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The impacts of a formal quality management system: a case study of implementing ISO 9000 at Farmers Cooperative Co., Iowa

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The impacts of a formal quality management system: a case study of implementing ISO 9000 at Farmers Cooperative Co., Iowa

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TABLE OF CONTENTS

ABSTRACT

We are in an age of great change for agriculture. The effect of globalization is changing the industry that 20 years ago were unforeseeable: the rise of biotechnology use, food safety concerns, fears of bioterroism, and increasing consumer demands. These developments result in an altered landscape of agribusiness management. Managing these developments requires an understanding of the collection of rules: regulatory (business/government), product requirements (business/consumer), and operating practices (business/customer) that defines how the modern company in agriculture operates in this environment.

In respond to these issues, the use of quality management systems (QMS) have filled in on some of these needs. A QMS is a set of policies, processes, and procedures that define how to create products and services in an organization. A formal QMS standardizes how these systems operate and their adoption has greatly increased in the same time frame as a more connected, global economy. This dissertation is case study of the impact of implementing a QMS at Farmers Cooperative Co. (FC) of Farnhamville, Iowa.

The results demonstrated that FC significantly improved the quality of meeting customer specifications, significant improvements in meeting Food and Drug Administration (FDA) requirements of food traceability, and increased monetary value of customer orders through better inventory management.

CHAPTER 1. GENERAL INTRODUCTION

Introduction

The agriculture industry is an important part of America and it is important to the overall economy as an example of what American ingenuity can accomplish. Demand for American foodstuffs has been strong for the last 50 years and has helped the United States maintain its position as the world's largest exporter for food products (Jerardo, 2004). However, competition in world commodity markets has steadily increased as the effects of globalization are being felt. Indeed, one can look at the American market, itself very large and important, as an example of what is taking place worldwide.

Since the 1950s, the United States has enjoyed a trade surplus in agriculture whereby exports have exceeded imports in every decade since then (Jerardo, 2004). The US has maintained a positive export position due to strengths in improved technology, better infrastructure, and trade policy. However, in the last 20 years, that position has eroded that has accelerated in the last decade.

Due to increased customer demand and cost competitiveness, the United States may become a net food importer, in both volume and value of agricultural products in the next few years if current trends continue (Jerardo, 2004). For instance, American food consumption due to imports, primarily due to horticulture products, has increased from 9 to 13 percent in the last 20 years (Jerardo, 2003). While an increase in customer demand for a wider variety of products accounts for part of this erosion, Jerardo (2004) states that increased cost competition from foreign producers is also a cause. This is partially due to a reduction of exports specific to agricultural crop products, as defined by grains, oilseeds and fruits and vegetables, where the volume of exports has fallen over eight percent by volume and 14 percent by dollar value since 1980 (Jerardo, 2003). Producers from developing nations have replaced the US as the low cost producer of food. To be competitive in agriculture markets, US agribusiness has to either improve customer benefits, become more efficient, or both.

Competition and customer benefits may be considered the quality factor in agriculture. The basis of commodity products, with regard to agriculture competitiveness, is to offer the same bundle of product attributes where perceived customer benefits cannot be altered. Therefore, purchasing decisions are based primarily on price (Kennedy, Harrison, Kalaizandonakes, Peterson, & Rindfuss, 1997). However, the definition of a commodity food product is changing through the increasing use of biotechnology in agriculture products.

Biotechnology crops, specifically, genetically modified (GM) crops, are crops which have been derived from microorganisms, plants, or animals which have been manipulated at the molecular level to provide the food with desirable traits. These genes are typically from another plant or animal species (Comstock, 2001). Generally, these traits are most beneficial to the producer in growing a crop more productively and efficiently. Examples include such as Bt corn to resist the European Corn Borer insect and Roundup Ready© soybeans for weed control. Due to the advantages of GM crops, their usage has become widespread in the US. For example, the recent use of herbicide-tolerant soybeans account for 87 percent of total US acreage and herbicide-tolerant cotton 60 percent of total cotton acreage (Fernandez-Cornejo & Caswell, 2006).

The use of differentiated products is complicated by customer attitudes over the use of biotechnology and wholesale acceptance by the consumers has not happened. This is described in numerous surveys taken in the United States which shows that the American consumer is more uneducated and wary of the use of GM crops. Currently, only 53 percent of those polled had heard “a lot” or “something” about GM crops. More importantly, almost half of those polled were uncertain that GM crops were safe and 25 percent said GM crops were unsafe (Hoban, 2001). Outside the US, and particularly, the European Union (EU), consumers are more educated and much more critical of GM foods due to such events as Mad-Cow disease and other scares and (Huffman, Rousu, Shogren, & Tegene, 2004).

The use of biotechnology has resulted in legislation in the US and abroad. In Europe, the European Commission has effectively banned the use of some GM crops through the use of stringent requirements. Article 47 of Regulation EC 1829/2003 states that the presence in food or feed of material which contains, consists of, or is produced from genetically modified organisms (GMOs) to be no higher a proportion than 0.5 percent (European Commission, 2003). These actions should be taken more seriously by American producers as the European market, one of the largest, was once a major buyer of US food exports. One such example has been South Korean purchase of Brazilian soybeans rather than US beans due, in part, to Brazil marketing itself as a source of non-GMOs (Harl, 2002). Thus, if the consumer responds positively to biotechnology trends, then the status quo may suffice. If response is negative, then results on trade may be affected.

Harl (2002) states that consumer choice will drive the market towards purchasing products based on preferences of the food's characteristics or traits, and the results will be quickly transmitted to the producer. Regardless of the positive or negative connotations of GM crops, this event demonstrates the need for the agriculture industry to focus on consumer wants and needs since agriculture is becoming more transparent and market-oriented whereby the consumer dominates commerce (Harl, 2002). However, unless major changes occur in the management of the US commodity supply chain, the EU will be effectively closed to American agriculture products since meeting the legal thresholds would be fiscally impractical for the for the traditional US system built on a 'blend and send' concept (Hurburgh, 2003a; 2003b).

In a period of increasing consumer demand for information, the consequence will be that global food markets will continue to shift from homogeneous foodstuffs to differentiated food products where customer specifications, rather than grades, define product requirements (Hurburgh, 2003a; 2003b). Though differentiation is a consequence of the biotechnology movement, American agriculture may benefit greatly if it is managed accordingly.

Hurburgh and Lawrence (2003) state that specificity and uniqueness of products seems to be the future of US agriculture due to the previously stated advantages that GM crops bring. Product differentiation can be defined by product attributes, or traits, or process related measures through certified and auditable systems (Clause, 2003). While testing is one way to preserve differentiation, the issue of separation through testing is primarily concerned with the added cost of doing business without regard to changing the way agriculture does business (Clause, 2003). A more prescriptive approach that relies on organizational change and consumer focus is an alternative to adapt to the changing food marketplace and international markets are not the only places where product differentiation is pushing traditional agriculture in a different direction.

The agriculture industry has started to acknowledge what the US manufacturing sector has come to understand: utilizing quality management systems to improve efficiency, while maintaining quality is a useful strategy in answer to the challenges of globalization. Moreover, since product identification and control is fundamental to quality management systems, the use of a quality management system (QMS) is likely the only way to reasonably deal with the transition costs (Hurburgh & Lawrence, 2003).

Quality Management Systems

Quality management systems focus producers on customer requirements and subsequently strengthen the supply chain through clear definition and control of operations and processes. In 1987, the International Organization for Standardization (ISO) published a series of works that created a quality management system standard, known today as ISO 9001:2000. A quality management system is a collection of processes to: (a) fulfill the customer's quality requirements, (b) applicable regulatory requirements, (c) aims to enhance customer satisfaction, and (d) achieve continual improvement (ASQ, 2000; ISO, 2005a).

The standard defines requirements for documenting processes to achieve operating consistency and increased credibility with customers and an organization may become certified to the standard through outside audits by external agencies (Weigers, 2001). A key task is certifying to compliance with the standard is a comparison of procedures with actual tasks being performed. Thus, customers know that an ISO 9001:2000 certified company meets certain management practices. This is one reason that ISO certification is so popular today. Widespread adoption of ISO 9001:2000 is what makes the standard so influential, and its adoption by businesses provides credibility for customers. The impact of QMS adoption in agriculture is also greatly increasing; agriculture (excluding the food sector) is the fastest growing area of ISO 9001:2000 with a 50 fold increase in certification in the last five years (ISO, 2005b).

ISO 9000 and Agriculture

Although ISO 9001:2000 (ISO) has been adopted worldwide in a variety of industries, there is relatively little information of the impact of a quality management system has had in agriculture. In addition, due to difficulties in measuring costs and benefits of certification, the few studies that have been conducted have been in a case study approach (Holleran, Bredahl, & Zaibet, 1999). For firms to gain benefit to ISO certification, it must be done for reasons that move the company forward in their strategic agenda. If the theme of value-added is an important aspect for revitalizing the agriculture industry in the US, then ISO could become prevalent if implemented based on operational efficiency. However, for this to occur, more research on the impact of the quality management system is needed, especially as applied to agriculture, given the variety of results noted above.

Capmany, Hooker, Ozuna, and Tilburgd (2000) state that the balance between costs and benefits of implementation is one of the most uncertain aspects of QMS in agribusinesses. Some initial research of the impact of ISO 9000 in agribusiness is positive. Mumma, Allen, and Couvillion (2000) identified six performance indicators that influence profitability including quality performance, and cost of non-conformity, in ISO certified agriculture businesses. A follow-up study also noted reduced lab analysis and product inspection costs (Mumma, Albert, Warren, Mugalla, & Abdulkadri, 2002). Capmany et al. (2000) assert that the biggest benefits from ISO certification for agribusinesses include customer satisfaction, product traceability, information quality, and sales. Holleran et al. (1999) noted that firms gained operational efficiency through reduction in production failures, improved management control of company activities, and familiarizing staff with production processes.

