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Quality Management System (QMS)

Manual and Appendix A

QUALITY MANAGEMENT SYSTEM (QMS)
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INTRODUCTION

This document is designed to give guidance to Processed Products Branch (PPB) personnel of the United States Department of Agriculture (USDA), by establishing PPB's Quality Management System Manual.

The information has been compiled or developed from sources available to the public as well as from technical knowledge of personnel in the USDA.

Compliance with the Agricultural Marketing Service (AMS) guidelines does not excuse failure to comply with the Food, Drug, and Cosmetic Act or any other applicable Federal or State laws or regulations. The PPB of the Fruit and Vegetable Programs (FV), AMS is responsible for conducting inspection (grading, certification, and auditing) and standardization programs for processed fruits and vegetables and miscellaneous related products. The legal authority for grading and standardization activities is the Agricultural Marketing Act of 1946.

Applicants may obtain inspections of any processed fruit and vegetable products for which they have a financial interest. The inspection service is voluntary and self-supporting, and is offered on a fee-for-service basis.

The Quality Management System described in this Quality Manual will enable PPB to:

- Recognize the need to continually change and improve our services;
- Minimize the variability of our services;
- Maintain flexibility while providing discipline and control over operating procedures; and
- Ensure the quality of our services consistently meet or exceed customer expectations.

This manual contains links to various internal and external sources of information. For inspection personnel without internet or intranet access, please contact your immediate supervisor to obtain hard copies of documents as needed.

GUIDE FOR ELECTRONIC USAGE

The Administrative, Inspection, and Management (AIM) System of instructional manuals is available electronically in Adobe Acrobat Portable Document Format (PDF) at the following intranet address: http://agnis/sites/FV/PPB/default.aspx.

When accessed electronically, AIM materials have hyperlinks and hypertext (visible as underlined blue text) available to the PDF user. Clicking on a hyperlink takes the reader to a web site with information relating to the subject. Hypertext will link the reader to a different page within the current manual - or even a different manual - with information relating to the subject. For example, the hypertext in the Table of Contents allows a reader to go directly to the section of interest in the manual by clicking on the section title within the Table of Contents.

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1.0 SCOPE

This Quality Manual documents the policies and procedures of the Processed Products Branch (PPB) of the Fruit and Vegetable Programs (FV), as required by the PPB Quality Management System. PPB developed its Quality Management System (QMS) based on the requirements of International Organization for Standardization (ISO) 9001.

2.0 NORMATIVE REFERENCES

The PPB Quality Manual is written to conform to the most recent version of the ISO 9001 standard. Additionally, PPB incorporates and complies with the applicable sections of ISO 19011 and all applicable Federal, USDA, and Agency regulations, guidelines, standards, and policies. PPB strives to apply the latest revisions of all normative documents. For undated references, the most applicable or latest edition of the reference will apply.

3.0 TERMS AND DEFINITIONS

Terms and descriptions used in this manual are generally defined within ISO 9001. Other terms and definitions can be found in the "Code of Federal Regulations (CFR) 7, Part 52, Sub-Part 52.2." Terms specifically used within this manual include:

3.1 **Management Review**: The forum in which PPB Management meets to review and take appropriate action on issues relating to the QMS to ensure the continuing suitability and effectiveness in satisfying customer requirements and the stated quality policy and objectives.

3.2 **PPB Manager**: The person in the highest position at each management level within PPB as follows: Branch Chief, Section Heads, Eastern Regional Director, Western Regional Director, and all the Officers-in-Charge of the Area Offices.

3.3 **PPB Top Management**: The people who direct and control PPB at the highest level; the Branch Chief and Assistant Branch Chief.

3.4 **PPB Management**: The group consisting of the Branch Chief, Assistant Branch Chief, Section Heads, Assistant Section Heads, Regional Directors, and Assistant Regional Directors.

3.5 **Product (or Service)**: Product is defined as those services or products that PPB provides to customers, to include certification, inspection, grading, audits, and the development of grade standards, grading references, color guides, etc. Throughout this document, the terms "product" and "service" are used interchangeably.

3.6 **Responsible Party**: The person who is accountable for (1) taking action to resolve a

specific non-conformance or potential non-conformance identified and (2) ensuring the action is effective.

4.0 PPB QUALITY MANAGEMENT SYSTEM (QMS)

4.1 General Requirements

PPB has documented and implemented a quality management system, and continually improves its effectiveness in accordance with the requirements of ISO 9001 and the Agricultural Marketing Service (AMS).

The QMS is based on PPB's performance of the following steps:

a) Define needed processes for the QMS and their application throughout the Branch;

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 monitoring of these processes;

e) Monitor, measure, and analyze these processes; and

f) Implement actions necessary to achieve planned results and continual improvement of these processes.

See QMS Appendix A for documentation, including process charts, of the above mentioned steps and analysis *(still under development)*.

Where PPB chooses to outsource any process that has been established as necessary for the QMS, PPB ensures control over such processes.

4.2 Documentation Requirements

4.2.1 General

The PPB QMS documentation includes:

a) Documented statements of a quality policy and quality objectives (see 5.3. and 5.4.1);
b) A quality manual;

c) Documented procedures required by ISO 9001 including:

   i. Control of documents (QMS B1.0)

   ii. Control of records (QMS BX.X) *(still under development)*

   iii. Internal audits (QMS B3.0)

   iv. Control of nonconforming products (QMS B5.0)

   v. Corrective actions (QMS B4.0)

   vi. Preventive actions (QMS B4.0)

d) Documents needed by PPB to ensure the effective planning, operation, and control of its processes; and

e) Records required by ISO 9001, Agency and Federal guidelines.

