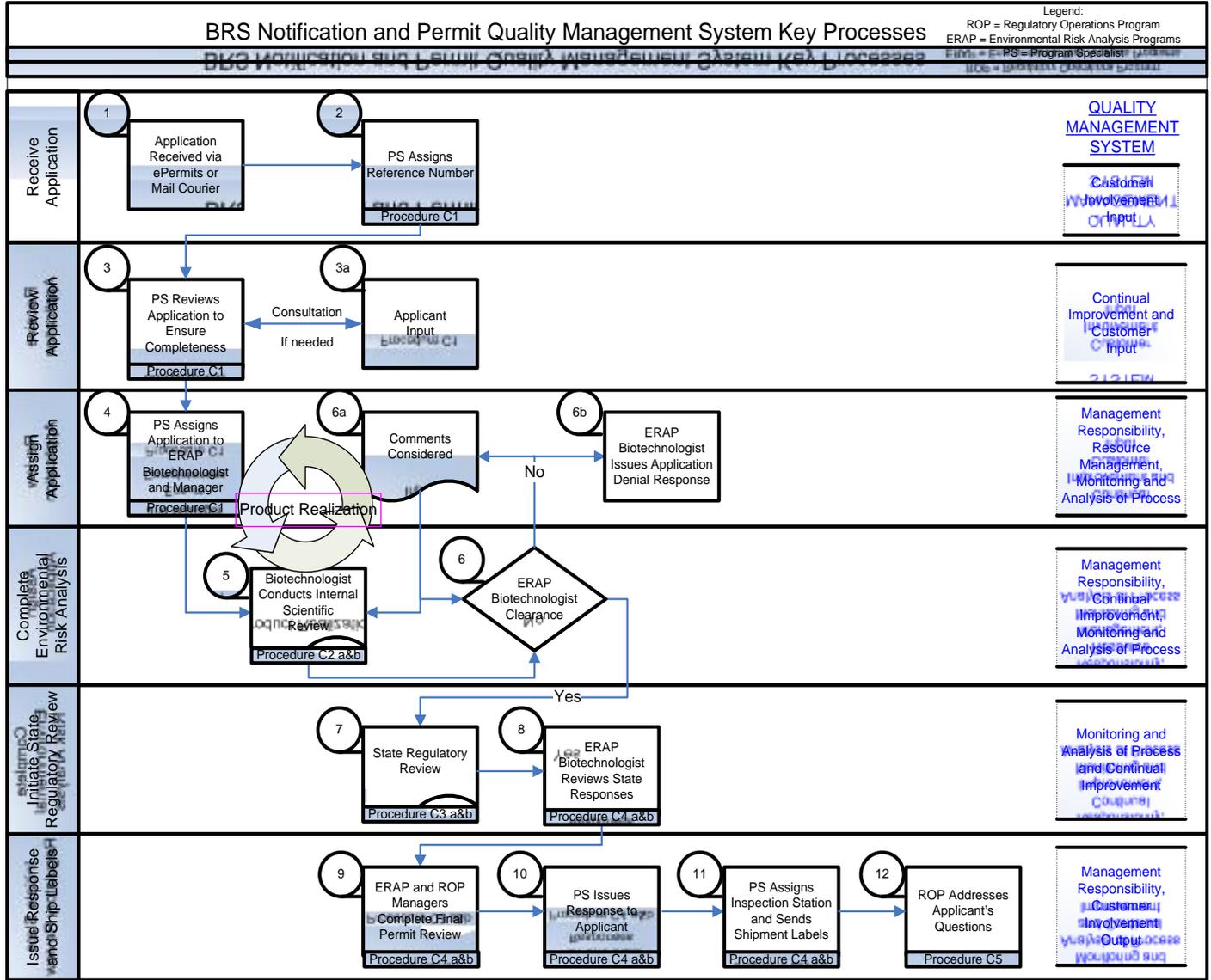
Figure 2. BRS Notification and Permit Quality Management System Key Processes displays the processes for management activities, provision of resources, product realization, measurement and analysis, continual improvement, and additional processes needed for the QMS.

Figure 3. BRS Regulatory Operations – Interaction of Key Processes presents the interactions of the ROP and ERAP key processes.