Conversely, there are significant cost changes due to the implementation of a quality management system. Capmany et al. (2000) noted that the largest cost increases were in audit and overall personnel costs in agribusinesses. Holleran et al. (1999) state that startup costs such as documentation of processes, auditing and corrective action follow through, and registrar costs must be included in addition to annual maintenance costs. Also, as compared to other industries, inventory costs were shown to be larger due to implementing process controls to account for the perishable nature of agriculture goods. However, since product waste and rejections also decreased, this could be due to increased quality control and not increased quantity of inventory (Capmany et al., 2000).

More recently, a case study of implementing ISO 9001:2000 at a large grain elevator operation, utilizing a benefit-cost ratio, showed results of two dollar cost savings for single dollar invested (Hurburgh, 2004). It is in this vein that additional research would benefit.

Mumma et al. (2000) state a more specialized benefit-cost analysis is needed to conduct a more focused study of the fiscal impacts of adopting a quality management system like ISO. Specifically, obtaining output measures pertaining to a single agribusiness would be illuminating (Mumma et al., 2002). Also, Capmany et al. (2000) note that as more information about the fiscal impact of QMS becomes clearer, the more agriculture firms will consider certification.

A recent survey of 15 economies found that the food sector ranked, as highest, obtaining quality improvements and capture of workers' knowledge as the main reason for adopting ISO (Corbett, Luca, & Pan, 2003). Furthermore, Corbett et al. (2003) suggest that relative to all other economic sectors, the firms in this industry were motivated by process related reasons. This suggests that the food industry may understand ISO adoption the best in relation to other economic sectors. However, in the same study, Corbett et al. (2003) report the food sector is among the lowest areas of ISO adoption with approximately four percent of businesses certified. This suggests a gap exists between knowledge of the standard and actual adoption by food/agriculture firms.

ISO adoption compels process control, traceability of product information, and continuous improvement in practices to agribusiness (Clause, 2003). ISO would bring an operational discipline that has not been traditionally associated with agriculture. Indeed, Hurburgh and Lawrence (2003) state that the primary benefits of widespread ISO adoption would be in operational efficiencies. Holleran et al. (1999) state in a study of competitiveness of the food and drink sector where operational efficiency was the primary reason for companies to adopt ISO. The main objective of this research project is to fill in the gap in research of the impact of QMS adoption in agriculture.

Project Background

Farmers Cooperative Co. of Farnhamville, IA, (FC) is the largest customer-owned cooperative in Iowa with over 300 employees serving over 4000 members. Since 1944, FC has grown through merger and acquisition to 49 locations covering a trade territory of approximately 19,000 square miles (Farmers Cooperative, 2005). Organized under a Chief Executive Officer, FC has four distinct divisions based on typical grain elevator operations: 1) Grain and Agronomy, 3) Administration, 2) Sales and Marketing, and 4) Feed (Farmers Cooperative, 2005). The Grain department was the first area to develop a quality management system at the location in Odebolt, Iowa. FC's development concept was to develop a quality management system at a single location, then replicate the development and implementation process at all strategic FC facilities (Hurburgh, 2003b).

FC tried to implement the ISO standard but found that it was unable to adapt FC's grain business to the general industry language of ISO 9001 (Sullivan & Hurburgh, 2002). Thus, the organization implemented a quality management system based on an industry specific standard: the American Institute of Baking's (AIB, Manhattan, KS) Quality System Evaluation (Sullivan & Hurburgh, 2002). With language more familiar to the grain handling industry, implementing a quality management system was easier based on the AIB standard. AIB's quality management system, the Quality System Evaluation (QSE), is a comprehensive audit developed to thoroughly evaluate a company's quality system. Similar but less comprehensive than ISO, the AIB standard has common elements such as process documentation, control, and verification (Stevenson, 2004). FC found the QSE a good intermediate step toward certification to the ISO standard (American Institute of Baking, 2006; Sullivan & Hurburgh, 2002). The mission of the American Institute of Baking (AIB) is to protect the safety of the food supply chain. AIB has created the quality system evaluation (QSE) quality management system with food safety is the main objective of certification (Stevenson, 2004).

For FC, there are a number of goals associated with this project. First, is to develop internal quality, customer, and learning objectives to measure the impact of the QMS on the business. These measurements serve as benchmarks, or baseline measurements to define and identify gaps between desired performance and targets identified through FC's business plan. Finally, the benchmarks will be used by management for implementing FC's quality policy to guide strategic improvement throughout the organization (Sullivan & Hurburgh, 2002). In addition, FC has reorganized the company, which includes facilitating QMS implementation (T. Miller, personal communication, June 7, 2005.)

General questions in this study were based upon objective data the business provided in this case study. What is the impact of QMS adoption upon FC? This overall question was answered in this study. How do the AIB and ISO quality systems compare? Comparing the AIB and ISO systems was a question the management of FC had to resolve how to manage two different quality management systems. How did the QMS perform over time? Some of the data of this study covered a timeline over a period of 6 years and provided an opportunity to study the maturation of the QMS at FC.

General Objectives

The objective of the first paper was to study the impact of QMS adoption on FC's ability to meet product customer specifications through analysis of corn shipped to customers. The objective of the second paper was to study how the QMS was utilized to create and improve upon a grain traceability system that met new federal regulations that met the requirements of the Bioterrorism Act of 2002. The last objective was to study the impact of QMS adoption FC's ability to manage inventory and subsequently, increase the value of shipped commodity corn to the customer.

ISO 22006

As a final part of this dissertation, a draft standard for implementing ISO in crop production is included in the appendix. Hurburgh and Lawrence (2003) note that many manufacturing industries have customized a "front end" for ISO standards to make them more user friendly for specific situations. This is happening in agriculture with custom programs such as the American Institute of Baking QSE program for flour mills and bakeries (Hurburgh & Lawrence, 2003). However, they also state that processors and end users in the food supply chain would have less confusion if a common terminology is used and that ISO 9000 is the international language of QMS. The need to harmonize national standards for food quality management has resulted in ISO 22006: guidelines for the application of ISO in crop production (ISO, 2006). A standard specific to production in the food chain is needed to address issues of commodity agriculture, namely, the increased use of biotechnology resulting in product differentiation, consumer pressure for traceability, food safety and terrorist concerns, and reduced operating margins (Hurburgh & Lawrence, 2003). As QSU (2004) note, the creation of an ISO guidance standard would help expand QMS by addressing specific issues in agriculture. In addition, if the future of US agriculture strategy focuses more on technology and differentiation as answers to these problems, then the organization and discipline of quality management systems is likely the only way to create the transition at reasonable costs (Hurburgh & Lawrence, 2003). Finally, to fully capture the benefits of implementing a quality management system, the general market must have the assurances that the right practices and systems are in place. The most practical way to accomplish this is through an internationally recognized format, such as ISO 9001:2000 (Hurburgh & Lawrence, 2003). Thus, adoption of an agriculture ISO standard would be beneficial to both producers and customers. Producers could gain the internal benefits of an ISO quality management system and their customers the assurances that their preferences are met.

Dissertation Organization

This dissertation is written in the alternative format. The General Introduction is Chapter one of this dissertation. The second chapter is a general literature review. Chapters three, four, and five are manuscripts of three research papers. Chapter six are the general conclusions. The appendix contains a working draft of ISO 22006: guidelines for the application of ISO 9001:2000 in crop production.

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CHAPTER 2. QUALITY MANAGEMENT SYSTEMS IN AGRICULTURE

Introduction

The management of biotechnology, food safety, and food security has created a number of changes in agriculture markets. Underlying this trend is what Tom Friedman called the flattening of the global economy due, in part, to the massive development and use of technology (Friedman, 2005). Quality management system adoption in agriculture has grown as the result of these changes.

Genetically Modified Food

Biotechnology may be defined as food and feed altered at the genetic level, or known as genetically modified (GM) crops (Comstock, 2001; Pretty, 2001). This process allows a beneficial response, such as herbicide tolerance and/or insect resistance during plant growth. Their use has been highly regulated or outright banned from many economic blocks (European Commission, 2002).

Consumer fears over the unintended consequences of biotechnology crops to human health or the environment have been well documented (Barbagallo & Nelson, 2004; Gaskell et al., 2006; Loureiro & Bugbee, 2005; Pretty, 2001). Perceived risks to humans include provoking an allergenic response, antibiotic resistance, and increased toxins to GM food (Loureiro & Bugbee 2005; Pretty, 2001). While there have been no documented cases of these problems, some hold a perception of an unknown threat from the long term effects of consuming GM food. (Barbagallo & Nelson, 2004).

Other perceived risks include the creation of novel and permanent transformed populations of super weeds exhibiting herbicidal tolerance or loss of wildlife (Council for Biotechnology Information, 2001; Pretty, 2001). Slow government response to food safety incidents, such as Mad Cow Disease in the United Kingdom (UK), have resulted loss of trust in government and industry institutions (Hobbs, 2004).

EU Food Concerns

European attitudes matter to the US in terms of agricultural trade. With 457 million inhabitants and one-fifth of global trade, the European Union (EU) has the world's third largest population and imports a majority of goods from the United States (EUROPA, 2006a; EUROPA, 2006b). European opinion is against the consumption of GM food (European Commission, 2006). Agriculture biotechnology, or GM food, compared negatively against other types of biotechnology. There is widespread support for medical (such as stem cell research) and industrial (i.e. biofuels, bioplastics, etc.) biotechnology, while there is general opposition to agriculture food. Only 27 percent of the EU general public supports GM food (Gaskell et al., 2006). GM food does not translate to general disenchantment with science and technology, but there is the belief that GM food is a risk to society (Gaskell et al., 2006).

EU Food Legislation

To restore public confidence in food safety, the EU has increased regulations. The General Food Law (EC 178) has organized EU member state rules regarding food safety under one law with the goal of protecting human life and the environment (European Commission, 2002). EC 178 also created the European Food Safety Authority (EFSA); an agency responsible of ensuring that food introduced into the EU is safe based on risk assessment and scientific analysis. However, if scientific uncertainty still exists, the precautionary principle still applies (European Commission, 2002). Subsequent enabling regulations specific to GM foods are EC 1829 and EC 1830 (European Commission, 2003a; 2003b).

