United States Department of Agriculture

Agricultural Marketing Service, Specialty Crops Program, Specialty Crops Inspection Division

Guidance for Writing a GroupGAP Quality Management System

The GroupGAP certification program requires that all Groups write and implement a Quality Management System (QMS) that is based on ISO 9001, or an equivalent process management system. The principles of ISO 9001 are outlined on the International Standards Organization (ISO) webpage. Each Group's QMS also must adhere to the GroupGAP Basic Requirements for Groups. This document provides helpful tips in interpreting basic requirements for GroupGAP applicants who are writing their Group's QMS. A full list of the Basic Requirements for Groups appears in Appendix I of the GroupGAP User's Guide.

Quality Management System *(GroupGAP User's Guide, Appendix 1, Item 1)*

Requirement
The Group must establish, document, implement, and maintain a QMS, and continually improve its effectiveness in accordance with the requirements of the USDA GroupGAP Certification Program. The QMS establishes the system by which the Group will ensure that its members are in compliance with the chosen Good Agricultural Practices (GAP) and/or Good Handling Practices (GHP) audit service.

Guidance
A QMS is a formalized system that documents the processes, procedures, and delegations of responsibilities an organization uses to achieve its quality policies and objectives. For GroupGAP, a QMS is a set of business practices that dictates how a Group functions and ensures it is delivering consistent, safe produce to customers.

Your QMS will describe how your Group plans to meet your customers' new and evolving requirements, and the resources you need to do that. Your Group should continually assess potential improvements both to your business processes and your QMS to ensure that the QMS helps your Group meet customers' and regulatory requirements, and continually improves the Group's effectiveness and efficiency.

Outsourcing Requirements *(GroupGAP User's Guide, Appendix 1, Item 2)*

Requirement
The Group must ensure control over any process it chooses to outsource that affect the GroupGAP certification. Control of the process must be identified in the QMS.

> Guidance
> Outsourced processes include anything that is not directly in control of the group (e.g., farm audits, education, and shipping). If a Group outsources any processes or responsibilities, it must demonstrate any function it does not directly perform will still meet the requirements of the chosen audit, GroupGAP, and the Group's QMS. The Group's QMS must describe who is performing the outsourced function(s), how they will be selected, the requirement(s) they must meet, the qualifications they must have, and how the Group will verify the requirements are met, including the effectiveness and oversight of the outsourced process(es).

ISO 9001 and Equivalent Systems *(GroupGAP User's Guide, Appendix 1, Item 3)*

Requirement
The QMS must be modeled on ISO 9001, a system that meets other recognized industry quality standards, or a process control system that is equivalent to or better than ISO 9001.

> Guidance
> ISO 9001 is an international standard that provides criteria for a QMS. The standard is based on quality management principles, including a strong customer focus, management commitment and involvement, a process-based approach, and continuous improvement. Using ISO 9001 helps ensure that your Group delivers consistent, high-quality products and service to your customers.
>
> ISO 22006 is a process control system that contains guidelines for applying ISO 9001 principles to crop production. This system is considered equivalent to ISO 9001, and may be more applicable for GroupGAP groups.
>
> More information about international process control systems is available at http://www.iso.org/iso/home/standards.htm.

Quality Policy and Quality Objectives *(GroupGAP User's Guide, Appendix 1, Item 4.a)*

Requirement
The QMS must state the Group's quality policy and quality objectives.

> Guidance
> The Quality Policy is the Group's mission statement: a brief description of the Group's commitment to meeting its customers' needs and to continual improvement.
>
> Quality objectives are measurable outcomes related to customer requirements that the Group will use to measure its success. Your quality objectives lay out your Group's goals and are the starting point for your QMS. The remainder of the QMS outlines how your Group will achieve those goals.
>
> For GroupGAP, the quality policy and quality objectives should relate to the Group's food safety goals, and must be communicated to all Group members.

Quality Manual *(GroupGAP User's Guide, Appendix 1, Item 4.c)*

Requirement
The QMS must include a quality manual.

> Guidance
> A quality manual is a written document that outlines the QMS' policies and procedures the Group will be required to follow, and establishes the scope of your Group's certification. Your quality manual must identify how Group membership will be defined, the products and processes that will or will not be covered by the QMS, and the rationale for any exclusions from the QMS.

Responsibilities and Authorities *(GroupGAP User's Guide, Appendix 1, Item 5.d)*

Requirement
The Group must ensure that responsibilities and authorities are defined and communicated within the organization, including creating an organizational chart or similar document that lists all personnel, and their responsibilities and authorities.

> Guidance
> Your QMS must describe the responsibilities of both the Group's members and management as related to the QMS, and identify the individual(s) with authority to ensure adherence to the policies and procedures in the QMS. A GroupGAP QMS must include a visual representation (e.g., organizational chart) that shows all personnel who work within the QMS, and their responsibilities and authorities. The Group must communicate this information to all members.