PPB QMS documentation is defined on the following levels:

a) Level I – The PPB QMS Quality Manual;

b) Level II - Federal regulatory requirements, Agency directives, and other procedures, standards and specifications under which PPB operates;

c) Level III - The standard operating procedures, such as the Administrative Inspection Management (AIM) Instructional System, Branch Notices, and Memorandums that detail the activities necessary to achieve the objectives of the QMS;

d) Level IV - Work instructions, such as grading manuals and office procedures, that are issued as required; and

e) Various records generated through application and performance of the QMS requirements and procedures.

The depth and detail required for the documentation is determined by PPB Management and is dependent upon the complexity and interaction of the processes, and the skills and training needed by personnel performing the activity.

4.2.2 PPB Quality Manual

PPB establishes and maintains a quality manual that includes:

a) The scope of the QMS;

b) A description of the elements of the quality system (see further chapters of this Manual);

c) The documented procedures established for the QMS, or reference to them (see Appendix A for PPB Process Charts *(still under development)*); and

d) A description of the interaction between the processes described in the QMS (see Appendix A for documentation of this interaction *(still under development)*).

4.2.3 Control of Documents

Documentation required by the PPB QMS is controlled and maintained to the degree needed to enable effective implementation of the QMS.

See QMS Appendix B – QMS B1.0, Document Control Procedures.

4.2.4 Control of Records

Records are established and maintained to provide evidence of conformity to QMS requirements and of the effective operation of the QMS.

Records required by the PPB QMS are controlled and maintained to the degree needed to enable effective implementation of the QMS.

See: QMS Appendix B – X.X Record Control Procedures *(still under development)*.

5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

The Office of the Branch Chief (OBC) is committed to providing services of the highest quality that completely satisfy customer expectations. OBC is committed to the development and implementation of the quality management system and continually improves its effectiveness by:

a) Communicating to the Branch the importance of meeting customer needs as well as statutory and regulatory requirements;

b) Maintaining a quality policy;

c) Maintaining quality objectives;

d) Conducting management reviews at least annually; and

e) Ensuring the availability of resources necessary to meet the expectations of our customers.

PPB managers demonstrate their commitment by:

a) Integrating quality objectives into Branch procedures and activities;

b) Communicating the importance of a customer orientation when fulfilling management and supervisory activities;

c) Participating in reviews of their work unit's quality system and in follow-up actions; and

d) Assuring communications, understanding, and implementation throughout the Branch.

5.2 Customer Focus

OBC ensures that customer needs and expectations are identified and fulfilled with the aim of enhancing customer satisfaction (see 7.2 and 8.2.1).

5.3 Quality Policy

"The Processed Products Branch continually strives to understand, meet, and exceed all customer and statutory requirements in the service we provide to promote the efficient marketing of agricultural commodities. The Branch accomplishes this by providing value-added services that display flexibility in a changing market place and that are continually evaluated for their effectiveness. The results of these evaluations are used to improve PPB's service processes based on objective practices and procedures."

PPB management ensures that the quality policy:

a) Is appropriate and reviewed to ensure compliance with requirements and to continually improve the effectiveness of the QMS; and

b) Is communicated and understood within and outside of the organization through the Branch's communication processes.

5.4 Planning

5.4.1 Quality Objectives

OBC has established quality objectives at relevant functions and levels with PPB. The following quality objectives are measurable and consistent with the PPB quality policy:

a) Uniformity in applying rules, procedures, and standards;

b) Quality in the data we collect and disseminate;

c) Effective use of human resources in staffing;

d) Efficient application of space and equipment; and

e) Quality services responsive to customer needs.

5.4.2 Quality Management System Planning

OBC ensures that:

a) The planning of the QMS is executed in order to meet the requirements given in 4.1 and in the PPB Quality Objectives; and

b) The integrity of the QMS is maintained when changes to the quality management system are planned and implemented.

PPB Management ensures that the following are considered during planning activities:

a) The QMS processes and procedures required;

b) Resources needed;

c) Review and assessment (measurement) activities; and

d) Continual improvement in fulfilling customer needs and meeting regulatory requirements.

See Appendix A – PPB Strategic Plan 2008 – 2012 for the application of the quality objectives to measurable operating objectives and management initiatives for PPB.

5.5 Organization, Authority, Responsibility, and Communication

5.5.1 Organization, Authority, and Responsibility

See QMS Appendix A for the PPB Organizational Chart *(still under development)*. See the AIM Inspection Series, Employee Manual for the USDA organizational structure and for PPB responsibilities.

OBC has allocated authority to staff to perform their assigned responsibilities. PPB staff also share the authority and responsibility for identifying possible improvements or non-compliances and recording these occurrences, so that preventive or corrective actions can be taken.

The following provides a summary of the principal responsibilities of Branch Management with respect to the QMS, which will be clarified in greater detail within the Branch AIM Instructional System and the procedures contained within QMS Appendix B.

Office of the Branch Chief:

- Management Review
- Internal Audit
- Documentation and Change Control
- Process Control
- Non-conforming Services
- Corrective Action and Preventive Action
- Training
- Internal Communications
- Customer Feedback
- Planning

Regional Management:

- Management Review
- Internal Audit
- Documentation and Change Control
- Process Control
- Non-conforming Services
- Corrective Action and Preventive Action
- Training
- Internal Communications
- Customer Feedback
- Planning

Area Office Management:

- Support of Management Reviews and Internal Audits
- Process Control
- Processing Requests for Service
- Scheduling and Providing Services
- Verification of Acceptability of Received Goods or Licensed Inspection Activities
- Inspection Services
- Reporting Results of Inspections and Services
- Non-conforming Services
- Corrective Action and Preventive Action
- Training
- Internal Communications
- Customer Feedback

5.5.2 Management Representative

OBC has appointed a member of management who has responsibility and authority that include:

a) Ensuring that processes needed for the QMS are established, implemented and maintained;

b) Reporting to PPB Management on the performance of the QMS and any need for improvement; and

c) Ensuring the promotion of awareness of customer requirements throughout the Branch.

