



Wallace Center
AT WINROCK INTERNATIONAL



QUALITY MANAGEMENT SYSTEMS

**A GUIDE FOR FOOD
AND FARM BUSINESSES**



INTRODUCTION

This guide is designed to help food and farm businesses, food hubs, and USDA GroupGAP administrators develop a basic Quality Management System to identify and meet customer requirements, and to create systems for continuous improvement. While the concept of Quality Management Systems (QMS) may be foreign to many, most businesses have asked themselves:

- What do our customers need from us?
- How do we ensure that we can consistently meet those needs?
- How do we train staff?
- How can we become more consistent in our operating practices?
- Who is responsible for what processes?
- How can we do better?
- How do we make sure that if a key staff person leaves the operation can continue to run smoothly?

These questions, and much more, can be addressed by a QMS.

For businesses using a Quality Management System, their QMS helps them manage operations and assists them in becoming a preferred supplier in their market. Though every industry has its own nuances and specifics, each uses tailored management systems based upon internationally-recognized best practices established by the International Organization of Standardization and laid out in industry-specific QMS manuals. The food and farming industry is a relative newcomer to Quality Management Systems; however, across the country food and farm operations are increasingly utilizing QMS as a management tool for food safety, production, inventory, and operational management. While there are many notable examples of farmer groups and food businesses utilizing QMS, there are few manuals or guidance documents written for these specific applications. That is what this guide aims to do. It will provide an overview of the basic components of a QMS, including application examples, as well as point the way for next steps. Good luck!

QUALITY MANAGEMENT SYSTEMS

Ask 10 people what a Quality Management System is and you'll likely receive 10 different answers, but a good definition to work with is: a **documented system that describes the processes, roles, and procedures necessary to meet customer requirements and continuously improve**. Quality Management Systems have been used for decades in myriad industries in countless ways, but all with the same ultimate goal: to meet customer requirements. Quality, by definition, refers to "the degree to which a requirement has been met." When a system is built around managing quality, to meet customer requirements in an ever-improving way, it's a quality management system. All QMS's, at their most basic, fundamental level, share this same design; whether the organization is manufacturing vehicles, baking loaves of bread, growing fresh produce, or tending to hospital patients.

Since 1987, the International Organization for Standardization's ISO 9001 standard has been the proverbial North Star for QMS development. A 2008 study published by Harvard Business School found that "ISO adopters have higher rates of corporate survival, sales, employment growth and wage increase than non-adopters." What's more, the same study found that the benefits achieved by implementing an ISO 9001 system were statistically higher in smaller organizations than larger organizations, meaning that small businesses achieve proportionally higher benefits from implementing these systems than larger ones (Levine, 2010).

While this guide was inspired by ISO 9001, it was not written explicitly with compliance to ISO 9001 in mind. However, it does share many of the fundamental principles, such as the Plan-Do-Check-Act structure. Organizations that implement any variation of a QMS, or even just utilize some of its tools, can unlock many of the same benefits. Once a basic QMS is established, adapting the QMS to meet the requirements of a program such as USDA GroupGAP, or going a step forward toward compliance with ISO 9001, becomes much more manageable.

WITHOUT A QMS,
ORGANIZATIONS
HAVE LITTLE CHANCE
OF SUSTAINING ANY
IMPROVEMENTS OR
INNOVATIONS THEY
MIGHT REALIZE."

Craig Cochran,
ISO 9001:2015 in Plain English

Q: Is my food safety plan a QMS?

A: While a food safety plan and associated SOPs share similarities with a QMS, and can be housed within a QMS, a food safety plan itself is not a QMS.



TERMINOLOGY

This is by no means an exhaustive list of definitions, but is intended to clarify some of the main terms used when talking about Quality Management Systems:

PROCESS - Any activity that converts an input to an output is a process. Sanitizing food contact surfaces, packing fresh produce, performing an internal audit, and onboarding new vendors are all examples of processes.

QUALITY - Quality is the degree to which a requirement has been met. It does not refer to the intrinsic or subjective value of a good or service; it is a measurement of how well that good or service meets customer requirements and expectations.

QUALITY MANAGEMENT SYSTEM (QMS) - A documented system that describes the processes, roles, and procedures necessary to meet customer requirements and continuously improve.