Figure 4. BRS ISO 9001:2008 Conformity Matrix displays cross-references between the BRS QMS processes and the requirements of the ISO 9001:2008 Standard.

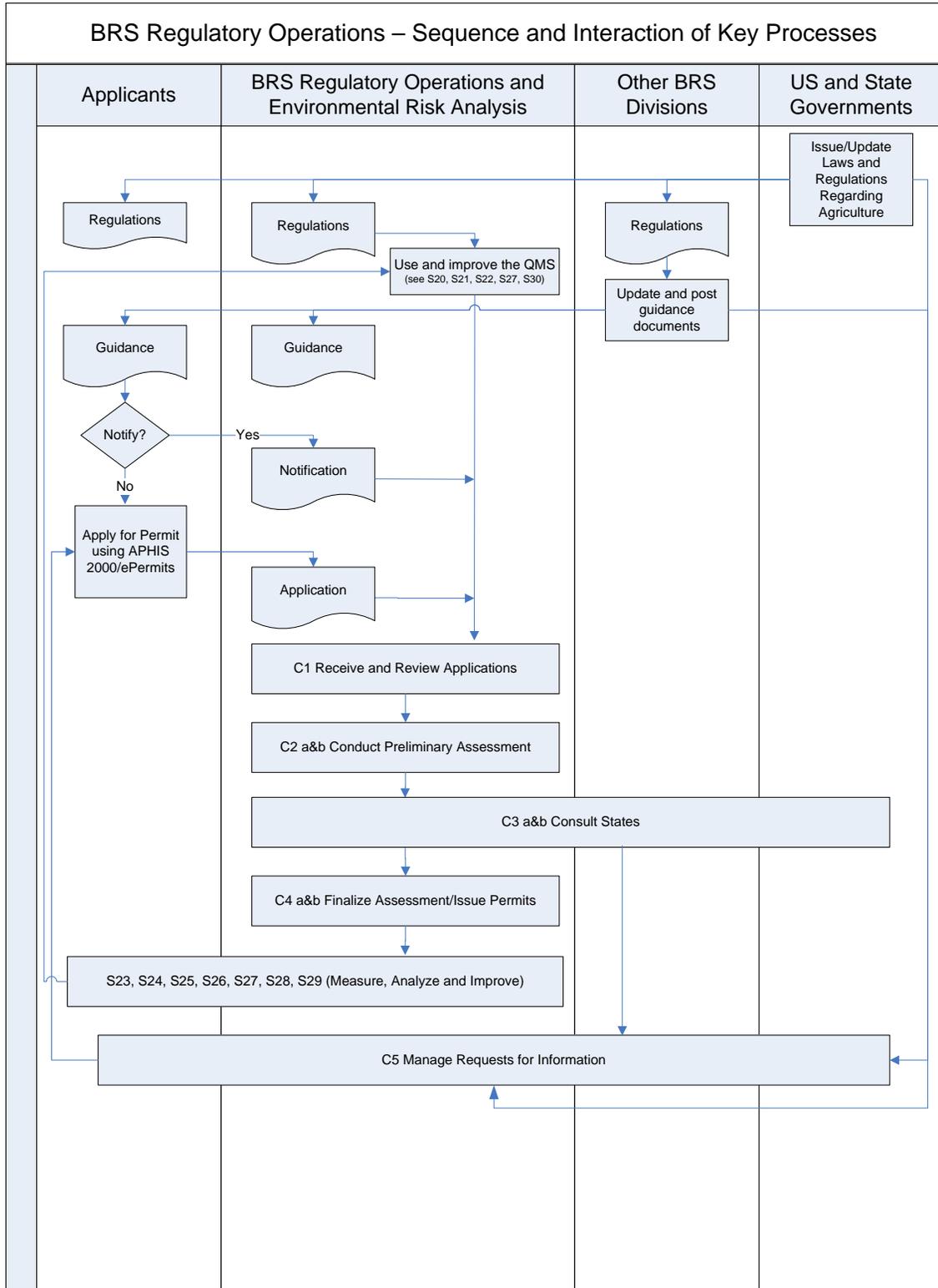
Outsourced processes are controlled by subject matter professionals (with necessary clearance levels) using documented policies and procedures that comply with the regulations used by the BRS ROP and ERAP.