5.5.3 Internal Communications

PPB Top Management ensures that appropriate communication processes are established within the Branch and that communication takes place regarding the effectiveness of the QMS.

Managers and/or supervisors are responsible for communicating to employees the policies and procedures that affect them as well as ensuring compliance. Employees may obtain copies of these documents from their supervisors, and PPB's homepage on the internet and intranet.

5.6 Management Review

Management review of the suitability, adequacy and effectiveness of the QMS takes place at least once per year. During the management review meetings, issues and actions

are discussed and recorded for continual improvement of PPB's Quality Management system.

Input to PPB's management review will include information on:

a) Results of audits;

b) Customer feedback;

c) Process performance and product/service conformity;

d) Status of preventive and corrective actions;

e) Follow-up actions from previous management reviews;

f) Changes that could affect the PPB QMS; and

g) Recommendations for improvement.

Output from PPB's management reviews include any decisions and actions related to

a) Improvement of the effectiveness of the QMS and its processes;

b) Improvement of product/service related to customer or regulatory requirements; and

c) Resource needs.

See: QMS Appendix B – QMS B2.0 Management Review Procedure

6.0 RESOURCE MANAGEMENT

6.1 Provision of Resources

PPB identifies and provides the necessary resources to implement, maintain, and improve the processes of the QMS and to enhance customer satisfaction.

6.2 Human Resources

6.2.1 General

PPB selects and places personnel based on their competency, education, training, skills, experience, and/or pre-employment testing.

6.2.2 Training

PPB continues to identify personnel training needs through a system of supervisory reviews and performance appraisals conducted throughout the fiscal year. PPB Managers are responsible for recommending the training needs of subordinate personnel and for ensuring that all employees, allocated specific tasks, are suitably qualified and experienced to execute those tasks. Once training needs are identified, appropriate training is provided by following the guidelines established by PPB Top Management and AMS Directives.

Records are maintained of training undertaken by employees.

6.3 Infrastructure

Facilities needed to support PPB services are identified, provided, and maintained. This includes buildings and workspaces, and associated facilities, environmental conditions, equipment (including hardware and software), and supporting services. These considerations are evaluated during supervisory and safety reviews.

6.4 Work Environment

The human and physical factors of the work environment needed to achieve conformity of service and maintain the safety of PPB staff are identified and managed. Consideration of such factors include health and safety conditions, work and handling methods, and pervading working conditions. These considerations are evaluated during supervisory and safety reviews.

7.0 SERVICE REALIZATION

7.1 Planning of Service Realization

PPB plans and develops the processes needed for service realization in a manner consistent with the requirements of the other processes of the QMS.

In planning service realization, PPB determines the following, as appropriate:

a) Objectives and requirements of the service;

b) The need to establish processes, documents, and provide resources specific to the service;

c) The degree to which verification, validation, monitoring, inspection, and test activities specific to the service and its acceptance criteria are required; and

d) Records needed to provide evidence that the realization processes and resulting service meets requirements.

The output of this planning is in a form suitable to the Branch's methods of operations.

7.2 Customer-related Processes

7.2.1 Determination of Requirements Related to the Service

PPB determines:

a) Requirements specified by the customer, including the requirements for service delivery and post-delivery activities;

b) Requirements not stated by the customer but necessary for specified or intended use;

c) Statutory and Agency requirements related to PPB services; and

d) Any additional requirements determined by PPB.

7.2.2 Review of Requirements

PPB reviews the requirements related to its services. The review is conducted prior to PPB's commitment to a customer to provide a service and ensures that:

a) Service requirements are fully defined;

b) Requirements differing from those previously expressed are resolved; and

c) PPB is capable of fully satisfying the requirements.

Records of the results of the review and actions resulting from the review are maintained as part of the documentation of the service development or customer service commitment. Where service requirements are changed, PPB ensures that relevant documents are amended and that relevant personnel are updated with the changed requirements.

7.2.3 Customer Communication

PPB has implemented effective arrangements for communicating with customers in relation to:

a) Service information;

b) Inquiries, contract requirements, or service delivery; and

c) Customer feedback, including customer complaints.

7.3 Design and Development

PPB performs design and development of new services, following the guidelines provided by PPB Top Management and in a manner consistent with the requirements of the other processes of the QMS.

7.3.1 Design and Development Planning

PPB plans and controls the design and development of a service by determining:

a) The design and development stages;

b) The review, verification, and validation required at each stage; and

c) The responsibilities and authorities for design and development.

PPB manages the interface between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output is updated, as appropriate, as the design and development progresses.

7.3.2 Design and Development Inputs

Inputs relating to service requirements are determined and records are maintained. These inputs include:

a) Functional and performance requirements;

b) Applicable statutory and regulatory requirements;

c) Where applicable, information derived from previous similar designs; and

d) Other requirements essential for design and development.

These inputs are reviewed for adequacy. Requirements are complete, unambiguous, and do not conflict with each other.

7.3.3 Design and Development Outputs

The outputs of design and development are provided in a form that allow verification against the associated inputs and are approved prior to release. These outputs:

a) Meet the input requirements for design and development;

b) Provide appropriate information for providing service;

c) Contain or reference acceptable service criteria; and

d) Specify the characteristics of the service that are essential for its intended use.

7.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development are performed in accordance with planned arrangements to:

a) Evaluate the ability of the results of design and development to meet requirements; and

b) Identify any problems and propose necessary actions.

Participants in these reviews include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions are maintained.

7.3.5 Design and Development Verification

Verification is performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions are maintained.