EC 1829 and 1830 address the deliberate release of GM foods, and GM food labeling/traceability. EC 1829 provides a harmonized procedure for the deliberate release of GM food and feedstuffs into the marketplace (European Commission, 2003a). Traceability of the food supply from origin to destination is required (Food Standards Agency, 2003). The traceability mandate facilitates a recall of GM food if necessary. It also transmits information about ingredients, origin of production, and history of product production.

Adventitious (unavoidable) presence of GM material is recognized by thresholds. Thresholds recognize the difficulty in detecting the presence of GM materials at low levels in bulk food/feed products. If a GM event has already been approved, 0.9 percent of GM material may be present. The threshold is lower (0.5 percent) if the event has not yet been fully approved for human consumption (Food Standards Agency, 2003).

While there is a process for declaring the presence of GM food, European food and retailing industries remain reluctant to market them. Fear of backlash is common (European Commission, 2006).

US Food Concerns

Negative opinions of GM food are not shared by US consumers (Gaskell et al., 2006). American consumers are more comfortable with GM food than European consumers.

American consumers believe GM food consumption to be safe (Mellman Group and Public Opinion Strategies, 2005). Overall, American consumer opinion is that genetic modification (GM) ranks low as a food safety risk (Gaskell et al., 2006; International Food Information Council, 2005).

Food safety events in the US have resulted in consumers demand for greater accountability (Gellynck, Januszewska, Verbeke, & Viaene, 2005; Hobbs, Bailey, Dickinson, & Haghiri. 2005; Opara & Mazaud, 2001; Schwagle, 2005). The US has experienced a number of food safety events lately such as Starlink™ corn, aflatoxin and melamine in pet foods, and E. Coli in fresh produce (Barboza & Barrionuevo, 2007; Bucchini & Goldman, 2002; Gussow, 2006).

The attack of 9/11 resulted in greater concern for food supply vulnerability. The trend to fewer, larger farms and processing firms has concentrated production and processing. Concentration increases the likelihood that a small volume event could become widespread (Chalk, 2004).

Bulk commodity grain markets are especially prone to propagating small events. In 2000, Starlink™ corn, unapproved for human consumption, was planted on 0.5 percent of total US corn acreage in 2000. The commingled total of Starlink™ with other corn eventually reached 124 million bushels in 2000 (Lin, Price, & Allen, 2002). A general lack of farm and food related security and surveillance is common (Chalk, 2004). Easy access to the food supply and low technology requirements are conductive to disseminating harmful agents (Chalk, 2004).

A bioterrorism event may occur with relative ease. A terrorist group could obtain a pathogen from a state or other sponsor (Casagrande, 2000). Enough countries are suspected of possessing anti-agriculture biological weapons make this possible (Casagrande, 2000).

The most substantial consequence of attacking the US food supply would be the economic effects of trade embargoes by trading nations. Member nations of the World Trade Organization (WTO) are entitled to ban imports of plant or animal materials unilaterally, regardless of international trade arrangements. When foot and mouth disease (FMD) hit the UK in 2001, the EU and other WTO countries immediately blocked British imports (Wheelis, Casagrande, & Madden, 2002). In 2003, the presence of Bovine Spongiform Encephalopathy (BSE) found in a cow in Washington State resulted in the ban of American beef in over 30 countries, including Japan, South Korea, and Taiwan (Thomas, 2004).

US Food Legislation

The Bioterrorism Act of 2002 (the Act) requires security in the US food supply. The Act requires all companies in the food industry to self register with the Food and Drug Administration (FDA). It also requires one up and one down traceability (FDA, 2002a). In the likelihood of an event, a location must produce requested records within a 24 hour period to FDA (FDA, 2002a). This includes the identification of immediate previous sources and the immediate subsequent recipients of the suspected food, including packaging. Simply providing customer and supplier lists to the FDA is not acceptable (FDA, 2002b). As best possible, the path of input raw materials through processes to specific outputs must be given (FDA, 2002b).

Food Traceability

Traceability is defined as the ability to trace the history, application or location of that which is under consideration (ASQ, 2000). The result is the ability by a food company to track information fully backward and fully forward in the system (Bollen, Riden, & Opara, 2006; Gellynck et al., 2005; Hobbs et al., 2005; Opara, 2003; Opara & Mazaud, 2001). Gellynck et al. (2005) adds that specific suppliers of raw materials and customers of end products should be included in a traceability definition. Traceability should include all individual components and ingredients. (Bailey, Jones, & Dickinson, 2002; Hurburgh, 2004).

There are three basic aspects of a traceability system: (a) breadth, (b) depth, and (c) precision (Golan et al., 2004). Breadth is the amount of information, or, the number of attributes that a traceability system collects. Depth is how far back in the processing history information was collected. Traceability may end at the retail store or go completely back to the producer. Precision is the degree of accuracy with which the traceability system can pinpoint a particular food item's movement through the chain.

A tracking unit defines precision and is typically referred to as a 'lot' in the system. A lot is typically defined by the amount of material that shares unique and similar characteristics with a common process history (Van der Vorst, 2006). In continuous flow processing, lot definition is more difficult since changes in conditions are not as easily identified (Moe, 1998). In this system, the lot may be determined by the raw material and a change in activities, such as the path and destination for storage for food stuffs (Moe, 1998). For instance, grain storage and handling typically offer poor precision since large lots are created in the definition of a lot (Golan et al., 2004).

Traceability is sometimes defined in more detail by what direction the product information flows in food manufacture (Schwagle, 2005). In a tracing system, the information flow moves backward through the supply chain from consumer to supplier. Tracking is following the information forward from the source to the end user.

Bailey et al. (2002) adds that the ability to trace/track food products occurs at different organizational levels. A company may have its own distinct internal traceability system, or the entire food chain may be involved. Food chain level traceability is created when organizations link company level traceability together (Gellynck et al., 2005; Moe, 1998; Van der Vorst, 2006).

Traceability fulfills a reactive function in food safety. Through the process of a reactive traceback, the responsible food products are identified and removed quickly from the market (Hobbs, 2004). Through a precise food recall, traceability minimizes the number of people exposed to potentially unsafe food in the supply chain. (Hobbs, 2003). Traceability may also minimize private costs such as damage to the brand and company reputation. Traceability could minimize costs to firms not responsible for the suspected food products in a food recall. By dissociation, the remainder of safe food products are cleared from an overall recall (Hobbs, 2004).

Traceability could assign litigation costs (Lupien, 2005). Traceability identifies liability for food safety problems to the parties involved, reducing the costs of liability for those not responsible (Hobbs, 2004). In the food industry, assigning fault is difficult. As a result, penalties may apply beyond the suspected organizations to the general area of production and processing (Hobbs, 2006; Lupien, 2005). Traceability may be done proactively if organizations understand that liability costs may be controlled.

Traceability alone does not lead to an improvement in food safety because there is no aspect of intervention during the production and manufacture of foodstuffs (Starbird & Amanor-Boadu, 2006). Traceability, per se, does not contain an active feedback loop to change manufacture. Traceability may cause scrutiny of operations that may result in process changes, if the organization has the information feedback system to implement the change.

Some consumers are willing to pay a premium for food products that are traceable. Information about manufacture may enhance the value of the product (Smyth & Phillips, 2002). These attributes are characteristics which consumers cannot detect and may relate to the content or process of the food product (Smith et al., 2005). The premise is that the customer will purchase, at a premium, based on how the food product was produced. The emergence of differentiated products has increased from targeting specific segments of the consumer population (Golan et al., 2004). Management of the differentiated product is usually handled by a common traceability system crossing organizational boundaries. The premiums gained are typically shared by parties in the supply chain for the system to work. Otherwise, companies could not recover the extra cost of traceability from additional revenue in the premium market.

Quality Management Systems in Agriculture

Saraph, Benson, and Schroeder (1989) state that companies need to compete on a basis of quality to remain competitive. Quality becomes a way to do business and the practice of quality management requires participation from the entire organization (Garvin, 1987).

A quality management system (QMS) may be defined as a system for management that is based on the following eight management principles (American Society for Quality (2000b):

1. Customer focus – organizations depend upon customers and should understand customer needs, meet customer requirements, and strive to exceed their expectations.
2. Leadership – leaders should create and maintain an environment in which people can become fully involved in achieving organizational objectives.
3. Involvement of people – personnel at all levels are the essence of the organization and should be fully engaged in their abilities in the workplace.
4. Process Approach – a desired approach is achieved more efficiently when activities and resources are managed as a process.
5. System approach to management – identify, understand, and manage interrelated processes to contribute to organizational effectiveness and efficiency.
6. Continual Improvement – continual improvement of the organization's overall performance should be a permanent objective.
7. Factual approach to decision making – effective decisions are based on data analysis and information.
8. Mutually beneficial supplier relationships – an organization and its suppliers are interdependent and mutually benefit one another.

ISO 9001:2000 (ISO) is a quality management system standard. Organizations may become independently certified as meeting ISO by an independent party. Assessment of

ISO conformance is limited to describing elements of an organization's QMS, supported by documentation (Van der Spiegel, Luning, Ziggers, & Jongen, 2005).

Adoption of a QMS based upon ISO 9001 is voluntary but the benefits of ISO 9001 recognition has resulted in worldwide growth. From the most recent survey of ISO adoption, over 770,000 individual certificates were issued as of 2005 (ISO, 2005a). In the five year period between 2000 and 2005, the overall growth of ISO certificates was 18 fold (ISO, 2005a).

Caswell, Bredahl, & Hooker, (1998) note that ISO certification will be the most likely course agriculture will take to remain competitive in the global marketplace. Three forces focus the issue on QMS adoption: consumer demands, regulation, and globalization (Kennedy, Harrison, Kalaizandonakes, Peterson, & Rindfuss, 1997).

QMS adoption allows an organization to meet regulatory requirements more efficiently (Hooker & Caswell, 1999). Increased concerns for food safety caused by biotechnology, several food safety incidents, and major changes in food law, have resulted in increased focus on QMS (Da Cruz, Cenci, & Maia, 2006; Efstratiadis, Karirti, & Arvanitoyannis, 2000).