RISK - The effect of uncertainty on an expected outcome. There are two components at work: uncertainty and what effect that uncertainty may have. A broken cooler thermometer creates uncertainty regarding cooler temperature, which may have the effect of spoiled product and foodborne illness. Risk, and how to evaluate and mitigate it, will be further explored later in this guide.

STANDARD OPERATING PROCEDURE (SOP) - Established or prescribed methods to be followed routinely for the performance of designated operations or in designated situations. An SOP provides the step-by-step instructions for how to perform a certain task or activity.

SYSTEM - An output of one process commonly becomes the input of the next. The term “system” refers to how the interaction and relationship of processes are described as part of a whole. Receiving product, inventory management, and delivery to the customer are all separate processes, but they all belong to the same overall system.



DOCUMENTATION

Good documentation is essential for an effective QMS. It's also essential for an effective business. Businesses are made up of dozens, if not hundreds, of moving parts maneuvered by employees, suppliers, and buyers. No business or organization can "describe the processes, roles, and procedures necessary to meet customer requirements and continuously improve" from memory.

There are two primary purposes of writing things down:

1. The first is for clarity, repeatability, and efficiency. Written plans and strategies can be referred to often. Written requirements allow processes and outcomes to be evaluated more efficiently and objectively. Written instructions allow processes to be performed in a consistent, repeatable manner. Documentation reduces risk, allows new trainees to get up-to-speed more quickly, and creates confidence that tasks are performed the same way every time. It also means that if an employee is out sick, leaves the business, or takes a vacation, the systems and procedures are in place for the operation to continue to run smoothly in their absence.
2. The second is for creating confidence that things went as planned. Comparing what actually happened to the instructions and plans that were in place can inform future improvements.

Where the first purpose refers to procedures and plans in place before an activity, the second refers to documentation of the activity after it happened. For example, a cleaning procedure instructs how to clean a piece of equipment, while a cleaning log shows that the cleaning actually happened.

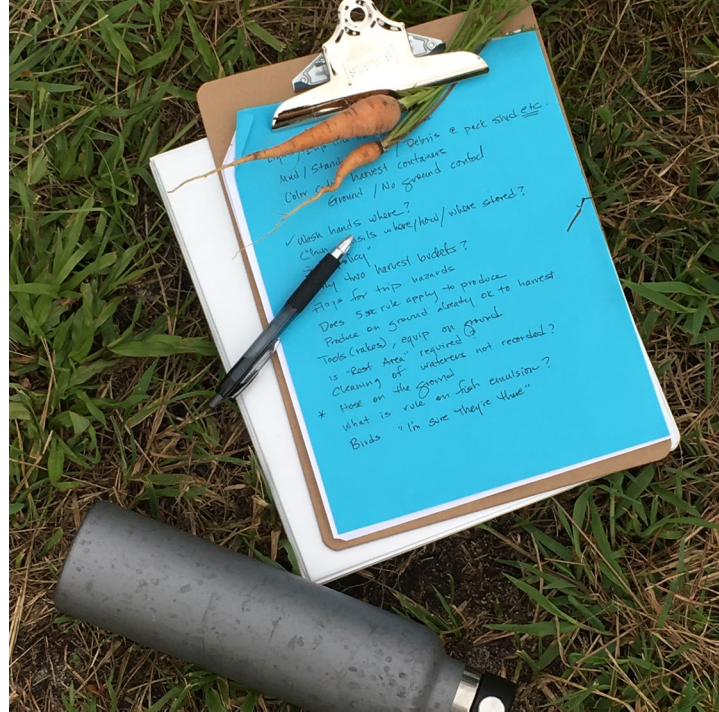
HOW MUCH DOCUMENTATION IS ENOUGH?

That answer is elusive and varies widely, but ultimately is based on the two purposes above as well as any additional requirements from your customers and/or regulating bodies. A better starting question is "what documentation do I need to ensure that my customer's requirements are met, and so that I can keep improving?"

Documentation should be as usable as possible for those that have to interact with it, including employees and contractors. Bloated procedures are hard to follow and risk being ignored or misused. Documentation should also be readily available when and where someone needs to use it. A written procedure does no good if it's kept in a binder in an office away from the process it is supposed to guide, and logs are not helpful unless they are kept up to date.