Necessary Competencies *(GroupGAP User's Guide, Appendix 1, Item 5.e)*

Requirement
The Group must outline the necessary competencies for personnel performing work affecting the quality of product, including the criteria for training.

> Guidance
> The QMS must outline the minimum competencies needed for all roles within the Group that relate to the QMS and food safety. Competencies can include work-experience, education, training, personal attributes, and ongoing job duties. The Group also must state how they will ensure the continued competence of their personnel, including how they will ensure the objectivity of personnel (e.g., internal auditors who serve as educators or consultants), achieve uniformity across auditors, and review auditors' performance.

Product Requirements *(GroupGAP User's Guide, Appendix 1, Item 5.f)*

Requirement
The QMS must specify product requirements, including the GAP and/or GHP audit selected for the food safety audit service.

> Guidance
> Product requirements are the minimum standards a product must meet to be considered acceptable by your Group. For GroupGAP, product requirements will include successful completion of the GAP & GHP audit the Group has chosen to use, and any addendums that have been required by the Group. This also could include any additional buyer requirements, or any additional requirements/procedures the Group has placed on its members.

Control of Documents (*(GroupGAP User's Guide, Appendix 1, Item 6.a)*

Requirement
The QMS must include a procedure to control documents.

> Guidance
> Your QMS must include procedures for controlling documents, including the Quality Manual, written policies and procedures, templates, and standard forms. Your policy should outline the process for developing new documents and editing existing documents; and, identify who has authority to change and approve documents, how and where master copies of documents will be kept and secured, and how outdated/obsolete versions will be discarded. The Group also must have a process for ensuring all Group members and staff are trained on and are using the most current document versions.

Control of Records *(GroupGAP User's Guide, Appendix 1, Item 6.b)*

Requirement
The QMS must include a procedure to control records.

> Guidance
> Your QMS must include a policy for controlling records, which are defined as documented proof of an event or process. Unlike documents, records are any forms or templates that are completed on a regular basis and show how the Group, or its members, are functioning. The master copy of a blank form is a document; the completed form is a record. The policy must identify your Group's records, and may also include members' records, at the Group's discretion. The policy also must indicate how and where records are stored and secured. If records must be approved, the policy should identify the personnel with this authority.

Internal Audit *(GroupGAP User's Guide, Appendix 1, Item 6.c and 6.g)*

Requirement
The QMS must include an internal audit procedure.

> Guidance
> Your Group must perform two types of internal audits: a QMS audit and an annual producer audit of each member. Your QMS should outline how you will carry out these audits.
>
> For the QMS audit, the policy will outline the frequency of internal audits, competencies required of an internal QMS auditor, the individual(s) authorized to perform the audit, and how the audit findings will be addressed (see Corrective Action below).
>
> For the producer audit, the policy will identify required competencies for internal auditors and the individual(s) authorized to perform the audits. If an internal auditor performs other functions within the Group (e.g., food safety education or training), the plan must identify precautions taken to ensure the individual's objectivity when functioning in the auditor role. If the Group has more than one internal auditor, the plan should include any measures that the Group takes to ensure uniformity in auditing practices across all of them. Finally, the plan should identify any review process for, or oversight of, the audits prior to being finalized, and the personnel responsible for these functions.
>
> The Group also must outline how it will perform any required unannounced audits for each member, as determined by the USDA unannounced audit policy; and, any required follow-up audits on members whose initial or unannounced audit fails to meet the USDA acceptance criteria.

Control of Non-Conforming Product/Farms *(GroupGAP User's Guide, Appendix 1, Item 6.d)*

Requirement
The QMS must include a control of nonconforming product procedure.

> Guidance
> Under GroupGAP, non-conforming product includes non-conforming farms. Your QMS must include a procedure for handling any farms that are no longer in compliance with the Group's food safety practices. Farms could be non-conforming based on the results of an internal or external audit, or reported issues in the operation. The procedure should outline how a non-conforming member will be identified, how the Group will treat that member's certification status, how product from this member will be segregated (if the Group takes physical control of product), and the steps a member can take to return to conformity. The QMS must identify the personnel authorized to decide the status of a non-conforming member, and to ensure the member and their product are segregated from the Group's. The procedure must describe the point at which a non-conforming member will be removed from the Group, the process for removal, and the procedure for notifying the member, the USDA, and customers. As part of this procedure, the Group may choose to address how members are to handle product that is determined to be non-conforming to Good Agricultural Practices, either by themselves or by an auditor.

Corrective Action *(GroupGAP User's Guide, Appendix 1, Item 6.e)*

Requirement
The QMS must include a corrective action procedure.