7.3.6 Design and Development Validation

Validation is performed in accordance with planned arrangements to ensure that the resulting service is capable of meeting the requirements for the specified application or intended use. Wherever practicable, validation is completed prior to the delivery or implementation of the service. Records of the results of validation and any necessary actions are maintained.

7.3.7 Control of Design and Development Changes

Design and development changes are identified and records are maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes includes evaluation of the effect of the changes on service already delivered. Records of the results of the review of changes and any necessary actions are maintained.

7.4 Purchasing

7.4.1 Purchasing Process

PPB ensures that purchased product[1] conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent service realization or the final service.

PPB evaluates and selects suppliers based on their ability to supply product in accordance with PPB's requirements. Criteria for selection, evaluation, and re-evaluation are established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

7.4.2 Purchasing Information

Purchasing information describes the product or services to be purchased, including where appropriate:

a) Requirements for approval of product, procedures, processes and equipment;

b) Requirements for qualification of personnel; and

c) Quality management system requirements.

PPB ensures that the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of Purchased Product

PPB establishes and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

7.5 Service Provision

7.5.1 Control of Service Provision

PPB plans and carries out service provisions under controlled conditions. These conditions include:

a) The availability of information that describes the characteristics of the service;

[1] Product includes subcontracted (cross-licensed) services, as well as contracted services, supplies, and equipment.

b) The availability of work instructions, as necessary;

c) The use of suitable equipment;

d) The availability and use of monitoring and measuring devices;

e) The implementation of monitoring and measuring activities; and

f) The implementation of service release, delivery, and post-delivery activities.

All work is planned and undertaken in accordance with the Branch's procedures, and any specific documents agreed upon for individual contracts (e.g., contract specifications).

7.5.2 Validation of Processes for Providing Service

PPB validates any processes for providing service where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results. PPB establishes arrangements for these processes including, as applicable:

a) Defined criteria for review and approval of the processes;

b) Approval of equipment and qualification of personnel;

c) Use of specific methods and procedures;

d) Requirements for records; and

e) Revalidation.

7.5.3 Identification and Traceability

PPB identifies a service by suitable means throughout service provision. Inspection and Certification services require the establishment of a lot identity, which is then carried through on documentation, to the end product – a certificate. The certificate is identified through a unique numbering system and its identity is documented. Audits and Surveys, Color Guides, Visual Aids, Grading Manuals, Commercial Item Descriptions, and U.S. Grade Standards are identified in ways that meet the requirement of this clause.

PPB identifies the status of service realization with respect to monitoring and measurement requirements. Where traceability is a requirement, PPB controls and records the unique identification of the service.

7.5.4 Customer Property

PPB exercises care with customer property[2] while it is under the Branch's control or being used by the Branch. PPB identifies, verifies, protects, and safeguards customer property provided for use in service delivery. If any customer property is lost, damaged, or found to be unsuitable for use, this shall be reported to the customer and records maintained.

7.5.5 Preservation of Service

PPB preserves the conformity of a service during provision and delivery to the intended destination. This preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a service.

7.6 Control of Monitoring and Measuring Devices

PPB determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity to determined requirements. PPB establishes processes to ensure that monitoring and measurement can be carried out, and is carried out in a manner that is consistent with the monitoring and measurement requirements. Where necessary to ensure valid results, measurement equipment is:

a) Calibrated or verified at specific intervals or prior to use, against measurement standards traceable to international or national measurement standards (where no such standards exist, the basis used for calibration or verification shall be recorded);

b) Adjusted or re-adjusted as necessary;

c) Identified to enable the calibration status to be determined;

d) Safeguarded from adjustments that would invalidate the measurement results; and

e) Protected from damage and deterioration during handling, maintenance and storage.

In addition, the Branch assesses and records the validity of the previous measuring results when the equipment does not conform to requirements. PPB takes appropriate action on the equipment and affected product. Records of the results of calibration and verification are maintained.

[2] Customer property can include intellectual property and proprietary information.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This is undertaken prior to initial use and reconfirmed as necessary.

8.0 MEASUREMENT, ANALYSIS, AND IMPROVEMENT

8.1 General

PPB plans and implements the monitoring, measurement, analysis, and improvement processes needed:

a) To demonstrate conformity of the service;

b) To ensure conformity of the QMS; and

c) To continually improve the effectiveness of the QMS.

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

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, PPB monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information is determined by PPB Top Management.

See specific requirements for appeal inspections, provided in the AIM Inspection Series, General Procedures Manual or in the Code of Federal Regulations (CFR), 7 CFR, Part 52, Sub-Part 52.23 through 52.28, which may be founs at the following internet address: http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1.

8.2.2 Internal Audits

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

a) Conforms to the planned arrangements (see 7.1), to the requirements of ISO 9001, and to the quality management system requirements established by PPB; and

b) Is effectively implemented and maintained.

An audit program is planned, taking into consideration the status and importance of the

processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, and methods are defined. Selection of auditors and conduct of audits ensure 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 (see 4.2.4) are defined in a documented procedure.

PPB management responsible for the area being audited ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results (see 8.5.2).

See: QMS Appendix QMS B3.0, Internal Audit Procedure

8.2.3 Monitoring and Measurement of Processes

PPB applies suitable methods for monitoring and, where applicable, measurement of the QMS processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective action is taken, as appropriate, to ensure conformity of the service.

8.2.4 Monitoring and Measurement of Service

PPB monitors and measures the characteristics of the service to verify that service requirements have been met. This review is carried out at appropriate stages of the service realization process in accordance with the planned arrangements. Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing release of the service. Service release and service delivery does not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by an appropriate authority and where applicable, by the customer.