### 4.1.1 Processed-Based Quality Management System Model



**FIGURE 2. BRS Notification and Permit Quality Management System Key Processes**

### 4.1.2 Interaction of Key Processes Model



**FIGURE 3. BRS Regulatory Operations – Interaction of Key Processes**

### 4.1.3 ISO 9001:2008 Conformity Matrix

ELEMENT	BRS QMS Document Code = Contributing to ISO 9001:2000 conformity																																							
	Section 1	Section 2	Section 3	Section 4	Section 5	Section 6	Section 7	Section 8	SPARE	SPARE	C1	C2 a & b	C3 a & b	C4 a & b	C5	SPARE	SPARE	SPARE	SPARE	SPARE	S20	S21	S22 a & b	S23	S24	S25	S26	S27	S28	S29	SPARE									
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FIGURE 4. BRS ISO 9001:2008 Conformity Matrix

## 4.2 Documentation Requirements

### 4.2.1 General

The BRS QMS documentation includes:

- a) BRS' Quality Policy in Section 2.1.
- b) BRS' Quality Objectives in Section 5.4.1.
- c) This Biotechnology Permits ISO 9001:2008 Quality Manual.
- d) Documented procedures required by ISO 9001:2008, which include 4.2.3, Control of Documents (S22a); 4.2.4 Control of Records (S22b); 8.2.2 Internal Audit (S25); 8.3, Control of Nonconforming Product (S29); 8.5.2, Corrective Action (S28); and 8.5.3, Preventive Action (S28). Where the term documented procedures appears within this Quality Manual, the procedures are established, documented, implemented and maintained and may be in any specified format or type of medium.
- e) Documents needed by the organization (i.e., procedures, work instructions) to ensure the effective planning, operation, and management of its processes.
- f) Records required by ISO 9001:2008, per Procedure S22b Manage Records.

The extent of the BRS QMS is based on:

- a) The size of the organization and type of activities.
- b) The complexity of processes and their interactions.
- c) The competence of personnel.

### 4.2.2 Quality Manual

This document is the Quality Manual for the BRS QMS. BRS has established and maintains this Quality Manual, which includes:

- a) The scope of the QMS, including details of and justification for any exclusion, per Section 1.2.
- b) Reference to the documented procedures established for the QMS. The relationship between the requirements of this Standard and the documented procedures is clearly shown, per Section 4.1.3.
- c) Description of the interaction between the processes of the QMS, per Sections 4.1.1 and 4.1.2.

The Quality Manual becomes uncontrolled after printed from the I-drive network server.

### **4.2.3 Control of Documents**

Documents required by the QMS are managed per Procedure S22a Manage Documents including:

- a) Approve documents for adequacy prior to issue.
- b) Review and update as necessary and re-approve documents.
- c) Ensure that changes and the current revision status of documents are identified.
- d) Ensure that relevant versions of applicable documents are available at points of use.
- e) Ensure that documents remain legible and readily identifiable.
- f) Ensure that documents of external origin are identified and their distribution managed using the BRS Document Warehouse.
- g) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The documents critical to the QMS are approved and controlled. These documents include the Quality Manual, Procedures, Work Instructions, Forms, and externally generated documents and records.

QMS documents are designated as approved when the DMBC's name appears in the approval section of the Revision History. The latest version of the controlled documents is available to all BRS employees on the I-drive network server. A printed copy of a QMS document is for reference use only and available upon request.

The Document Control Officer maintains a "Master List of Documents" which includes all internal and external documents used within the QMS.

### **4.2.4 Control of Records**

The BRS QMS controls the records to provide evidence of conformity to requirements and the effective operation of the QMS. These records are collected, filed, and stored in a suitable environment to prevent damage, deterioration, or loss.

Procedure S22b Manage Records has been established to define the mechanisms needed for the identification, storage, protection, retrieval, retention time, and disposition of records.

## **Section 5 Management Responsibility**

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### **5.1 Management Commitment**

Management communicates its commitment to continually improve the QMS and meet customer/stakeholder, statutory, and regulatory requirements by:

- Establishing and communicating the Quality Policy and Quality Objectives to BRS.
- Conducting Management Reviews.
- Ensuring a provision of resources needed to attain objectives and customer satisfaction.