> Guidance
> Corrective actions are taken by the Group, or by a member, to correct the cause of an identified issue. Issues can be identified by an audit (internal or external), customer or member complaints or feedback, Group staff observations, and management reviews. The QMS should contain procedures for documenting corrective actions by members and the Group, and identify personnel responsible for ensuring corrective actions are implemented, and, if applicable, who is authorized to approve the action. If the Group chooses to enforce timelines on corrective actions, the timelines and repercussions of not meeting them should be outlined in the procedure.

Preventive Action *(GroupGAP User's Guide, Appendix 1, Item 6.f)*

Requirement
The QMS must include a preventive action procedure.

> Guidance
> Preventive actions are taken by the Group, or by a member, to preclude an identified potential issue from occurring. Potential issues can be identified by an audit (internal or external), customer or member complaints or feedback, Group staff observations, and management reviews. The QMS should contain procedures for documenting preventive actions by members and the Group, and identify personnel responsible for ensuring preventive actions are implemented, and, if applicable, who is authorized to approve the action. If the Group chooses to enforce timelines on preventive actions, the timelines and repercussions of not meeting them should be outlined in the procedure.

Membership List *(GroupGAP User's Guide, Appendix 1, Item 7.a)*

Requirement
The QMS must include a record of participating producers/members.

> Guidance
> For each member, the Group's membership list must include:
>
> - Member name
> - Street address (mailing), city, state, zip code
> - Member telephone and email contact information
> - List of fruits and/or vegetables produced
> - Physical location of the production area, including acreage of each fruit and/or vegetable and/or nut, or production site in square footage
> - Harvest season (start and stop months for the year)
> - Labor (contract or direct hire)
> - Harvest type (mechanical or manual)
> - Specific audit service type and scope covered by certification (e.g., Harmonized Field and Harvest Operations, USDA GAP&GHP Farm Review, Field Harvesting and Field Packing Activities, or House Packing Facility)
> - Last date of USDA GAP and/or GHP individual audit certification for the member locations

Written Membership Agreement *(GroupGAP User's Guide, Appendix 1, Item 7.b)*

Requirement
The QMS must include a record of a written agreement or contract with each member that grants permission for personnel authorized by the USDA Agricultural Marketing Service (AMS) to enter any and all farms and/or facilities covered by the specific audit program to conduct an audit.

> Guidance
> The Group's written membership agreement should outline what it means to be a member of the Group, including the roles, responsibilities, and expectations related to food safety and the Group's QMS for each member and the Group as a whole. The written agreement must grant the Group's internal auditor(s) and AMS-licensed auditors access to each member's operation. Each member must sign the written membership agreement. Copies of all written membership agreements should be retained with the Group records.

Records Associated with Product Realization *(GroupGAP User's Guide, Appendix 1, Item 7.e)*

Requirement
The QMS must include records associated with product realization.

> Guidance
> Product realization is the work the Group does to develop, grow, and deliver the products desired by their customers. The QMS must include a comprehensive approach to getting from product concept to finished product. These steps include:
> - **Review the requirements of specified audit standard (i)** to ensure the Group is aware of changes to the audit requirements, audit checklists, and internal auditor guidance, and incorporates these changes into its system.
> - **Review of inputs related to production and food safety requirements (ii)** to identify and set requirements for shared inputs or resources (including service contracts), how the requirements are communicated to the supplier, and records of conformance to these requirements.
> - **Verification and validation of food safety control measures (iv)**, including records of internal audits, any records of food safety measures the Group uses, and member GAP audits.
>
> *Continued on next page*

- **Review of results of evaluations of suppliers' goods and services (vi)** to ensure that suppliers meet the Group's minimum requirements. This includes supplier evaluations of any shared products and services that are purchased for or on behalf of Group members, and for outsourced processes.
- **Maintenance of customer property, accounting for property that is lost, damaged, or unsuitable for use (viii)** to demonstrate the Group is properly caring for any customer property (e.g., packaging and equipment) of which it has taken control.
- **Calibration and verification of measuring/monitoring equipment (ix)** to record the calibration of the Group's measuring and monitoring equipment, including any calibration done for or on behalf of members. This might include temperature devices, agricultural chemical application devices, and water treatment equipment.

Procedures and Records Required by Chosen Audit Standard *(GroupGAP User's Guide, Appendix 1, Item 8)*

Requirement

The QMS must include, at a minimum, the procedures and records required by the chosen GAP or GHP audit standard. The audit services available for the USDA GroupGAP Certification Program are located at www.ams.usda.gov/gapghp.

Guidance
The QMS should include a means of ensuring that Group members have the documents they need to meet the requirements of the audit service that the Group has selected. Groups can choose to (1) provide their members with a food safety plan based on the chosen audit service type and any additional Group requirements, or (2) make a food safety plan template available to their members that be adapted for each member's operation.