8.3 Control of Nonconforming Service

PPB ensures that service which does not conform to service requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming services are defined in a documented procedure. PPB deals with nonconforming service by one or more of the following ways:

a) By taking action to eliminate the detected nonconformity;

b) By authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable, by the customer, and

c) By 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. When nonconforming service is corrected, the service is subject to re-verification to demonstrate conformity to the requirements. When nonconforming service is detected after delivery or use has started, PPB takes action appropriate to the effects, or potential effects, of the nonconformity.

See: AIM Inspection Series, General Procedures Manual or the Regulations, 7 CFR 52.19, which may be founs at the following internet address: http://www.access.gpo.gov/nara/cfr/cfr-table-search.html#page1.

8.4 Analysis of Data

PPB identifies, collects, and analyzes data, as appropriate, to demonstrate the suitability and effectiveness of the QMS and to determine where continual improvements 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;

b) Conformity to service requirements;

c) Characteristics and trends of processes and services including opportunities for preventative action; and

d) Suppliers.

8.5 Improvement

8.5.1 Continual Improvement

PPB continually improves the effectiveness of the QMS through the use of the PPB quality policy, PPB quality objectives, audit results, analysis of data, corrective and preventive actions, and management reviews.

8.5.2 Corrective Action

PPB takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate for the effects of the nonconformities encountered. PPB's corrective action procedure defines requirements for:

a) Reviewing nonconformities (including customer complaints);

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) Recording the results of action taken; and

f) Reviewing corrective action taken.

See: QMS Appendix QMS B4.0, Corrective Action and Preventive Action Procedure

8.5.3 Preventive Action

PPB determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate for the effects of the potential problems. PPB's preventive action procedure defines requirements for:

a) Determining potential nonconformities and their causes;

b) Evaluating the need for action to prevent occurrence of nonconformities;

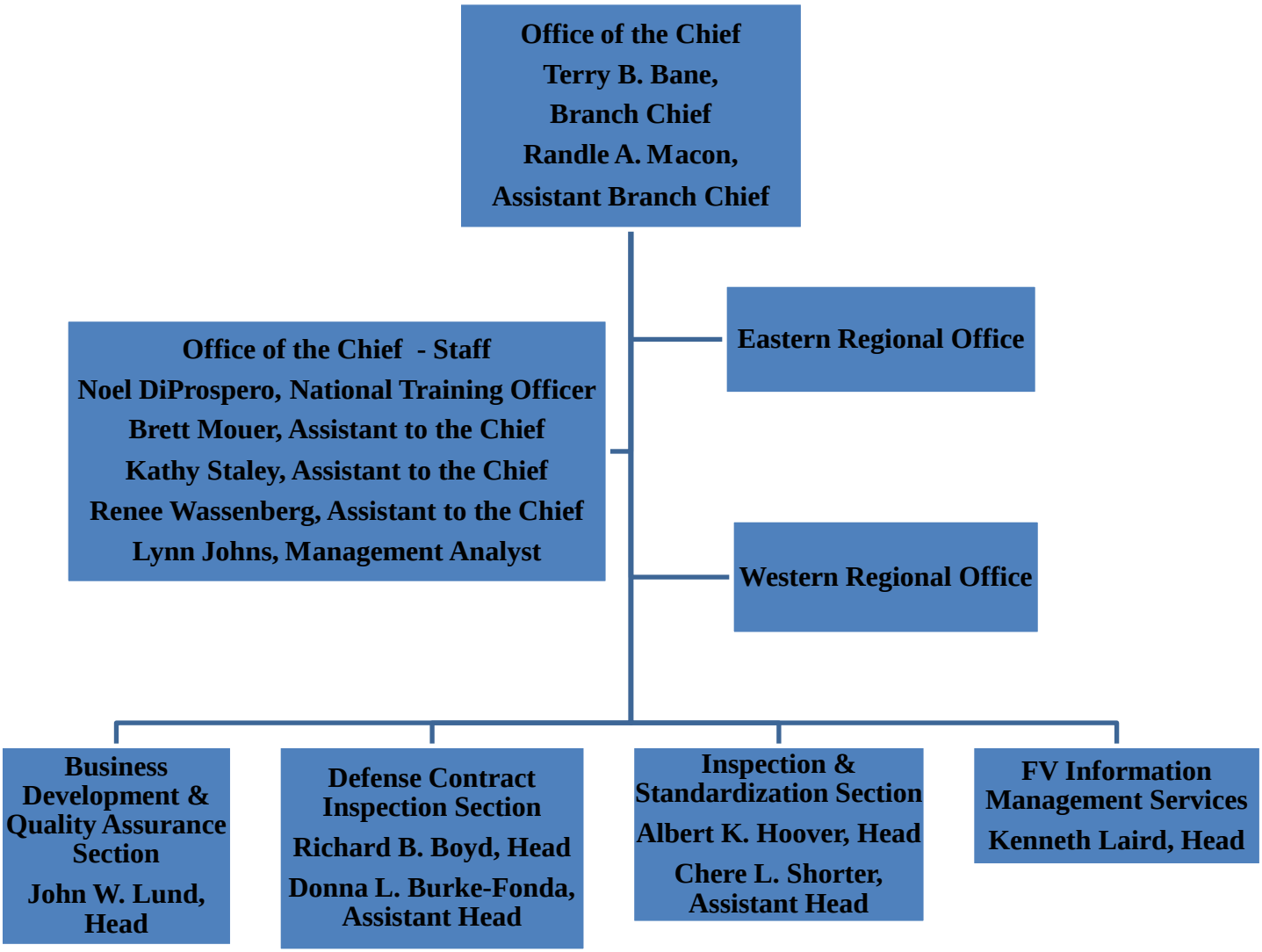
c) Determining and implementing action needed;