FORMATS

Documentation can be in physical (paper) format or electronic, such as MS Office files, Google Docs, or a cloud-based wiki. Formats should be chosen based on the purposes above, with a focus on ease of use. Documentation should be available where it's needed and used.



EXAMPLE: a farmer cooperative may have a series of procedures and blank forms stored on a cloud-based file server, such as Dropbox. Some procedures are printed and used in areas, like in a delivery vehicle, where there is no computer access. Blank forms are printed and completed by hand, and then scanned and uploaded back to the cloud-based storage site.

PLAN-DO-CHECK-ACT FRAMEWORK

This guide is structured around the Plan-Do-Check-Act cycle of continuous improvement. Popularized by W. Edwards Deming, this method was incorporated into the 2015 revision of ISO 9001 and can be summarized as follows:



PLAN

Determine customer requirements and the desired outcomes of the system or process, and allocate resources accordingly. Identify risks and opportunities and address them as applicable.



DO

Implement and carry out the activities according to the Plan.



CHECK

Monitor how well the activities performed against the plan, and the degree to which customer requirements were met.



ACT

Take action to improve the system and/or processes based on the Check step and begin the cycle anew.



The rest of this guide will explore how this framework can be used to design and implement a QMS for food and farming businesses, organizations, and USDA GroupGAP programs.



Q PLAN

Building a quality management system begins with planning. This section will delve into defining customer requirements, understanding the context the organization operates in, leadership commitment, and evaluating risks and opportunities. This is an important step, because it's the foundation the rest of the QMS rests on. Once the planning phase is complete, the work is performed according to the plan, the completed product or service is checked against the plan, and improvements and adjustments are implemented into ongoing plan revisions.

LEADERSHIP

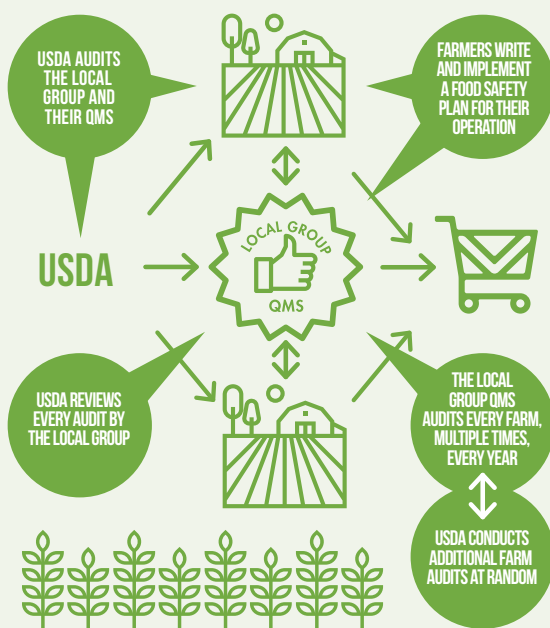
It's easy for a QMS to exist in a vacuum, as a task that is part of someone's job description rather than a method embraced by the entire organization. A QMS cannot be effective without commitment, involvement, and accountability from leadership, as well as all employees that will implement the QMS. The organization's leadership should own the QMS or assign responsibility for ownership to an individual with the authority to manage it for the organization. One way to ensure leadership engagement and focus on QMS activities is through a management review-- a structured review of QMS performance and planning discussed further on page 13.

QUALITY POLICY & OBJECTIVES

Another foundational component of QMS effectiveness is development of a quality policy and objectives. A quality policy is simply a statement of intent regarding the organization's commitment to meeting customer requirements. It's the "mission statement" of the QMS and should support the organization's overall strategy, as well as contribute to developing quality as part of the company culture. Quality objectives take that statement one step further and lay out 3-5 measurable goals relevant to quality. Quality objectives answer the question "What do we want this QMS to accomplish?" The rest of the QMS is designed to work toward accomplishing these goals. The quality policy and objectives should align with the previous work of identifying customers, interested parties, and organizational context, as well as overall goals and operations of the organization.

USDA GROUPEGAP FOOD SAFETY PROGRAM

USDA GroupGAP is a food safety certification program designed to help farmers of all sizes meet federal regulations and wholesale buyer food safety requirements. Through this program, individual farms can certify their practices together as part of a centrally managed group. In GroupGAP, a food hub, support organization, or central business entity coordinates a group of producers and establishes best practices for complying with a food safety standard (e.g. GAP/GHP, Harmonized GAP, or Harmonized Plus). The group's practices are managed through a centralized QMS that is audited by the USDA. Using the QMS, both the local group and the USDA audit farms in the group every year, multiple times per year.