Internal improvements are also a reason for QMS adoption in agriculture (Mumma & Couvillion, 2000). In the case of a commodity first handler, the first activity is obtaining incoming food material with the required initial properties, which must be maintained by appropriate storage conditions. Kennedy et al. (1997) states that first handlers/processors will be compelled to utilize quality management systems to compete due to globalization of the food, and now, the biofuel industry.

Quality management systems specific to food and agriculture have been created. ISO 22000 is a quality management standard that has been created for organizations operating in the food chain (ISO, 2005b). ISO 22000 specifies the requirements for a food safety management system that combines food safety principles and quality management systems (ISO, 2005b). The standard is closely aligned with ISO 9001. ISO 22000 promotes the adoption of a process management system approach when developing a food safety management system.

ISO standards for specific food sectors are also in development. ISO 22006 has been created to assist agriculture producers in developing a quality management system in crop production (ISO, 2006). The agriculture sector alone is the fastest growing area of ISO certification with a 50 fold increase in the number of certificates issued over the same five year period (ISO, 2005a).

Food traceability is also an area of QMS development. ISO 22005: traceability in the feed and food chain is being created to describe the general principles and basic requirements for traceability in a QMS (ISO, 2005c). The standard can be applied by any organization operating in the food chain and may be used in conjunction with ISO 9001:2000, 22000, and 22006.

ISO 9001 requires internal traceability where required. If traceability is a company requirement, certification to ISO 9001 is required. For organizations with a traceability requirement, then ISO certification requires internal traceability (Opara & Mazaud, 2001). This may not be widely recognized. A recent study of international food companies found that most food processors focus on safety prevention through quality assurance (QA) systems instead of traceability systems (Van der Vorst, 2006).

Traceability is a reason that agriculture is adopting QMS (Da Cruz et al., 2006; Efstratiadis et al., 2000). Luning and Marcelis (2007) propose QMS be used to manage decision making in agriculture quality management, including traceability. Beulens, Broens, Folstar and Hofstede (2005) state that the use of QMS allows organizations to respond to food safety events through traceability.

QMS Benefits Inquiry

To measure the impact of quality management in agriculture requires knowledge of crucial operations (Manning, Baines, & Chadd, 2006; Van der Spiegel et al., 2005). Binner and Jansen (2005) recommend a process management approach for evaluation of crucial operations. Utilizing business measurements which Mumma and Couvillion (2000) recommend, the focus was on internal improvements per QMS adoption.

QMS can be studied according to business process management (BPM) principles. BPM is based on the concept that work is structured around a small number of business processes or work flows, which link activities employees in a functional enterprise. This process orientation is different from the traditional organizational structure. A traditional organizational structure is defined by departments, or units, which employ personnel doing the same function, in a vertical, or functional, fashion (Ostroff & Smith, 1992).

In a process-driven enterprise, the primary benefits come from an alignment of the strategic objectives and customer needs of the business (Lee & Dale, 1998). In a process-driven enterprise, the primary benefits come from an alignment of the strategic objectives and customer needs of the business.

Identification and organization of business processes is based on the idea that there are processes that are common to all businesses (Melao & Pidd, 2000):

1. Core process - process which include the primary activities that add value to the product or service to the external customer
2. Supporting process– process which concern secondary, or support activities and are primarily the concern of the internal customer

Core processes are the primary means by which the company adds value. These processes should be treated as the core competency of the enterprise to meeting customer expectations (Melao & Pidd, 2000). Business process management focuses the organization on core processes (Elzinga, Horak, Chung-Yee, & Bruner, 1995). Therefore, the QMS and documentation must show lateral connection and quality audits done across a wide variety of job functions.

Case Study at Farmers Cooperative Co.

A case study of the impact of QMS in agriculture is taking place at Farmers Cooperative Co. (FC) of Farnhamville, IA. FC is the largest customer-owned cooperative in Iowa with over 300 employees serving over 4000 members (Farmers Cooperative, 2007). The quality policy of FC is total customer satisfaction through operational excellence (Farmers Cooperative, 2004a).

This same principle was used to identify FC's core processes in multiple meetings with upper management. A list of core activities was defined by top management to answer what processes are crucial to the success of FC:

1. Receiving – process of receiving, identifying, sampling and grading, and acceptance of inbound grain (corn and soybeans) purchased from producers or transferred from other FC locations (Farmers Cooperative, 2004b)
2. Storage – process of handling and storage activities of corn and soybeans to minimize grain breakage, inventory changes, and quality deterioration until grain is ready for loading for shipment (Farmers Cooperative, 2004c)
3. Shipping – process of loading, final inspection of grain through sampling and grading, release of grain shipments, and collection of post shipment information to assure contract conformance and grain grade consistency as established by grain marketing personnel and the external customer (Farmers Cooperative, 2005a; 2005b; 2005c)

This activity answered two questions of interest: (a) what is the overall process of grain handling as defined by the company's quality management procedures, and (b) what is the impact of these QMS processes? Figure 1 shows the overall process of grain and information flow at FC.

The process map describes the core processes of FC and identified performance measurements of the overall activity. It connected the different core processes of the operation.

The output of grain production was a core activity of the elevator and value-added to the company. It provided the most direct evidence of the impact of quality management system implementation. Concentration on product realization would provide direct evidence of how preservation and handling activities performed. The impact of the entire QMS was evaluated by analysis of delivery of products and/or services.

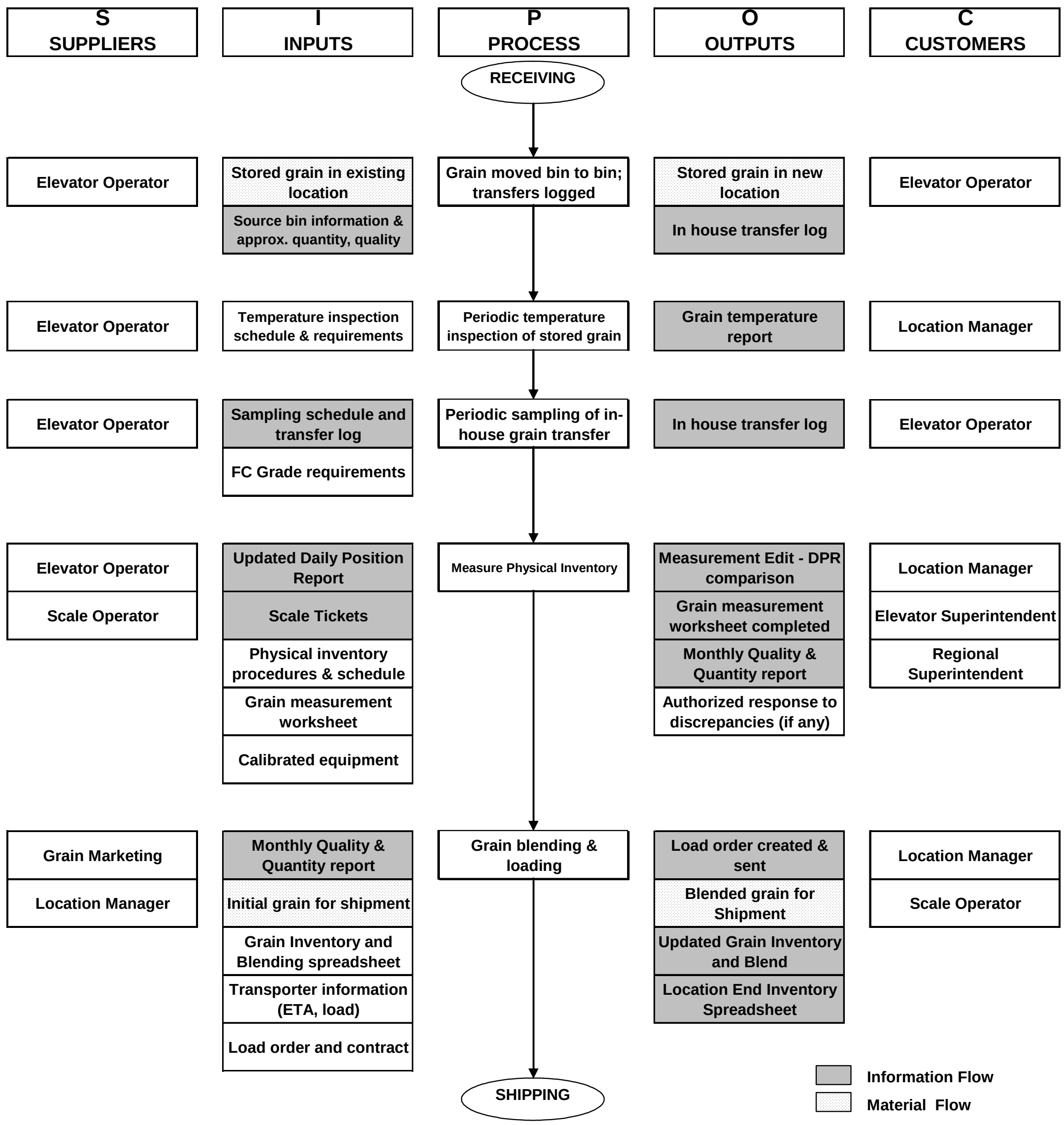

Figure 1. Process map of Farmers Cooperative core product preservation activities

Kueng (2000) describes two approaches in developing the appropriate measurements, or indicators: (a) utilize an existing, generic set of indicators and picking the correct ones, or (b) starting from scratch. Since FC was motivated by internal information to expand the QMS, relevance of existing data was selected.

Conclusions

This project was done in a series of studies to determine the impact of quality management systems in grain elevator operations. Agriculture must improve operational efficiencies to meet the challenges of globalization. The quality of measurement data is important in the continuous improvement of business processes. The first study focused on the impact of QMS upon quality control and measurement of grain shipped to customers.

The events of 9/11 and food safety events have raised public awareness and resulted in legislations mandating traceability in commodity grain operations. To meet the requirements of the FDA, the second study focused on the creation of a grain traceability system at FC utilizing the QMS as a foundation.