d) Recording the results of action taken; and

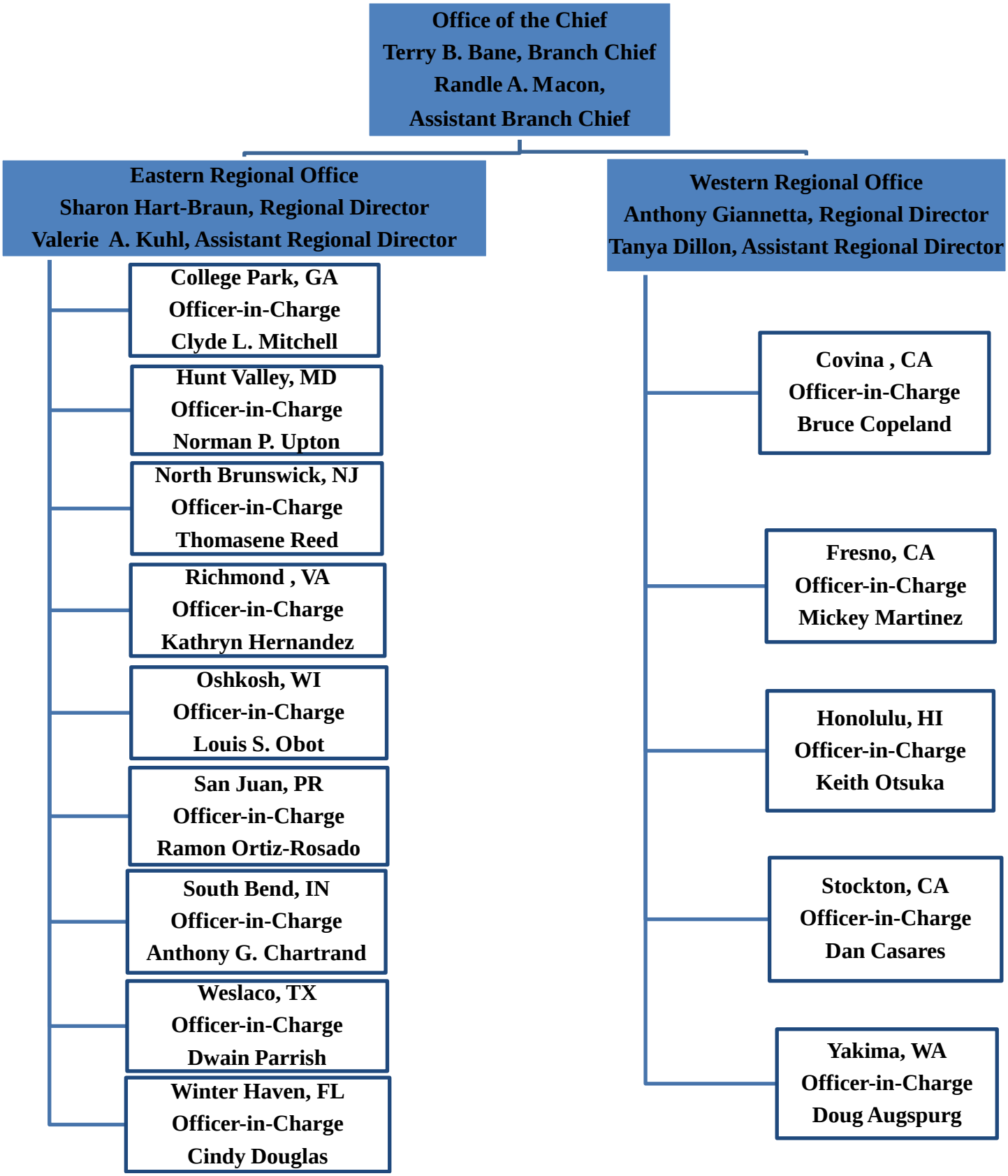
e) Reviewing the preventive action taken.