EXAMPLE - QUALITY OBJECTIVES (GROUPEGAP)

1. Successful USDA GroupGAP Certification for all members.
2. Access to relevant technical assistance and food safety training for all members.
3. Documentation of successes and lessons learned to serve as a resource for other groups wishing to implement USDA GroupGAP.

THE CUSTOMER

If the purpose of a QMS is fundamentally to identify and meet customer requirements, then one of the earliest steps in developing a QMS is to define and document who those customers are. For some organizations, especially non-profits, the term “customer” might be better stated as “beneficiary;” essentially this is referring to those on the receiving end of what good or service the organization provides.

Once the customer(s) have been identified, the next step is to determine what their requirements are. Finally, the products and/or services the organization provides are lined up against those requirements. If new requirements are identified through this process, they should be flagged so that new products and/or services can be developed to meet them.

EXAMPLE: FOOD HUB

CUSTOMER	REQUIREMENT	PRODUCT/SERVICE
Locally-Sourcing Restaurant	Fresh produce sourced from within 100 miles	All product is sourced from within a 100-mile radius; produce is at peak freshness
Individual Consumers	Convenient access to local produce	Webstore, CSA delivery
Grocery Stores	Single source for a variety of local produce	Aggregation from multiple farms, single invoice, online ordering platform

INTERESTED PARTIES

The process above isn’t limited to just customers, but rather to all “interested parties.” These may be regulatory bodies, shareholders, collaborators, etc. – essentially anyone who has an impact on the organization or an effect on its ability to meet customer requirements. Interested party needs and expectations should be identified, as well as how the organization meets or complies with them.

EXAMPLE: GROUPEGAP

INTERESTED PARTY	REQUIREMENT	REQUIREMENTS MET THROUGH:
USDA	GroupGAP program requirements	QMS complies with program requirements
Institutional Purchasers	Robust food safety program	GroupGAP is a USDA program, their standards are used throughout the industry
Grocery Stores	Single source for a variety of local produce	Aggregation from multiple farms, single invoice, online ordering platform

ORGANIZATIONAL CONTEXT

The two processes above can be seen as successive concentric circles, the first being the direct customers or beneficiaries the organization serves, and the second being the indirect interested parties that the organization engages with. A further step out would include taking stock of the context the organization operates in. This could include geographic location, the current for/non-profit environment, industry trends, etc. One common tool used to determine this operational context is a Strengths/Weaknesses/Opportunities/Threats (SWOT) analysis, though there are many other ways to examine the organization’s surrounding environment. The point is to evaluate and discover anything external to the organization that may affect its ability to meet customer and other interested party requirements, and then to determine appropriate action, as necessary.



EXAMPLE: SWOT (FOOD HUB)

STRENGTHS <ul style="list-style-type: none"> Current customer base is very loyal. Positive, personal relationships with producers. Excellent customer service. 	OPPORTUNITIES <ul style="list-style-type: none"> Increasing popularity of local food. Local college has expressed interest in purchasing larger volumes.
WEAKNESSES <ul style="list-style-type: none"> Rural geography, low population density. Missing expertise in key areas. Only a small fraction of farmers has GAP certification, and several wholesale buyers, including local college, require GAP certification for produce. 	THREATS <ul style="list-style-type: none"> National broadline distributors offer lower price point. The value of local food is largely disregarded or misunderstood by a majority of purchasers.

CHARTING THE COURSE

Evaluating the organization’s context and environment likely uncovered some potential risks, both to the organization itself and to its ability to meet customer requirements. As stated earlier, risk is “the effect of uncertainty on an expected outcome.” Planning should also include strategies to mitigate identified risks, as well as ongoing methods to identify new risks. Risks can be evaluated based on severity (how bad the effect would be if it happened) and probability (how likely it is to happen). Some risks, after evaluation, may have such a low severity or probability that efforts to mitigate them would prove fruitless, but the evaluation is still an important step. Risk-based thinking is one of the core tenets of ISO 9001:2015.