### **5.2 Customer (Stakeholder) Focus**

The BRS Management Team ensures that customer/stakeholder requirements are defined and expectations are achieved with the goal of enhancing customer satisfaction, per Procedure S26 Manage and Resolve Customer Feedback.

### **5.3 Quality Policy**

The Quality Policy, as documented in Section 2.1 of this manual, is reviewed by management for suitability and revised as necessary per Procedure S20 Establish and Maintain BRS Plans and Objectives.

### **5.4 Planning**

#### **5.4.1 Quality Objectives**

The Management Team establishes and updates quality objectives using Procedure S20 Establish and Maintain BRS Plans and Objectives and Procedure S23 Collect and Analyze Performance Data.

Overall quality objectives are translated into performance standards and measures for processes, which are integrated into the process descriptions.

Changes to the quality objectives are planned using the S20 Establish and Maintain BRS Plans and Objectives process and are controlled and formalized through amendments in QMS documents using the process outlined in Procedure S22a Manage Documents and S22b Manage Records.

BRS' quality objectives include:

- Maintaining customer satisfaction of more than 3.5 (moving average basis).
- Complying with federally mandated timeframes to process permits and notifications.
- Maintaining zero non-complying permits or notifications.

## 5.4.2 Quality Management System Planning

The Management Team ensures that the planning of the QMS is completed in order to meet the requirements outlined in Section 4.1 of this Quality Manual and the quality objectives featured in Section 5.4.1 of the Quality Manual. The Management Team also ensures that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.

## 5.5 Responsibility, Authority, and Communication

### 5.5.1 Responsibility and Authority

The Management Team ensures that responsibilities, authorities, and competencies (i.e., corresponding abilities, skills, knowledge) of the personnel within the scope of the QMS are defined and communicated within the organization per the organizational chart, QMS procedures, and each position description maintained by APHIS HR.

Figure 1, in Section 1.4 of this manual, displays the organizational chart with positions of authority and responsibilities for all who manage and produce work results that affect quality.

The responsibilities and authorities are summarized below:

**Branch Chief, BRS Document Management Branch (Management Representative):** Manages and provides leadership in coordinating and consolidating matters pertaining to processing permits, processing environmental assessments, identification, processing risk assessments, and action decisions. Responsible for the overall implementation and continued compliance of the quality management system including:

- Conformity of QMS to ISO 9001:2008 with provision of advice and support to others relative to the quality management system.
- Oversight of Liaison with the external registrar.
- Oversight of the internal audit and document control processes that support continual improvement.
- Process Owner of the objective development and management review processes.
- Communicates with all Leadership regarding ISO related activities.

**CAR/PAR Initiator:** Any employee who determines that a Corrective Action Request (CAR) or Preventive Action Request (PAR) are required or should be implemented.

### 5.5.1 Responsibility and Authority, cont.

**Director, BRS Regulatory Operations Programs:** Supervisor; manages and provides leadership for the two branches within Regulatory Operations Programs. Responsible for the performance of the Division including:

- The overall achievement of quality objectives.

**Document Control Officer:** Provides guidance and assistance with the oversight and management of documents within the scope of the quality management system including related training, document version control, and confidential business information. Also assists with ongoing initiatives related to the QMS.

**Management/ISO Analyst:** Responsible for the effective day-to-day implementation of the processes that fall within the scope of the BRS quality management system.

- Ensures that process measurement data is collected, analyzed and those opportunities for improvement are identified and acted upon.
- Approves changes to processes.
- Responsible for providing support and expertise to Process Owners and others in BRS in areas relating to the use of statistical data and improvement activities.
- Tracks and monitors CARs and PARs to ensure corrective and preventive action requests are completed and verified for effectiveness before being closed out. Informs management of any barriers encountered in this process.

**Program Specialists:** Provide customer and stakeholder service, reviews incoming applications and correspondence, and processes permits for previously documented regulated articles. Responsible for the processes and tasks as distributed per the procedure, which includes monitoring processes for effectiveness.

- Suggest changes using the formal change process.

**Risk Assessment Scientists - Biotechnologist:** Subject matter specialist who provides risk assessments for introduction of genetically engineered organisms for regulatory matters (notifications and permits). Responsible for the proper conduct of risk assessment tasks for which they have ownership.

- Suggest changes to the work methods using the formal change process.