See: QMS Appendix QMS B4.0, Corrective Action and Preventive Action Procedure

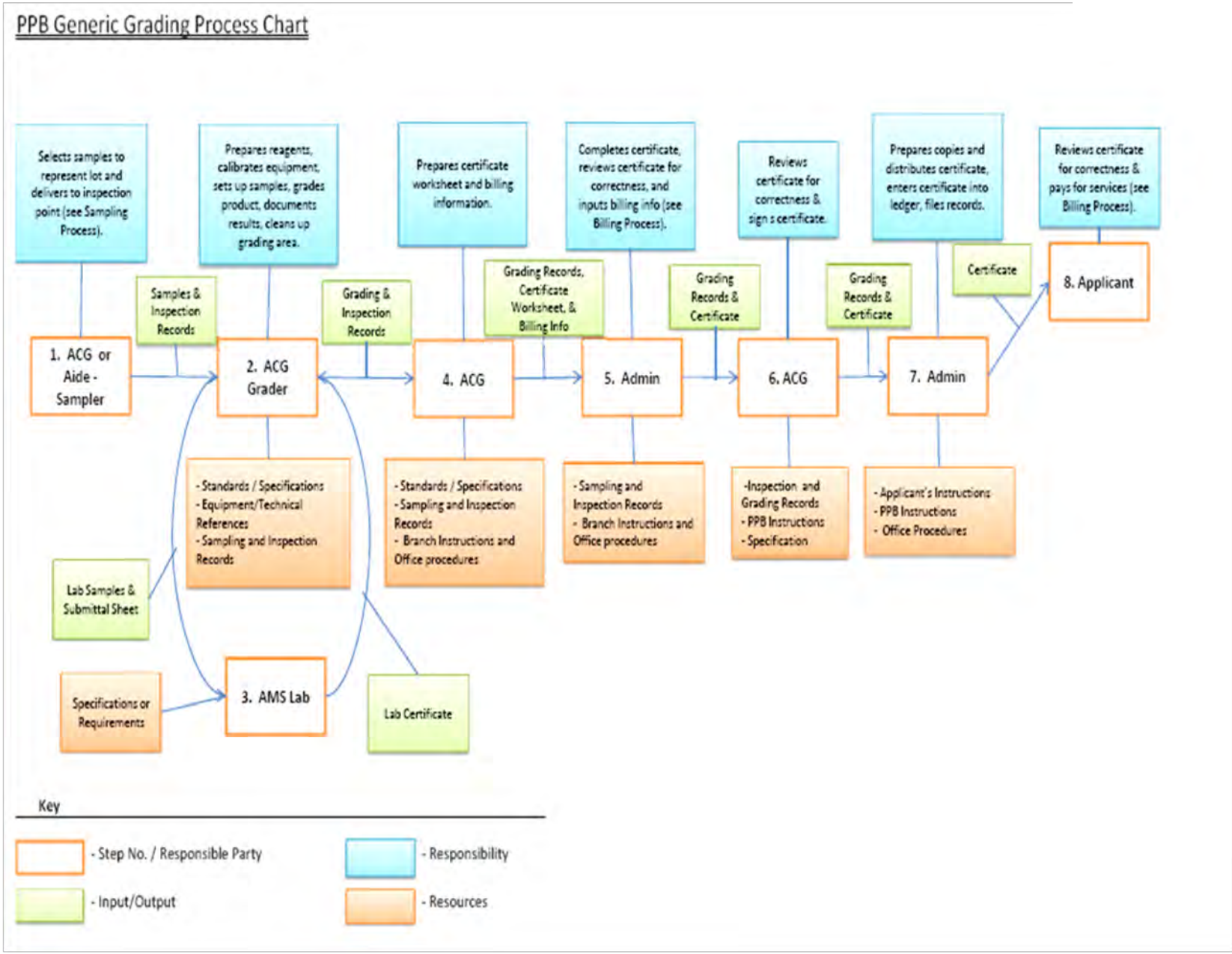
ORGANIZATIONAL CHARTS



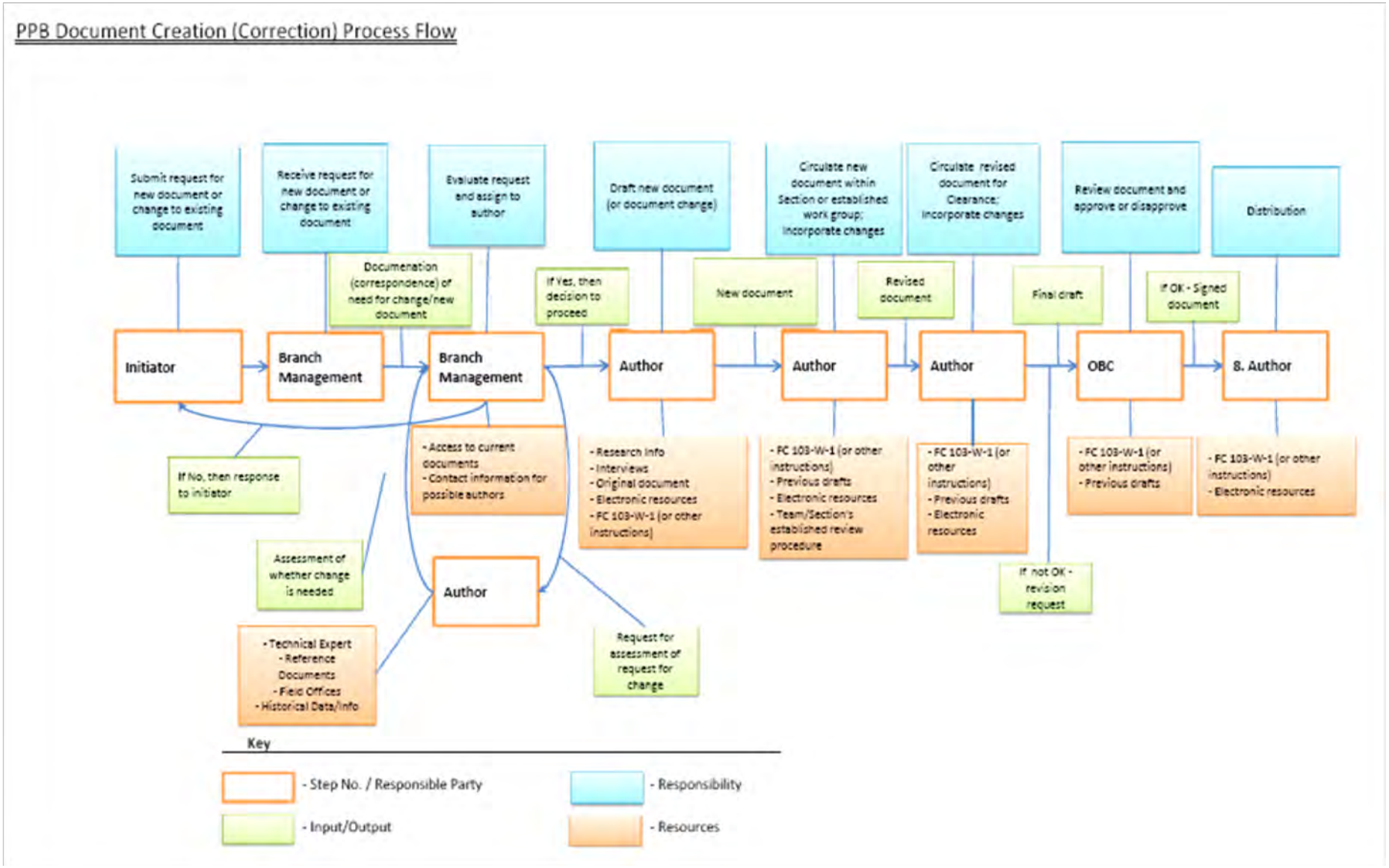
ORGANIZATIONAL CHARTS



PPB PROCESSES



PPB PROCESSES



REFERENCE TO RESOURCE DOCUMENTS

QMS Requirement	**Resource Documents**
Introduction	
	AIM Inspection Series, General Procedures Manual, Regulations Governing Inspection and Certification of Processed Fruits and Vegetables and Related Products
Section 1.0 – Scope	
	Agricultural Marketing Act of 1946 (7 U.S.C. 1621-1627)
	AIM Inspection Series, Employee Manual, Organization of U.S. Department of Agriculture
Section 2.0 – Normative Reference	
	International Standard 9001, Quality Management Systems - Requirements
Section 3.0 – Terms and Definitions	
	ISO 9001
	AIM Inspection Series, General Procedures Manual
	Code of Federal Regulations (CFR) 7, Part 52, Sub-Part 52.2
Section 4.0 – PPB Quality Management System	
4.1	AIM Administrative Site, Licensed Samplers
4.2.4	AIM Administrative Site, Routing and Approval of Documents, Document Control SOP
	AIM Administrative Site, Distribution of Materials
	AIM Administrative Site, Disposition and Storage Procedures for “Software Copies” of Approved Branch Documents and Correspondence
	PPB AGNIS Home Page, Processed Products Branch (PPB) Headquarters Continuity of Operations Plan (COOP)
	AIM Administrative Site, Records Retention and Disposition
4.2.5	AIM Administrative Support Site, Standard Operating Procedures for Records Management in the National Office, Control of Records SOP
	AIM Inspection Series, General Procedures, Certification Manuals, Certification - Appeals and Re-Inspections
	AIM Administrative Site, Forms Retention Requirements Index and General Records Schedule
Section 5.0 – Management Responsibility	
5.1	AIM Inspection Series, Employee Manual, Organization of U.S. Department of Agriculture
5.2	
5.3	
5.4	

REFERENCE TO RESOURCE DOCUMENTS

5.5.1	AIM Inspection Series, Employee Manual
5.5.2	AIM Inspection Series, Employee Manual
5.5.3	
5.5.4	
5.6	AIM Management Site, Field Office Review and Evaluation
	AIM Inspection Series, General Procedures Manual, Review Program for OM for Futures Contracts
	AIM Inspection Series, General Procedures Manual, Review Program for Processed Raisins
	AIM Inspection Series, General Procedures Manual, Review Program for Canned Ripe Olives
Section 6.0 – Resource Management	
6.1	
6.2	AIM Management Site, Performance Standards for Agricultural Commodity Graders GS-5 Through GS-10