EXAMPLE: GROUPEGAP

RISK	SEVERITY	PROBABILITY	MITIGATION
Product spoilage due to malfunctioning refrigerated truck	High - Consumers could become sick, customer frustration, financial loss due to disposal of product	Low - trucks are all newer and maintained on a regular basis.	None
Product spoilage due to malfunctioning storage cooler	High - Consumers could become sick, customer frustration, financial loss due to disposal of product	Medium - Coolers are older, power occasionally goes out during summer thunderstorms.	Hired [COMPANY] to perform regular cooler maintenance, developed policy to inspect product after thunderstorms.
Grocery Stores	Single source for a variety of local produce	Single source for a variety of local produce	Aggregation from multiple farms, single invoice, online ordering platform

Planning is an ongoing process, as organizations and the context they operate in are constantly changing. Therefore, planning activities should also include a process for responding to and incorporating change. This process should include addressing these questions:

- Who is authorized to make what kinds of changes?
- Who approves changes?
- How is documentation updated?
- How are those affected by this change notified?
- What kinds of events or information trigger changes?



This section covers implementing the planning activities discussed above. Now that the organization knows its customers and interested parties, is committed across the organization to meeting its customers' requirements, and has set a Quality Policy and Objectives... how does that get put into practice?

SUPPORT

One of the initial steps in converting plans into action is to ensure resources are adequately allocated to carry out those plans. This includes raw materials, equipment, financial resources, infrastructure, working environment, and most importantly the people involved in providing the product or service to the customer. If adequate resources are unavailable, the organization could develop a plan to acquire the needed resources or adjust plans to accommodate the shortcoming.

The organization should determine what specific roles are involved throughout the process of implementing the plans and procedures, what those in the roles are responsible for, what training requirements or other qualifications must be met for each role, and any applicable evaluation criteria. While people usually wear several hats in a small business, it is necessary to define what those hats are, and what is supposed to happen when each of those hats is worn.

A training program can include on-the-job training, such as shadowing another employee for a set period, and/or external training, such as an online or in-person course offered by another organization. Training should also include any additional training requirements mandated by customers or interested parties, such as USDA Group-GAP auditor training. Keeping detailed documentation on staff roles and responsibilities is necessary to ensure that each individual has met the requirements of the particular role(s) they're filling.

EXAMPLE: FOOD HUB

ROLE	REQUIRED TRAINING	DOCUMENTATION	PERSONNEL IN ROLE
Warehouse Team	<ul style="list-style-type: none"> General Warehouse Practices Food Safety Forklift Operation 	<ul style="list-style-type: none"> Signed food safety commitment form Passed Forklift 101 test 	<ul style="list-style-type: none"> [NAME A] [NAME B]
Truck Driver	<ul style="list-style-type: none"> General Warehouse Practices Food Safety Truck Operation 	<ul style="list-style-type: none"> Signed food safety commitment Driver's License Commercial Driver's License 	<ul style="list-style-type: none"> [NAME A] [NAME C]
Food Safety Coordinator	<ul style="list-style-type: none"> Food Safety Modernization Act (FSMA) Preventive Controls Rule Course University Extension Food Safety Program 	<ul style="list-style-type: none"> Record of attendance for both classes 	<ul style="list-style-type: none"> [NAME D]
GroupGAP Internal QMS Auditor	<ul style="list-style-type: none"> ISO 9001 Internal Auditor Course Shadow audits 	<ul style="list-style-type: none"> Certificate/record of attendance Record of audit attendance 	<ul style="list-style-type: none"> [NAME E]
GroupGAP Internal Producer Auditor	<ul style="list-style-type: none"> FSMA Produce Safety Rule Course USDA Auditor Training – Harmonized Produce GAP Shadow audits 	<ul style="list-style-type: none"> Certificates/records of attendance Record of audit attendance 	<ul style="list-style-type: none"> [NAME F]

As the organization evolves over time and its people gain experience, a collective pool of knowledge and experience begins to accumulate. This can become an incredibly valuable asset, if managed properly. How are lessons