### **5.5.2 Management Representative**

BRS has appointed the Branch Chief, Document Management Branch as the Management Representative who is responsible for the following:

- Ensures the processes needed for the QMS are established, implemented, and maintained.
- Reports the performance of the QMS and needs for improvement to the Management Team.
- Ensures the awareness of customer requirements are promoted throughout BRS.

### **5.5.3 Internal Communication**

Internal communication is accomplished in person, via e-mail, staff meetings, newsletters, and QMS employee orientation training.

## **5.6 Management Review**

### **5.6.1 General**

The BRS Management Team reviews the organization's QMS per Procedure S24 Conduct Reviews of System Performance. The Management Team conducts these reviews at least once a year to ensure continuing suitability and adequacy, discuss overall performance in achieving targets, and determine requirements to address gaps.

Records of management reviews are maintained per Procedure S20 Establish and Maintain BRS Plans and Objectives.

### **5.6.2 Review Input**

The input to management review includes, but is not limited to:

- Results of audits.
- Customer and stakeholder feedback.
- Process performance and product conformity.
- Status of preventive and corrective actions.
- Follow-up actions from previous management reviews.
- Planned changes that could affect the QMS.
- Recommendations for improvement.
- Quality Policy and Quality Objectives.

### **5.6.3 Review Output**

The output from management review includes decisions and actions related to:

- Improvement of the effectiveness of the QMS and its processes.
- Improvement of product related to customer and stakeholder requirements.
- Resource needs.

## **Section 6 Resource Management**

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### **6.1 Provision of Resources**

BRS' Management Team plans and provides resources to implement and maintain the QMS, continually improve its effectiveness, and enhance customer satisfaction by meeting customer requirements per Procedures S20 Establish and Maintain BRS Plans and Objectives and S23 Collect and Analyze Performance Data. Plans identify the need for:

- Adequate personnel to conduct the activities identified in the BRS processes so that process performance requirements can be met.
- Appropriate organizational structure necessary to manage the processes.

### **6.2 Human Resources**

#### **6.2.1 General**

Human Resources are allocated based on the overall establishment of BRS QMS Plans and Objectives. The Management Team ensures that personnel, who perform work that affects quality of product, are competent on the basis of appropriate education, training, skills and experience.

#### **6.2.2 Competence, Awareness, and Training**

The Immediate Supervisors provide orientation to new employees and ensure that performance element standards are defined in employee performance plans to impart relevance and importance of an employee's activities and how they contribute to the organization's quality objectives per Procedure S21 Provide Training and Knowledge.

Employee Performance Reviews are conducted by the Immediate Supervisor twice a year to evaluate effectiveness and training needs are assessed to determine whether formal/on-the-job training will enhance product quality and customer satisfaction. Records of training are maintained in USDA's secured AgLearn system, which records training activity for staff members. Records of education, skills, and experience are maintained in the APHIS Human Resources office.

### **6.3 Infrastructure and Work Environment**

BRS is provided with needed workspace, services, and information technology as a part of the overall APHIS budgeting and provisioning process. BRS Biotechnology Permitting uses special facilities for maintaining the security of intellectual property and other information that belongs to applicants for permits and notifications as outlined in Procedure S27 Maintain the ePermits System.

## **Section 7 Product Realization**

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### **7.1 Planning of Product Realization**

BRS plans and develops the processes needed for product realization consistent with the requirements of the other processes of the QMS per Section 4.1 of this Quality Manual. In planning product realization, BRS determines the following, as appropriate:

- Quality objectives and requirements for the product.
- The need to establish processes, documents, and provide resources specific to the product.
- Required reviews and audits specific to the product.
- Records needed to provide evidence that the realization processes and resulting product fulfill requirements, per Procedure S22b Manage Records.

### **7.2 Customer (Stakeholder) – Related Processes**

#### **7.2.1 Determination of Requirements Related to the Product**

Customers request BRS permitting services by accessing the APHIS ePermits web-based system to apply for a permit/notification online, check the status of the application, view issued permits/notifications, and view other responses. The web-based system is designed to ensure that all the information including statutory and regulatory requirements, which are required to perform the service, are supplied by the customer or stakeholder.