The setup and maintenance of a QMS requires company resources. Grain elevators handle large amounts of inventory to operate grain elevator operations. The management of inventory is important to meet fiscal goals of the company. A QMS requires resources to setup and maintain. The third study focused on the impact of QMS upon inventory management practices and the fiscal benefits of QMS adoption.

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CHAPTER 3. MEETING CUSTOMER SPECIFICATIONS IN COMMODITIES: A CASE STUDY FOR QUALITY MANAGEMENT SYSTEMS

A working paper to be submitted to *The Journal of Quality Management*

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Abstract

From the latest ISO world survey, agriculture is the fastest growing industry for ISO certification. Grain elevator operations are an important segment in the food supply chain and as the number of certifications grows, there is a demand to demonstrate the effectiveness of quality management. This case study examines the impact of implementing a quality management system based at Farmers Cooperative Co. of Farnhamville, IA, a large, multi-site grain elevator company. After certification, FC reduced the grain quality variation between company employees and federal inspectors by 6.91 percent for damaged corn, 0.32 percent for foreign material content, and 0.1 percent for test weight. This resulted in an added value of $240.00 per railcar of corn shipped.

Introduction – QMS in Agriculture

The use of quality management systems, such as ISO 9001:2000, has increased rapidly over the past 20 years to meet increasing customer demands for product quality. A quality management system (QMS) is the collection of coordinated activities that directs organizational policy to meet customer expectations (American Society for Quality 2000a). Released in 1987, the ISO 9001 quality standard was derived from the BSI 5750 quality assurance standards developed by the British Standards Institute, and has since been revised twice (Zaibet and Brendahl 1997). ISO 9001:2000 (ISO) is a formal quality standard an organization can be certified to meet the ISO standard requirements through an independent audit system. ISO certification facilitated business transactions with one another since certification implies that the organization uses a certain number of core practices in guiding operations (Simmons and White 1999; Van der Spiegel et al. 2005). Over 700,000 ISO 9001 certificates have been issued to date worldwide (ISO 2005). It has become the predominant global quality management (QM) system because it is used to address both peer competition and customer requirements (Chang and Lo 2005).

External pressure is not the only reason for ISO adoption and certification. Organizations adopt QMS to standardize operations, reduce product defects, and become more efficient (Jones et al. 1997). Recent studies of agriculture businesses (agribusiness) reveal that these organizations are looking for ISO certification to improve internal abilities to meet customer specifications (Mumma et al. 2002; Rubia and Arias 2005).

Since QMS adoption is only recently expanded in agriculture, there are few studies of QMS impact (costs vs. benefits) in agriculture (Capmany et al. 2000; Mumma et al. 2000; Sullivan and Hurburgh 2002; Hurburgh 2003a; Van der Spiegel et al. 2005). Assessment of QMS's in the food industry varies by the type of food product and by the type of processing involved. Efstratiadis et al. (2000) assessed the impact of ISO on companies working in particular food areas, regardless of organizational or business type. Other studies promoted the use of QMS's for food safety assurance in areas such as meat, cereal grains, or fresh produce (Zaibet and Bredahl 1997; Schroder and McEachern 2002; Fouayzi et al. 2004; Da Cruz et al. 2006).

Other studies focused on specific food processing areas to answer how QMS implementation impacts industry performance. Food manufacturing studies are the most predominant areas of research where particular processing measurements were used to assess QMS implementation (Hooker and Caswell 1999; Van der Spiegel et al. 2005). QMS impact assessment typically included the entire food supply chain (Caswell et al. 1998; Steenkamp 1999; Capmany et al. 2000; Manning et al. 2006). More in-depth research is needed to fill in the gaps in specific industry sectors (Mumma et al. 2000).

Company level information is hard to obtain (Rubio and Arias 2005). Company data is valuable because performance information can provide objectivity in evaluating QMS effectiveness. Overcoming the reticence of companies' to divulge business information is crucial to the success of a case study (Rubio and Arias 2005).

Grain Industry Case Study

This case study was conducted in partnership with Farmers Cooperative Co. (FC) of Farnhamville, Iowa, USA. The objectives of this project were to develop internal quality, customer, and learning metrics to measure the impact of quality management systems in grain handling, then to use these benchmarks to identify gaps between desired performance and targets of FC's business plan (Sullivan 2004). The goals were used to implement the FC quality policy: Total Customer Satisfaction Through Operational Excellence (Farmers Cooperative 2004). Using actual measures, such as internal performance and product performance data, that Mumma et al. (2000) prescribe, this case study was conducted to determine what benefits the QMS brought to FC. This study is the first of three studies: conformance to customer specifications is the focus of this study. The second study focused on creation of a QMS food traceability program in grain elevator operations. The third study focused on the impact of QMS upon inventory management in grain handling.

FC is a customer-owned cooperative which receives, stores, and sells cereal grain (such as corn and soybeans) for producers. FC is the largest customer-owned cooperative in Iowa with over 300 employees serving over 4000 members (Farmers Cooperative 2007). The trade area of FC is shown in figure 1.

As a user-owned and user-controlled business, a cooperative distributes benefits on the basis of customer-owner use and are a common business structure for grain elevators (Barton 1989). In an elevator operation, the use of the cooperative comes from the services and supplies for the producer to use that otherwise may be inaccessible: providing the seed and inputs (fertilizer), chemicals in the growing of the crop, and the provision of storage facilities for preservation of the harvested grain, and selling the marketed grain for the producer on the open market (Barton 1989). This is reflected in the mission statement: To Do for Farmers What Farmers Cannot Economically Do for Themselves (Farmers Cooperative 2007).

Preparation for an expanded external market was the initial reason for adoption of the QMS at FC. Since initial implementation, internal benefits have been noted and are listed in Table 1. Most benefits have been more qualitatively identified than actually quantified.

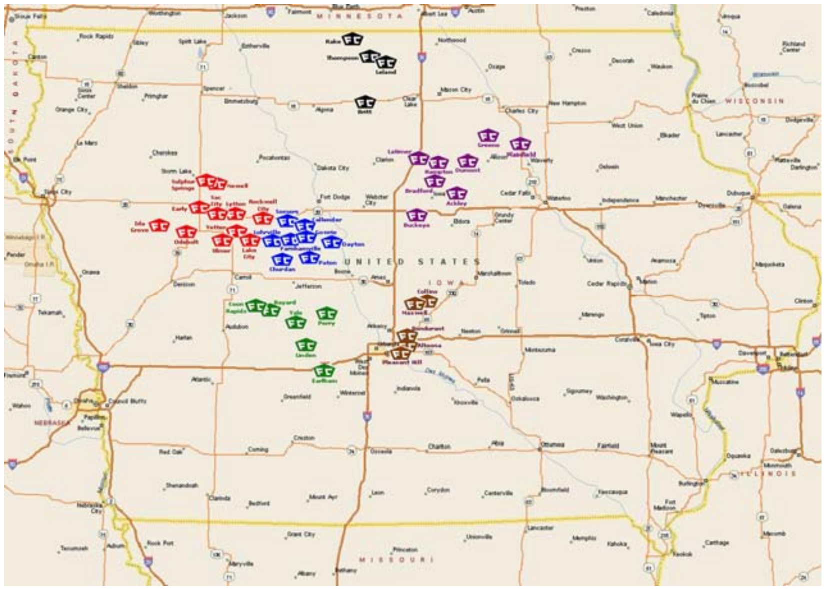

Figure 1. Trade region of Farmers Cooperative Co.

Quantifying benefits were the focus of the project. Utilizing process management principles, the most important business processes of FC's business plan were identified.

Business Process Management (BPM) is based on the idea that work is structured around a small number of business processes or work flows, which link activities employees in a functional enterprise (Ostroff and Smith 1992).

Table 1. The benefits of quality management in grain elevator operations

Cost Effectiveness	**Reference**
Improvement of operational efficiency and cost effectiveness of quality management system	Hurburgh, 2003b Hurburgh and Lawrence, 2003 Hurburgh, 2004 Hurburgh and Sullivan, 2004
Process Documentation	
Authority of job responsibility is defined for cooperative employees	Hurburgh, 2003a Hurburgh, 2004

Table 1. The benefits of quality management in grain elevator operations

Cost Effectiveness	**Reference**
Documentation of job descriptions and work instructions for process control and consistency of elevator operations	Sullivan and Hurburgh, 2002 Hurburgh, 2003a Hurburgh, 2004 Stevenson, 2004
Employee Development	
Establishment of training criteria and evaluation for effectiveness	Hurburgh, 2003b Hurburgh, 2004 Hurburgh and Sullivan, 2004
Clarification of assignments and distribution of decision making responsibilities	Sullivan and Hurburgh, 2002 Hurburgh, 2003a
Career development options more transparent	Hurburgh, 2004
Quantitative methods	
Statistical analysis provides targets and forms the basis of improved quality control of product grading	Sullivan and Hurburgh, 2002 Hurburgh, 2002 Hurburgh, 2003b Hurburgh, 2004 Hurburgh and Sullivan, 2004
Improvement of inventory management of identification and quantity for blending at shipping	Hurburgh, 2004 Hurburgh and Sullivan, 2004
Establishment of methods for problem solving and rectification through corrective action	Hurburgh, 2003a Stevenson, 2004
Regulatory Compliance	
Compliance with FDA Bioterrorism regulations	Hurburgh and Sullivan, 2004 Hurburgh, 2003b
Improvement of site security and creation of bioterrorism controls	Hurburgh, 2003b
Improved precision of grain traceability in elevator operations	Hurburgh and Sullivan, 2004 Karaca et al., 2006
Change in employee perspective of grain as ‘food grade’ for better concentration on job duties	Hurburgh and Sullivan, 2004 Stevenson, 2004
Reduction of point-in-time inspections for grain industry regulations	Hurburgh, 2002
Improvement of housekeeping and employee safety and compliance with food safety requirements	Stevenson, 2004

Processes may be categorized by core or supporting processes (Melao and Pidd 2000). Core processes include the primary activities what add value to the product or service to an external customer. Supporting processes are secondary to core processes and primarily concern internal customers (Melao and Pidd 2000).