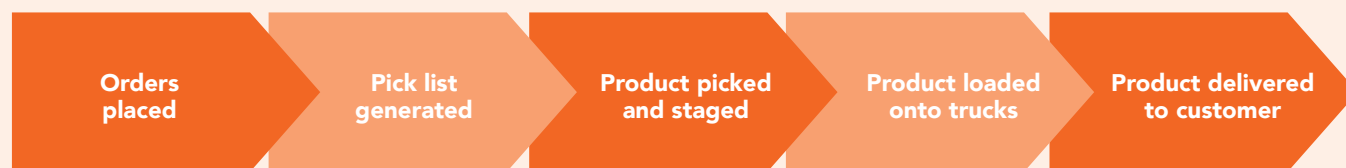
learned from successes and failures documented for future reference? What is the history of the organization, and how does that affect decision-making today? The people within an organization bring with them a diverse set of knowledge and skills, from the wisdom of the seasoned employee to the fresh ideas of the intern; how are they given voice? This will look vastly different from organization to organization, but it is important to develop a process to capture the knowledge and experience the organization gains through operation, and that is brought to it through the people within.

OPERATIONS

Earlier, a process was defined as “any activity that converts an input into an output.” There are many processes within an organization that contribute toward providing the product or service to the customer, but some may be more critical, technical, or sensitive to risk than others. For these processes, documented work instructions or Standard Operating Procedures (SOPs) may be needed to ensure that the process is performed correctly and reliably each time. Documented procedures also help ensure efficiency in training and may be a result of accumulated organizational knowledge. Further, some documented procedures may be required by third party agencies or certifiers.

Often, the outcome of one process becomes the input of the next, and these relationships can be shown with lines and arrows. Once the entirety of the organization’s processes is laid out, it becomes easier to see which ones play a more critical part than others, or where risk needs to be reduced through the development of procedures to ensure requirements are met. One way to determine whether or not a process needs a procedure is to first map out all the inter-connected processes. This could be done visually, either drawn on a piece of paper or whiteboard or on a computer, or it could be done as a bulleted list, or even a group of sticky notes on a blank wall.

EXAMPLE PROCESS MAP



OUTSOURCING

Few organizations handle everything in-house. For activities that are outsourced, it is the responsibility of the organization to ensure that the outsourcing does not have a negative effect on meeting customer and QMS requirements. This can be done by documenting specifically in your QMS which processes are outsourced, as well as clear expectations for the product or service being outsourced, including a process for ensuring those expectations have been met.

EXAMPLE OUTSOURCING SOP

[GROUPGAP GROUP] outsources Internal QMS Auditing services

INTERNAL QMS AUDITOR QUALIFICATIONS:

- ISO 9001 Internal auditor course
- Previously shadowed a USDA GroupGAP QMS audit

DOCUMENTATION NEEDED:

- Certificate from ISO 9001 auditor course
- Record of attendance

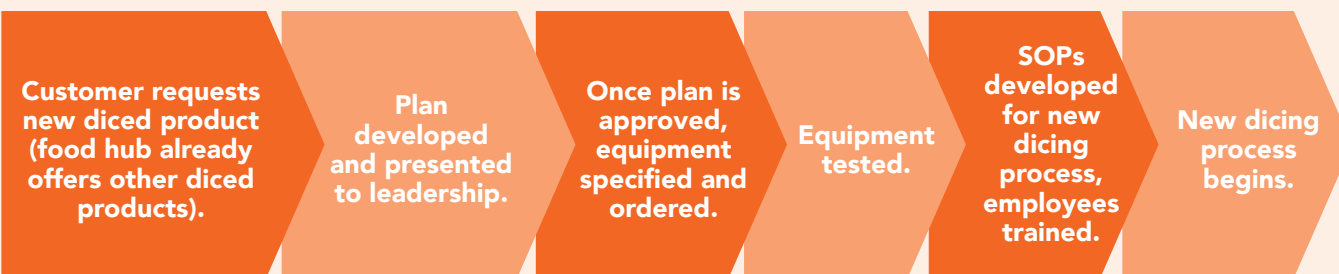
RESPONSIBILITIES:

- Audit [GROUPGAP GROUP]’s QMS according to USDA GroupGAP program requirements.
- Submit final report to Group Administrator

DESIGNING SOMETHING NEW

Organizations, their customers, and the contexts they inhabit evolve and change over time. A new opportunity may arise or customer requirements may shift, which may prompt the organization to provide a new product or service. Designing a new product or service should begin back in the Plan phase. How does this fit in with the organization's Quality Policy and Objectives? Are the new customer requirements documented? Does this affect the context of the organization? Does the organization have the resources or have a plan to acquire the resources necessary to provide the product or service? Does this new offering require any new roles and/or training requirements? These and other applicable questions should be addressed as part of the design and development process.