#### **7.2.2 Review Requirements Related to the Product**

The customer and stakeholder requirements are reviewed to ensure that product requirements are adequately defined and BRS is equipped to fulfill the requirements.

Adequate records of stakeholder requirements and the outcome of the review are maintained.

Where product requirements are changed, BRS ensures that relevant documents are amended and relevant personnel are made aware of the changed requirements.

#### **7.2.3 Customer (Stakeholder) Communication**

BRS has determined and implemented effective arrangements for communicating with customers and stakeholders in relation to:

- Biotech Query (e-mail: [bioquery@aphis.usda.gov](mailto:bioquery@aphis.usda.gov))
- Messaging (ePermits and email)
- Customer and stakeholder feedback, including customer complaints per Procedure S26 Manage and Resolve Customer Feedback.
- Amendments (Contracts do not apply to BRS ROP and ERAP and are not applicable.)

## **7.3 Design and Development**

Exclusion: This element does not apply to BRS ROP and ERAP. Justification: ROP and ERAP do not have design capabilities. In the event that BRS receives design capabilities, the ISO/Management Analyst is responsible for ensuring this element is addressed where necessary.

## **7.4 Purchasing**

Exclusion: This element does not apply to BRS ROP and ERAP. Justification: ROP and ERAP do not have purchasing facilities/functions or products, which require purchased product inspections. This function is handled through other government agencies. In the event that BRS receives purchasing facilities or functions, the ISO/Management Analyst is responsible for ensuring this element is addressed.

## **7.5 Production and Service Provision**

### **7.5.1 Control of Production and Service Provision**

BRS plans and implements the procedures for delivery of services to ensure that they are completed in a controlled manner. Processes are fully developed in procedures, work instructions, and in supporting/reference documentation to facilitate process execution.

The procedures incorporate verification steps where required and are monitored to ensure that they are completed under controlled conditions. If problems in delivery of service arise, customers (stakeholders) are encouraged to immediately report situations and prompt resolution is initiated per Procedure S26 Manage and Resolve Customer Feedback.

### **7.5.2 Validation of Processes for Production and Service Provision**

Exclusion: This element does not apply to BRS ROP and ERAP. Justification: The changes to existing key processes are validated prior to use of product or service. In the event the current process changes, the ISO/Management Analyst is responsible for ensuring this element is addressed.

### **7.5.3 Identification and Traceability**

Where appropriate, BRS identifies the product by suitable means throughout product realization. BRS identifies the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, BRS controls and records the unique identification of the product as referenced in Section 4.2.4 of this manual.

## **7.5 Production and Service Provision, cont.**

### **7.5.4 Customer (Stakeholder) Property**

BRS exercises care with Customer (Stakeholder) property while it is under the organization's control or being used by BRS. BRS identifies, verifies, protects, and safeguards Customer (Stakeholder) property provided for use or incorporation into the product.

If Customer (Stakeholder) property is lost, damaged, or unsuitable for use, the event is reported to the Customer (Stakeholder) and records are maintained.

Note: Customer (Stakeholder) property may include intellectual property and confidential business information.

### **7.5.5 Preservation of Product**

BRS preserves the conformity of the product during internal processing and delivery to the intended destination by using appropriate resources (i.e., ePermits secured web-based system, Lotus Notes e-mail system, and the Document Warehouse data repository). Preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product.

## **7.6 Control of Measuring and Monitoring Devices**

Exclusion: This element does not apply to BRS ROP and ERAP. Justification: ROP and ERAP do not have equipment or special tools to take measurements that verify the conformity of product to specifications. In the event this element becomes applicable, the ISO/Management Analyst is responsible for ensuring this element is addressed.

## **Section 8 Measurement, Analysis, and Improvement**

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### **8.1 General**

BRS plans and implements the monitoring, measurement, analysis and improvement needed to:

- Demonstrate conformity of the product.
- Ensure conformity of the QMS.
- Continually improve the effectiveness of the QMS.

This includes the determination of applicable methods, including statistical techniques, and the extent of their use.

### **8.2 Monitoring and Measurement**

#### **8.2.1 Customer (Stakeholder) Satisfaction**

BRS measures customer satisfaction in a number of ways:

- Utilizing periodic customer surveys and analysis of feedback data.
- Analyzing customer complaints per Procedure S26 Manage and Resolve Customer Feedback.
- Evaluating process performance standards and measures which are derived from customer requirements.