Within elevator operations, the core processes are receipt, storage, and shipping of grain to end users. Measurement of grain quality was identified as an important indicator of core elevator operations at FC (American Society for Quality 2000b). Measurement of grain quality for end use focused the study on ISO section 7, Product Realization, and 8, Measurement, Analysis, and Improvement, in the ISO 9001:2000 standard (American Society for Quality 2000b). Table 2 shows the ISO procedures that most closely aligned with grain quality and quantity as shipped to customers.

Table 2. FC quality management system grain quality measurement procedures

ISO Number	**Relevant QMS Process**	**FC Procedure Objective**
5.6.1	Management Review Procedure	Provide a forum for personnel to discuss the QMS, review information the system is creating, and continuous improvement of the system
7.6	Control Charts Review and Evaluation Procedure	Establish a program for the review and use of control charts
8.1	Quality Control and Data Management, Outbound House Grading Comparison Procedure	Maintain accuracy of FC product quality on outbound shipments at equal or superior levels to US government levels
8.2.2	Internal Quality Audits Procedure	Provide a system, instructions, and assign responsibilities for conducting internal quality audits
8.2.5	Final Inspection Procedure	Define a system to assign responsibilities for performing the final product inspection

Data Description and Collection

The project team was focused on existing measurements which the team could describe process performance of the QMS based on Table 2. Crucial to business performance in commodity grain elevators is the maintenance of grain quality while in the elevator. Grain elevators consolidate, handle and ship grain at a quality that benefits the cooperative and meets customer specifications (Barton 1989). Elevators gain efficiencies by blending and sending of increasingly larger trade units for market (Barton 1989). Inventory management of grain is important since grain becomes defective over time.

Managing grain is an important inventory management strategy. For corn and soybeans, US grades cover (a) grain defects, such as foreign material and damage, and (b) shipment/storage factors, such as moisture, infestation, and odor, which make the grain unstable and increase defects (Hurburgh and Brumm 1994). If the grain is of low quality, there are risks for buyers in the receipt of lower quality grain, namely, the grain decomposes at a higher rate than higher grain grades (Hurburgh and Brumm 1994). Improving the measurement of grain quality would allow the company to revise the process of targeting grain quality characteristics to better meet customer specifications (Sullivan and Hurburgh 2002).

At customer delivery, grain may be blended to produce a consistent level of grain quality, matching the customer specification. The ability to create higher grade quality grain from lots of material at lower levels enables the grain elevator to generate revenue in handling and storage operations. Figure 2 shows how grain flows through an elevator operation.

Grain is inspected, dumped and stored according to the quality grade. It is commingled with other grain for blending at a uniform quality level at rail load out.

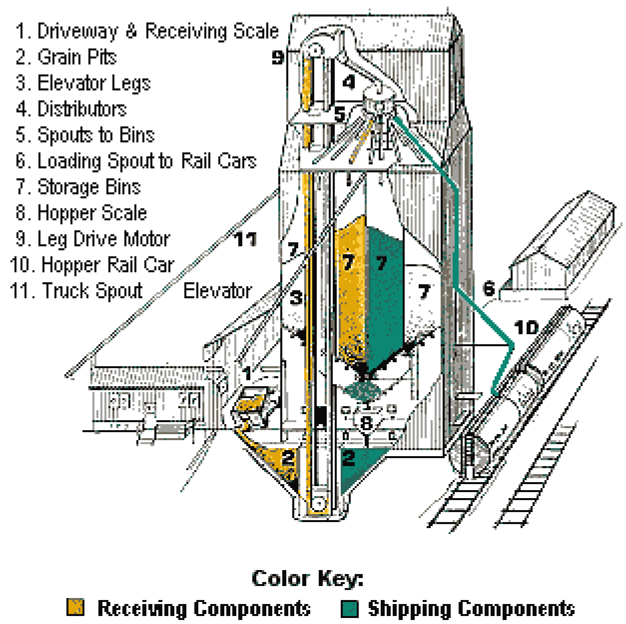

Figure 2. Grain flow in a commodity grain elevator

Through this process, an elevator operation may receive grain at a lower quality and purchased at a discount; blend it with a higher quality amount of grain to create lot of material at a new, different quality level for sale (Hennessy and Wahl 1997; Hurburgh and Brumm 1994).

Grain blending is also a management tool for grain defects. Grain defects not only reduce the value of grain but also make it unstable in shipment and/or storage. Grain defects impact the ability to manage grain storage and preservation processes, requiring an effective blending strategy to reduce discounted grain stocks while maximizing the value of shipped grain (Hurburgh and Brumm 2002).

A discount in value is typically charged to the elevator to account for out of specification conditions. Errors in either direction are costly. If grain is assigned a lower grade, then discounts are taken in the price settlement. If grain is assigned a higher grade, then the elevator is giving a higher quality product at a lower price. Matching customer expectations for quality are important. In rare instances, rail cars may be reloaded, adding rework time to the process (Hurburgh 2004).

Inspection of grain is the process of assigning to a representative grain sample defined by USDA, a quality attribute according to (USDA) criteria. In the United States, standards for inspection, or grading, are determined by Grain Inspection, Packers, and Stockyards Administration (GIPSA), an agency of the United States Department of Agriculture (USDA). Results obtained by official inspectors are considered the reference or benchmark for all other applications of grades (USDA 1997). Though all grain destined for international trade must be inspected by GIPSA, grain traded domestically may either be graded by official inspectors or by the elevator (called house grades). Official grades are often required in domestic contracts since official grades have the credibility of the US government.

Grain quality measurement is difficult to standardize since some grading measurements are arbitrarily defined. As Hurburgh (2002) notes, fundamental dimension of measurements in the United States are based on the reference standards based on the National Institute of Standards and Technology (NIST) for weight, volume, and length. There is no ‘absolute’ measure in grain grades, which means official grades also contain measurement error. Thus, the consistency of grading (precision) and closeness to the true value (accuracy) are important measurement characteristics in grading (Hurburgh 2002).

Since 2000, FC personnel have been grading the grain samples that were also graded by an official inspector to improve FC measurement of grain quality (Hurburgh 2002). Official grading processes follow guidelines of the USDA administered through GIPSA. For all FC locations, a representative sample was taken from each outbound railcar and inspected by a FC employee and subsequently sent to a GIPSA certified agency for later inspection. The following list defines the four primary grading factors of corn:

1. Test weight – The pounds per Winchester bushel (1 bushel=1.245 ft^3) of grain sample (Hurburgh and Brumm 1994; USDA 1997).
2. Moisture content – The fraction (percent) of water on a total weight basis in grain sample.
3. Damage – The fraction (percent) of kernels with mold, or insect, disease, heat, or otherwise materially damaged in grain sample.
4. Foreign material – The fraction (percent) of all matter that passes readily through a 12/64 round-hole sieve and all other non-grain material that remains in a sieved grain sample.

To compare results based on QMS implementation, the difference between official and employee grades on single corn samples was done on the four primary grading factors of test weight, moisture content, damage, and foreign material. The basic metric was:

$$\left|\text{FC Grade Factor} - \text{Official Grade Factor}\right| = \text{Absolute Mean Difference}$$

This study involved only corn; corn represents 60-70 % of grain volume at a typical Iowa elevator. Since there is no true standard for grading factors, the difference between grading results is the most important quality characteristic in grain grading. The above equation represents the absolute mean difference between the grading results of the FC employee quality control and official, government, inspections. Since there is no "true" value in cereal grain quality grades, the closeness of repeated measurements to one another is the de facto (substitute) criterion for judging the product quality of grain. An absolute difference in measurements quantifies the closeness quality control inspectors (Hurburgh 2003b; Hurburgh 2004). Official grades take more time to do, adding cost. Duel inspection could reduce the number of official grades done per train. Duel inspection was done for blending control as well.

Better quality control would allow FC to more aggressively remove defective grain during train blending. To maximize the blending value at rail shipment, FC measured grain inventory for discounted, or defective grain, at 5 FC elevator locations operating a QMS. 95 trains were measured for the discount value added per railcar per train:

$$\frac{\text{Discount Grain Value Loaded on Train}}{\text{Number of Railcars per Train}} = \text{Discount Blend Value per Railcar}$$

Four years of discount blend value (2004-2007) were collected at six elevators. The data for this set study consisted of reports filed by the location managers. This meant that the some data (or quality of data) was not available. As a result, five elevators reporting discount value are different from the two elevators reporting double inspection results. The ISO certified location had data in both the discount value data set and the double inspection data set. This consisted of three trains in the discount value data. The results were compared based on certification of the QMS: train results before certification of the location and train results after certification of the location. The discount value data was analyzed to capture the value of the train grading improvements.

Six years of double grading inspection (2000-2006) were collected from two FC elevator locations. One elevator had adopted a QMS based upon the ISO 9001:2000 requirements. One elevator had adopted the Quality System Evaluation (QSE) system created by the American Institute of Baking (AIB) (AIB 2006).

Grade results of accuracy (absolute individual mean difference) and precision (standard deviation) were also compared within individual QMS elevators based upon the event of outside certification. Grade results were compared before certification of the QMS and after certification. The double inspection data represents samples of shipped railcar grain representing approximately 56 million bushels of corn. There was little control over the data size using existing company data.

Results

An objective of this study was to develop and use metrics to measure the impact of the QMS at FC. Another objective was to use these metrics to measure the quality performance of elevator locations. To do this, the quality of measurement data must be high. Variation in measuring adds to the variation of production systems. To reduce product variation, measurement variation must be eliminated. The results demonstrated in Table 3 (ISO location results) and Table 4 (QSE location results) show that the quality of measuring grain was improved by more closely meeting customer specifications. Improvement across all four factors was not the same. Measurement of grade factors that do not have human judgment as a significant portion in measurement error were mixed.