EXAMPLE DESIGN PROCESS STORY – FOOD HUB



Does this align with and support existing Quality Policy and Objectives? If not, should the request be turned down, or should the Quality Policy and Objectives be updated?

Will the new process introduce any new risks? How are they addressed?

WHEN THINGS GO WRONG

The organization should not only have a process in place for normal operations, but also for what happens when things go wrong. If a product or service fails to meet customer or QMS requirements, then what? Does production need to stop until the cause is identified? How is the issue corrected? What happens to out-of-specification product? This will be revisited later in the Act section.





CHECK

Customers have been identified and their requirements defined. The organization developed a plan to fulfill those requirements, and then put that plan in motion. The question now is: how did it go? How well did the organization adhere to its plan, and how well did it fulfill customer expectations? This section will explore various ways to gather the supporting data to answer these questions.

PERFORMANCE EVALUATION

Arguably the most important source of information is customer feedback. This feedback could come from a variety of sources, such as complaints, reviews, social media comments, customer surveys, focus groups, and casual conversations. Feedback from other stakeholders should be considered as well. The organization should have a process for collecting this information and compiling it for review and/or corrective action as appropriate.

Another way to check the organization’s performance is to perform an internal audit of its QMS. This exercise is a requirement of most third-party certification standards. An internal audit, usually performed by someone within the organization, looks at each component of the QMS and evaluates (1) did the organization adhere to its plan, procedures, and other applicable requirements, and (2) are there gaps, inconsistencies, and inefficiencies in those plans and procedures?

If the organization is seeking to certify to a third-party standard, such as ISO 9001:2015 or USDA GroupGAP, compliance to those requirements is evaluated through internal audits as well as external audits from an authorized body. In some cases, an organization’s customer may ask to perform an audit, to verify that their requirements are being met and to ensure that the organization will be able to meet them in the future.

Key Performance Indicators (KPIs) are important to evaluating the health of any organization. While metrics like sales growth and labor costs may be important from a business standpoint, and employee engagement and turnover may be important from an organizational culture standpoint, metrics such as customer complaints and erroneous deliveries can be important indicators of QMS performance. The organization should determine which metrics are relevant to its Quality Policy, Objectives, plans, and procedures.

When things don’t go as planned, or when errors and mistakes happen, how are they detected? Risks were identified and evaluated based on severity and probability as described in the Plan section above. Detection measures are also a valuable component of a risk mitigation strategy. Monitoring and Detection of risks can confirm or correct risk estimates from the Planning stage and will inform process and SOP updates over time.

EXAMPLE: FOOD HUB

RISK	SEVERITY	PROBABILITY	DETECTION	MITIGATION
Product spoilage due to malfunctioning refrigerated truck	High - Consumers could become sick, customer frustration, financial loss due to disposal of product	Low - trucks are all newer and maintained on a regular basis.	Installed temperature monitor in each truck, developed policy for truck drivers to check temperatures at delivery.	None
Product spoilage due to malfunctioning storage cooler	High - Consumers could become sick, customer frustration, financial loss due to disposal of product	Medium - Coolers are older, power occasionally goes out during summer thunderstorms.	Installed temperature monitoring system that alerts warehouse manager if thresholds exceeded or if there’s a power outage.	Hired [COMPANY] to perform regular cooler maintenance, developed policy to inspect product after thunderstorms.

MANAGEMENT REVIEW

So far, this section has explored various methods of gathering data on the organization’s performance. Once compiled, this data may be used to inform future plans. Management review is an exercise in which an organization’s leadership meets and reviews customer feedback, KPI’s, audit results, corrective actions (see next section), etc. on a routine basis - monthly, quarterly, annually, or whatever frequency is appropriate for the current state of the business. This allows leadership to have a comprehensive, high-level view of the organization’s performance and to be able to adjust existing plans and/or develop new plans accordingly.



The Plan-Do-Check-Act cycle is an iterative process. The output of the previous section becomes the input into the next. The Act section bridges the results from the data gathering and evaluation of the Check phase into the next round of planning. The organization acts on what it has learned from the previous cycle and the process begins anew.