	AIM Management Site, Qualification Standards for GS-1981 Agricultural Commodity Aid (Excepted Position)
	AIM Administrative Site, Licensed Samplers
	AIM Inspection Series, General Procedures Manual
6.3	AIM Inspection Series, General Procedures Manual, In-Plant Inspection, General Instructions
	AIM Inspection Series, Sanitation and Safety manual
	AIM Inspection Series, General Procedures Manual, Inspection Procedures
6.4	AIM Inspection Series, Sanitation and Safety Manual, Hazard Communication, A Program Guide for Federal Agencies
	AIM Inspection Series, Sanitation and Safety Manual, AMS Handbook 4790, Safety and Health Handbook
	AIM Inspection Series, Sanitation and Safety Manual, Part 1960-Elements for Federal Employee Occupational Safety and Health Programs
	AIM Inspection Series, Sanitation and Safety Manual, Fruit and Vegetable Programs Occupational Safety and Program Manual
Section 7.0 – Product Realization	
7.1	AIM Inspection Series, U.S Grade Standards, Grading Manuals, CID, MILSPC, Customer specs, PPB At your Service glossy, as applicable
7.2	
7.2.1	AIM Inspection Series, as applicable
7.2.2	AIM Inspection Series, as applicable
7.3	

REFERENCE TO RESOURCE DOCUMENTS

7.3.1	AIM Administravie Site, Ordering Supplies,
7.3.2	AIM Administravie Site
7.3.3	AIM Inspection Series, Child Nutrition Manual,
7.3.4	
7.3.5	
7.3.6	
7.3.7	
7.4.1	AIM Inspection Series, as applicable
7.4.2	AIM Inspection Series, as applicable
	AIM Inspection Series, CN Manual
7.4.3	AIM Inspection Series, Certification and DCIS Manuals as applicable
7.4.4	AIM Inspection Series, Certification Manual
7.4.5	AIM Inspection Series, General Procedures Manual
7.4.6	U.S. Grade Standards, Grading Manuals, CID, MILSPC, AIM Inspection Series, as applicable
7.4.7	AIM Inspection Series, as applicable
7.4.8	AIM Administravie Site as applicable

Section 8.0 – Measurement, Analysis, and Improvement	
8.1	AIM Inspection Series, Personnel Manual
8.2	AIM Inspection Series, General Procedures Manual, Internal Audit SOP
	AIM Inspection Series, Certification Manual
	AIM Inspection Series, Personnel Manual
	AIM Administravie Site, Accounting System Reports
8.3	AIM Inspection Series, General Procedures Manual, Investigation Reports on Misbranding
	Control of Nonconforming Product or Service SOP
8.4	
8.5	
8.5.1	
8.5.2	AIM Management Site, Employee Responsibilities and Conduct, Corrective Action and Preventative Action SOP
8.5.3	AIM Management Site, Employee Responsibilities and Conduct, Corrective Action and Preventative Action SOP