The results of double inspection of test weight (TW) measurements were mixed. Surprisingly, the absolute mean difference (AMD) at the ISO location was significantly greater after QMS certification. Less accuracy in measuring TW at the ISO location was not expected. Closeness of measurements of TW is based on a mechanical process. Practical use of TW measurement is impacted by moisture content of the grain sample. Thus, TW results could be related to the moisture content of the test sample. Nevertheless, precision (standard deviation) was not significantly reduced after QMS certification at the ISO location. Less precise results could result in a process statistically out of control.

At the QSE location, the process did not become significantly more accurate after outside certification. However, the process became more consistent with a significant reduction in the standard deviation of the double inspection results. Certification of the QSE system was a significant event in measured improvement of TW quality data.

MC measurement is based on machine instrumentation. Measurement quality of MC data is closely monitored by state and federal programs (USDA 1997). Calibration of machine instrumentation is closely controlled. The human grain grader has a minimal role in measurement error in this process. Nevertheless, there was improvement of MC measurement precision at the ISO and QSE locations. The SD was significantly reduced and the process became more consistent after outside certification at the QMS locations. The lack of significant improvement in measurement accuracy was not entirely unexpected since the control of measurement variation is tightly controlled.

The quality of measuring damaged grain data was significantly improved after outside certification. Measurement of damaged grain is subjective. The human inspector is a significant factor in the measurement error in the process of measuring grain samples. The process is based upon comparison of grain against official visual aids for damage. The process became more accurate after certification: the AMD between FC and federal inspectors was significantly improved at the ISO and QSE locations, reducing measurement variation and improving the measurement process.   Precision was also significantly improved with a reduction of the SD; the process became more consistent and would be less likely to be statistically out of control.

The quality of foreign material (FM) inspection data improved after QMS certification at the ISO location. A reduction in the AMD and SD resulted in a reduction of the difference between FC and federal graders, improving measurement accuracy and precision. Improvement in FM performance data didn’t occur after QSE certification. This was surprising since FM is a subjective in nature. Practically, FM measurement required mechanical separation of FM from the grain. Inherently subjective, it requires an inspector to handpick FM to determine a grade for the test sample (USDA 1997). At our two locations, better control of FM measurement was inconsistent.

A reason for improving the quality of measurement data was so process improvement could be done. Train blending cannot be improved without better measuring of the process. Double inspection serves that purpose. By improving measuring, elevator personnel can more accurately improve blending opportunities, resulting in greater value to the elevator.

Take damage for instance. If DM was the deciding factor in the grade assignment, a quantitative value may be assigned, based on the results in Tables 3 and 4.

Table 3. Absolute differences between FC and federal inspectors at the ISO certified location

	Grade Factor							
All samples avg, std dev	Test Weight		Moisture Content		Damage		Foreign Material	
	n	lbs/ bu	n	% pts.	n	% pts.	n	% pts.
Absolute mean error								
after certification	279	0.65	279	0.21	110	1.77	94	0.53
before certification	2864	0.60	1749	0.19	1637	8.68	367	0.85
Difference, mean		0.05[a]		0.03		-6.91[a]		-0.32[a]
Standard deviation								
after certification	279	0.55	279	0.19	110	1.26	94	0.46
before certification	2864	0.50	1749	0.28	1637	4.41	367	0.94
Difference, std dev.		0.05		-0.09[a]		-3.15[a]		-0.48[a]

[a]Significant at the 95% Confidence Level

If current market rates for damaged corn is approximately 1-2 cents (per % point) per bushel, this results in approximately seven cents/bu gained at the ISO location. In a typical hopper car, that equates to approximately $241.00 or approximately $24,000 per 100 car train (at 350,000 bu).

The double inspection results validate the gain in value for FC in blending operations. The added value of discount grain is shown in Table 5. The trains (n=95) averaged 110 cars per train. The quantity of discount grain was measured for each train and a market value assigned.

Table 4. Absolute differences between FC and federal inspectors at the QSE certified location

	Grade Factor							
All samples avg, std dev	Test Weight		Moisture Content		Damage		Foreign Material	
	n	lbs/bu	n	% pts.	n	% pts.	n	% pts.
Absolute mean error								
after certification	218	0.52	218	0.25	79	1.44	27	0.49
before certification	2924	0.61	2821	0.25	1197	2.71	272	0.76
Difference, mean		-0.09[a]		0.00		-1.27[a]		-0.27
Standard deviation								
after certification	218	0.43	218	0.19	79	0.99	27	0.79
before certification	2924	0.48	2821	0.36	1197	2.98	272	0.89
Difference, std dev.		-0.05		-0.20[a]		-1.99[a]		-0.10

[a]Significant at the 95% Confidence Level

From Table 5, the mean of added value for railcars per train ($240.00) is approximately the same as the estimate calculated for damage. FC had previously estimated that the QMS would add value to elevator operations (T. Miller, personal communication, June 5, 2005). Based on Table 5, the added value of discount grain per railcar provides validation of the performance improvement of QMS adoption. More accurate quality data means the elevator superintendent can have more confidence in the quality and quantity of grain inventory. This measurement improvement results in a more aggressive strategy to remove discount grain from inventory, and thus maximizing on train value.

Table 5

Train blend discount grain value per rail car at load out

ISO and AIB QMS Comparison	Discount Grain Railcar Value (USD)		
	n (trains)	Mean	Std Dev
Trains from Certified Locations	66	214.1	108.0
Trains from Non-Certified Locations	29	240.0	153.1

Conclusions

The objectives of this project were to develop internal quality, customer, and learning metrics to measure the impact of quality management systems in grain handling, then to use these benchmarks to identify gaps between desired performance and targets of FC's business plan (Sullivan, 2004). This has been done through the 3 studies conducted at FC. This study demonstrated that an improvement in measurement data resulted in company performance improvement. The use of actual internal company data demonstrated that a case study of QMS impact is positive. At FC, the goal of operational excellence resulted in QM processes that improved the accuracy and precision of quality inspection. This data was demonstrates that a commodity business can increase the value of shipped product by adoption and certification of a QMS.

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CHAPTER 4. TRACEABILITY IN COMMODITY GRAIN: AN ELEVATOR CASE STUDY USING QUALITY MANAGEMENT SYSTEMS

A working paper to be submitted to *Applied Engineering in Agriculture*

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Abstact

Due to the events of 9/11, the US Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act) requires that all companies involved in the food and feed industry to self register with the Food and Drug Administration (FDA) and maintain records and information for food traceability purposes. Farmers Cooperative Co., of Farnhamville, IA (FC) used a quality management system (QMS) to create a traceability system. 41 mock recalls at grain elevators were done and demonstrated that the company met the requirements for the Act. A traceability index was created that quantifies a lot size of grain in an elevator. The time duration of a recall event was impacted by the backward or forward information flow of the event. Commingling of large quantities of grain did not significantly impact the time required to meet the FDA 24 hour mandate. The quantity of grain of the recalled lot size did not have a significant impact upon lot size of suspected contaminated grain.

Introduction

The events of 9/11 have amplified concerns about safety of the food supply. Legislation requirements for food traceability presented special challenges for US grain handlers in meeting new regulations of the Food and Drug Administration (FDA) (Iowa Grain Quality Initiative, 2006). With the goal of protecting the US food supply, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 was signed into law in June 2002 (Iowa Grain Quality Initiative, 2006). Specifically, sections 305 and 306 give the FDA responsibility for food protection and tracing to the source, incidents of food adulterated by terrorist groups or from naturally occurring events (Iowa Grain Quality Initiative, 2006).

The Act requires that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the FDA. This produced a database of all facilities engaged in food handling and processing activities (FDA, 2002a). Facilities handling raw agricultural commodities are included (Iowa Grain Quality Initiative, 2006). The Act also increased the need for traceability in US commodity production with the regulatory requirements of as noted on the FDA website: http://www.fda.gov/oc/bioterrorism/bioact.html.

Section 306 of the Act requires that registered locations maintain records which identify the immediate previous sources and the immediate subsequent recipients of food, including packaging (FDA, 2002a). By connecting the records of suppliers and customers of suspected food product(s), a chain of evidence may allow the FDA to trace food forward or backward in the supply chain. To facilitate efficient traceback, the FDA requires that a location produce requested records within a 24 hour period (FDA, 2002b).

Timeliness is important because limiting the scale of a product recall depends, in part, upon a prompt determination of what organizations are involved, or what lots contain suspect product, and those locations not affected. The Act allows for innovation in meeting the traceability requirements by not dictating how the one up and one down approach will be done.

Traceability has become the overall moniker applied to information flow of food processing in either direction. There are differences between tracking and traceability. In a tracing system, the information flow moves backward through the supply chain from consumer to supplier. Tracking is following the information forward from the source to the end user (Schwagle, 2005).

If a location has existing records which allows the FDA to identify the immediate supplier(s) and the subsequent recipient(s) of the food in question, then the organization does not need to create an entire new record system (FDA, 2002b). While this should reduce the overall cost of organizations in meeting the records requirements, the ability of a commodity grain handler to meet the Act will test that organization’s management system.

A number of recall events concerning cereal grains highlight the difficulty of grain traceability. When Karnal Bunt was found in American wheat in 1996, the Animal and Plant Health Inspection Service (APHIS) of the USDA spent over $60 million to contain and eradicate the disease in the small original area. The reduction of exports was estimated at $250 million even though area of actual infection was limited to a small portion of Arizona (Casagrande, 2000). In 2001, volunteer plants of genetically engineered corn, genetically engineered by Prodigene Co. for pharmaceutical purposes, grew among a field of soybeans in Nebraska, resulting in the soybeans to be considered adulterated. The 500 bushels of adulterated soybeans were delivered to an elevator and mixed with other soybeans that resulted in a total of 500,000 bushels of adulterated soybeans that had to be destroyed (BioTrek, 2002). Starlink corn, unapproved for human consumption, was planted on one percent of total US corn acreage in 2000. Discovery of Starlink corn in the human food chain resulted in the recall of over 300 food products and caused major disruptions in the food chain (Lin et al., 2002). The commingled total of Starlink with other corn eventually reached 124 million bushels in 2000 (Lin et al., 2002). These events demonstrate the consequences of poor traceability. Considering these events, will a commodity grain elevator be able to meet new traceability expectations of the FDA?