BRS uses the information generated from these sources in the review process to assess the level of satisfaction and determine the need for improvement actions per Procedure S23 Collect and Analyze Performance Data and Procedure S24 Conduct Reviews of System Performance.

## **8.2 Monitoring and Measurement, cont.**

### **8.2.2 Internal Audit**

BRS conducts internal audits at planned intervals to determine whether the QMS:

- Conforms to the planned arrangements (refer to Section 7.1).
- Conforms to the requirements of the ISO 9001:2008 International Standard and to the quality management system requirements established by BRS.
- Demonstrates effective implementation and maintenance.

An audit program is planned, taking into consideration the status and importance of the processes and areas to be audited and may encompass the results of previous audits. The audit criteria, scope, frequency, and methods are defined. Selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors do not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (refer to Section 4.2.4) are documented in Procedure S25 Conduct Internal Audits.

Management responsible for the area audited ensures that actions are taken without unwarranted delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results (refer to Section 8.5.2).

### **8.2.3 Monitoring and Measurement of Process**

BRS applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action are taken, as appropriate, to ensure conformity of the product.

### **8.2.4 Monitoring and Measurement of Product**

BRS monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements (refer to Section 7.1).

## **8.2.4 Monitoring and Measurement of Product, cont.**

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing release of product (refer to Section 4.2.4).

Product release and delivery does not proceed until all the planned arrangements (refer to 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable, by the customer (stakeholder).

## **8.3 Control of Nonconforming Product**

BRS ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are documented in Procedure S29 Manage Nonconformity.

BRS deals with nonconforming product by taking action to eliminate the detected nonconformity and/or taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained (refer to Section 4.2.4).

When nonconforming product is corrected, it is subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, BRS takes action appropriate to the effects, or potential effects of the nonconformity.

## **8.4 Analysis of Data**

BRS determines, collects, and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system to evaluate where continual improvement of the effectiveness of the quality management system can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

- a) Customer satisfaction (refer to 8.2.1).
- b) Conformity to product requirements (refer to 7.2.1).
- c) Characteristics and trends of process and products including opportunities for preventive action to BRS.

## **8.5 Improvement**

### **8.5.1 Continual Improvement**

BRS continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

### **8.5.2 Corrective Action**

BRS has established and maintains a documented Procedure, S28 Perform Corrective and Preventive Actions, to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered. Procedure S28 Perform Corrective and Preventive Actions defines requirements for:

- a) Reviewing nonconformities (including customer comments).
- b) Determining the causes of nonconformities.
- c) Evaluating the need for action to ensure that nonconformities do not recur.
- d) Determining and implementing action needed.
- e) Records of the results of action taken (refer to Section 4.2.4).
- f) Reviewing corrective action taken.

### **8.5.3 Preventive Action**

BRS has established and maintains a documented Procedure, S28 Perform Corrective and Preventive Actions, to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems. Procedure S28 Perform Corrective and Preventive Actions defines 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) Records of the results of action taken (refer to Section 4.2.4).
- e) Reviewing preventive action taken.

## Appendix A Document History

Revision Number	Revision Date	Authorized By	Page Number	Description of Change
0	10/31/05	Steven Bennett	Entire Document	Initial Release
1	3/20/08	Steven Bennett	Entire Document	The Business Processes were updated to include processing functions in ePermits.
2	4/17/08	Steven Bennett	Page 8	Formatting modification for ERAP Biotechnologists in Figure 1. BRS Permits and Environmental Risk Analysis Teams.
			Page 9	Quality Policy applies to the Biotechnology Regulatory Services organization.
3	12/29/08	Steven Bennett	Entire Document	Editorial updates (i.e., acronym modifications for ERAD, RPS, FOIA), formatting, punctuation, revision of Procedure S22 title and addition of Procedure S22b.
			Pages 3 - 4	Section and Figure titles updated.
			Pages 17 - 18	Addition of Procedure S22b to Figures 3 and 4.
4	10/19/09	Steven Bennett	Entire Document	ISO 9001:2008 Updates Editorial updates (i.e., acronym modifications, definition additions) and modifications to Figure 1 and Figure 4.

## **Appendix B Quality System Procedures**

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