CORRECTIVE ACTION

Customer complaints, errors, mistakes, and unforeseen speed bumps are unavoidable. When these are discovered, they should be remediated in a way that reduces the likelihood of their recurrence. They should also be documented, to serve as a reference to aid future corrective action and decision making. This should include recording:

1. **Description of the occurrence** - What happened and when? How was it discovered?
2. **Root cause** - Why did this happen? What were the circumstances that led to it happening?
3. **Correction** - How was it immediately fixed?
4. **Corrective Action** - What was done to address the root cause, to ensure it doesn't happen again?

EXAMPLE TABLE

DESCRIPTION	ROOT CAUSE	CORRECTION	CORRECTIVE ACTION
Customer didn't receive product. Error was detected when driver returned with product still in truck.	Driver misplaced delivery sheet	Product was delivered the next morning, customer was credited the order amount on updated invoice.	Delivery sheets updated to show "Page X of Y" so drivers can notice missing pages.

The corrective action process may uncover new risks that may need mitigating action, as well.

EXAMPLE TABLE: REVISIT RISK TABLE AND ADD NEW

RISK	SEVERITY	PROBABILITY	DETECTION	MITIGATION
Product spoilage due to malfunctioning refrigerated truck	High - Consumers could become sick, customer frustration, financial loss due to disposal of product	Low - trucks are all newer and maintained on a regular basis.	Installed temperature monitor in each truck, developed policy for truck drivers to check temperatures at delivery.	None
Product spoilage due to malfunctioning storage cooler	High - Consumers could become sick, customer frustration, financial loss due to disposal of product	Medium - Coolers are older, power occasionally goes out during summer thunderstorms.	Installed temperature monitoring system that alerts warehouse manager if thresholds exceeded or if there's a power outage.	Hired [COMPANY] to perform regular cooler maintenance, developed policy to inspect product after thunderstorms.
Customers don't receive product, delivery incorrect	Medium - Customer frustration, loss of business	Medium - The delivery process is manual and prone to human error.	Page numbers on delivery sheets alert drivers if any sheets are missing.	Exploring feasibility of a software platform that will generate routes and schedule deliveries, removing the need for physical sheets.

CONTINUOUS IMPROVEMENT

As the organization checks its performance, reflects on what it has learned, adjusts course as necessary, and begins the process again, this will lead to continuous improvement over time. Each management review becomes more informed than the last, and its outputs more targeted with better impacts. Each iteration of the Plan-Do-Check-Act cycle becomes more refined, which ultimately leads to greater satisfaction from those the organization exists to serve - the goal of a Quality Management System.

CONCLUSION

Quality Management Systems are a powerful tool for businesses large and small and have application for a variety of food and farm businesses. Their strength lies in their adaptability to a wide variety of scenarios and applications, but that strength also means they can be hard to conceptualize. This guide is designed to provide a basic understanding of the core elements of a QMS, and how an organization can utilize one to further their work. Implementing a QMS can be an important step towards achieving the organization's goals, satisfying its customers, and instilling confidence in its products and services.

APPENDIX A - ADDITIONAL RESOURCES

See below for a list of additional resources in support of developing a quality management system:

- The Small Business Owner's Simplified Guide to ISO 9001 and Business Improvement – BSI Group (<https://www.bsigroup.com/LocalFiles/en-GB/small-business/UK-SB-BSI-ISO-9001-Whitepaper-UK-EN.pdf>)
- USDA GroupGAP: <https://www.ams.usda.gov/services/auditing/groupgap>
- ISO 9001:2015: <https://www.iso.org/standard/62085.html>
- Food Systems Leadership Network (<https://foodsystemsleadershipnetwork.org/>) – Food Safety and Quality Community of Practice

APPENDIX B – PROJECT BACKGROUND

This Quality Management System Guide for Farm and Food Businesses was made possible through a Cooperative Agreement between the United States Department of Agriculture – Agricultural Marketing Service and the Wallace Center at Winrock International. The goal of this project was to create a resource to help food and farm businesses, food hubs, and GroupGAP and other food safety certification administrators understand the benefits of a Quality Management System and how to implement a QMS. The guide was drafted by Phil Britton, of Fresh Systems, LLC with assistance from Steve Warshawer and Elizabeth Atwell of the Wallace Center. Special thanks to Lindsay Gilmour, Evan Smith, and Joe Colyn for their review and feedback on the guide and to members of the Food Safety and Quality Community of Practice for their input throughout the research process.





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