Quality Management Systems and Traceability

The increased use of quality management systems (QMS) could meet these demands in an efficient way. While QMS have been widely adopted in other industries such as manufacturing and professional services, the agriculture sector has begun to understand the internal benefits that such initiatives bring.

A QMS focuses on the achievement of results, in relation to quality objectives, to satisfy customer needs and expectations. To create a coherent format for quality management requirements, the International Organization for Standardization (ISO) created the ISO 9001:2000 series (American Society for Quality, 2000a).

Historically, ISO 9001:2000 was based on BS 5750, a quality management standard developed by the British Standards Institute co-released in 1987 as BS 5750/ ISO 9000 (BSI, 2006; Campany et al., 2000; Zaibet and Brendahl, 1997). Since then, ISO

9001:2000 has been revised to promote a process management approach (American Society for Quality, 2000b). Certification to the standard has become demonstration that defined performance has been reached by an organization (Meuwissen et al., 2003). As a result, the ISO standard has become the dominant QM system. Over 770,000 individual certificates have been issued, an 18 fold increase between 2000 and 2005 (ISO, 2005). Many other organizations use the standard but do not become certified.

There are some studies of ISO 9000 and traceability. The ISO standard states that an organization, where appropriate, shall identify the product, and its components, by suitable means throughout production (American Society for Quality, 2000a; 200b). A recent benchmarking study of international food companies found that most food processors focus on safety prevention through quality assurance (QA) systems instead of traceability systems (van der Vorst, 2006). Manning and Baines (2004) state that such QA schemes are based on company needs rather than on meeting mandatory requirements of traceability. Bailey et al. (2002) note that meeting traceability requirements will be most difficult for commodity handlers due the blending from multiple sources before processing.

According to Golan et al. (2004), the grain supply chain is based on infrastructure built to move large flows of product based on a limited variety of attributes. Large scale marketing affords elevators creates lower per-unit handling costs. However, cereal crops are commingled immediately upon receipt by a grain elevator based on quality attributes such as moisture, damage, or foreign material. During this process, a record of type of commodity sold, weight, price received, time of purchase, and any premiums and discounts is created by the elevator. This recordkeeping process typically ends here as the grain is blended to achieve a homogeneous quality level. In the overall supply chain, elevators are crucial in the system as they monitor and control product by transforming grain according to safety and quality characteristics (Golan et al., 2004). Hurburgh (2004; 2006) described how source verification may be achieved utilizing a certified quality management system, such as ISO 9001. Hurburgh and Sullivan (2004) note that a large grain elevator cooperative should be able to track raw material through elevator operations based on the implementation of a quality management system certified to the ISO 9001 standard.

The tracking unit defines the maximum possible precision and is typically referred to as a ‘lot’ in the system. A lot is typically defined by the amount of material that share unique and similar characteristics with a common process history (van der Vorst, 2006). Batch processing has higher precision because a batch is a unique unit in the view of traceability. Alternatively, in continuous flow processing, lot definition is more difficult since changes in conditions are not as easily identified (Moe, 1998). For the grain elevator example, the lot is typically defined as the bushel amount on a single scale ticket.

The basic traceability metric for a grain elevator is based upon a traceability index (Hurburgh, 2006). The Act only requires 24 hour reporting, not precision. To develop guidelines for the grain industry, the definition of a traceability index (TI) for quantitative measure is as follows:

$$\text{Traceability Index} = \text{suspect volume} / \text{volume being tracked}$$

By the process of elimination separating where problem grain could not have been located, the amount of possibly contaminated grain becomes progressively less than the entire amount of grain within an elevator facility (Hurburgh, 2006; 2007). Explicitly, the traceability goal should be 1:1; one unit of suspected grain is narrowed down to one unit of tracked material. While this is unlikely in practice, TI provides a method of continuous improvement supported by an objective target.

Farmers Cooperative Elevator Co, Farnhamville, IA, (FC) implemented a quality management system to create additional opportunities for marketing grain. The objective was to have a universally recognized quality system in place, so that as end-users (food processors) sought specialty grain origination, the company could present a program that would have an immediately recognizable creditability. However, Hurburgh (2003) notes the benefits of the quality management system were through improvements to operations management such as systematic inventory management and grain accounting. In the context of food safety, adoption of a quality management system changed the mindset of the employees from handling a commodity product to grain as a foodstuff (Sullivan and Hurburgh, 2002). The resources needed for food tracking were put in place with requirements such as standard operating procedures, discipline in process control and documentation of responsibility throughout the production history (Hurburgh, 2004). Table 1 describes the relevant quality management system procedures that FC uses with regard to grain traceability.

Table 1
Farmers Cooperative Co. quality management system procedures

ISO Number	Relevant QM system Process	FC Procedure Objective
5.6.1	Management review	Provide a forum for personnel to discuss the quality management system, review information the system is generating, and continual improvement of the system

Table 1
Farmers Cooperative Co. quality management system procedures

7.5.3	Grain identification and tracking	Provide a system and instruction to determine the location of grain lots within bulk storage across the elevator
7.5.3	Commodity grain receiving and storage assignment	Establish a process and authority for receipt and identification of inbound grain for storage by grade quality
7.5.4	Recalling commodity grain	Provide a system and responsibilities for conducting a mock recall to identify and isolate the origin of contaminated grain and any remaining suspect grain within the elevator

Materials and Methods

To demonstrate the effectiveness of procedures in Table 2, FC conducted a total of 41 mock recall events at 27 FC elevator locations in 2006 and 2007. Of the 41 total mock recalls in 2006 and 2007, 17 were forward and 24 were backward. Of the 41, 14 elevator locations did repeated recalls: 1 forward event in 2006 and 1 backward event in 2007 for a total of 28 repeated recall events. The time duration was recorded in both 2006 and 2007 recalls. The traceability index was recorded in the 2007 recall events. The data for the study consisted of reports filed by the location managers. This meant that the some data (or quality of data) was not available for every recall.

A forward recall is defined following grain identity from a known supplier to an unknown customer and/or elevator location. A forward recall is typically used as a good business practice and would not be the method of recall initiated by FDA in the likelihood of a trigger event. The FDA (2002a; 2002b) would instead utilize a backward recall where suspect material in the hands of a known customer would be traced backward through the food supply chain to unknown sources and initial locations.

Table 2

Farmers Cooperative Co. mock recall data set	
Mock Recalls by Year	Recall Events (n)
First Round (2006)	
Forward	21
Backward	0
Second Round (2007)	
Forward	3
Backward	17
New	3
Repeats	14

The forward recall process was initiated electronically by the Quality Management department with information concerning the suspected commodity (corn or soybeans), quantity, scale ticket number, and producer name. Scale tickets were chosen randomly by the Quality Manager. The elevator management was to track the suspected lot of grain forward through the facility, identify the customer(s) of the grain, locate all possible storage bins that would still have contaminated material, and identify all bins that did not have possible contamination. A record of the recall time was kept.

The backward recall event included the lot size, amount of suspect material, and scale ticket number loaded out on a specific date. The elevator management was to trace backward the grain and identify all supplier(s), contaminated storage bins, and bins not contaminated. Again, the Quality Manager chose outbound lots randomly. All statistical analysis was done in Minitab® Release 14 statistical software.

With the QM system procedures in place, the principal research questions were:

1. Does the QMS-based traceability system meet the FDA guideline for 24 hours maximum recall duration under the Act?

This is only mandatory requirement of the Bioterrorism Act at this time. Quality and acceptability of data are at the judgment of investigators should an event arise.

2. Does the forward or backward information flow impact the time duration of a recall?
3. Is time duration of the mock recall event impacted by the level of precision of traceability (TI)?
4. Is grain traceability precision (TI) impacted by the forward or backward information flow?
5. Does the quantity of suspect material (lot size) impact the time duration of the recall event?
6. Does the lot size of suspect material impact the traceability index of the recall event?

Results

As shown in Table 3, the results show that most FC facilities met the 24 requirement. The average time was 13.42 hours with a standard deviation of 11.18 hours, well below the 24 maximum time limit. 25 percent of the elevators reported results within three hours. Thus, a quarter of locations only needed a few hours time to demonstrate results.

The summary results in Table 3 also demonstrate the variability of grain traceability precision through the TI. The mean TI was 180 with a wide standard deviation of 300. Fewer facilities reported sufficient data since elevator managers reported results. Since the traceability index is not a requirement of FDA, it is a guideline for future improvement in traceability for the grain handling industry. The range of TI results was of 8 - 942. While the range was large, a minimum of 8:1 demonstrates possibility of grain traceability using a QMS. At the other end, a large traceability index of 942 demonstrated a lack of grain traceability. This elevator location did not follow all the requirements of the QMS noted in Table 1. The operator reported that he had no idea where the grain came from, which made the entire inventory of the elevator suspect.

Table 3

Overall results of mock recall exercises at FC grain elevator locations

Mock recall description	Time Duration (hours)			TI (2007 only)		
	n	Mean	SD	n	Mean	SD
All elevator locations	41	13.42	11.18	16	180	300

Since the 24 hour limit is the single requirement of the Act, distributions of the results in 2006 and 2007 are displayed in figure 1. In the 2006 events, all of the mock recall events were forward and the distribution displayed a right skew.

One elevator location required 39 hours required to report results. This elevator location had the responsibility to follow grain through another FC elevator due to intra-company transfer of the tracked grain. The longer the grain flow in the cooperative, the longer it takes to track grain. The Act requires an organization maintain records while the product is in the organization's custody. FC often transfers grain from one elevator location to another by truck. Still having custody of the grain, significant time was added to the recall event.

In the 2007 mock recalls, the results displayed a more normal distribution of duration. In the 2007 set, four elevators did not meet the 24 hour rule. Two of these locations were new to FC, merged into the company from another elevator company within six months prior to the mock recalls. Three of the elevators that reported results past the 24 hour limit conducted backward recalls.

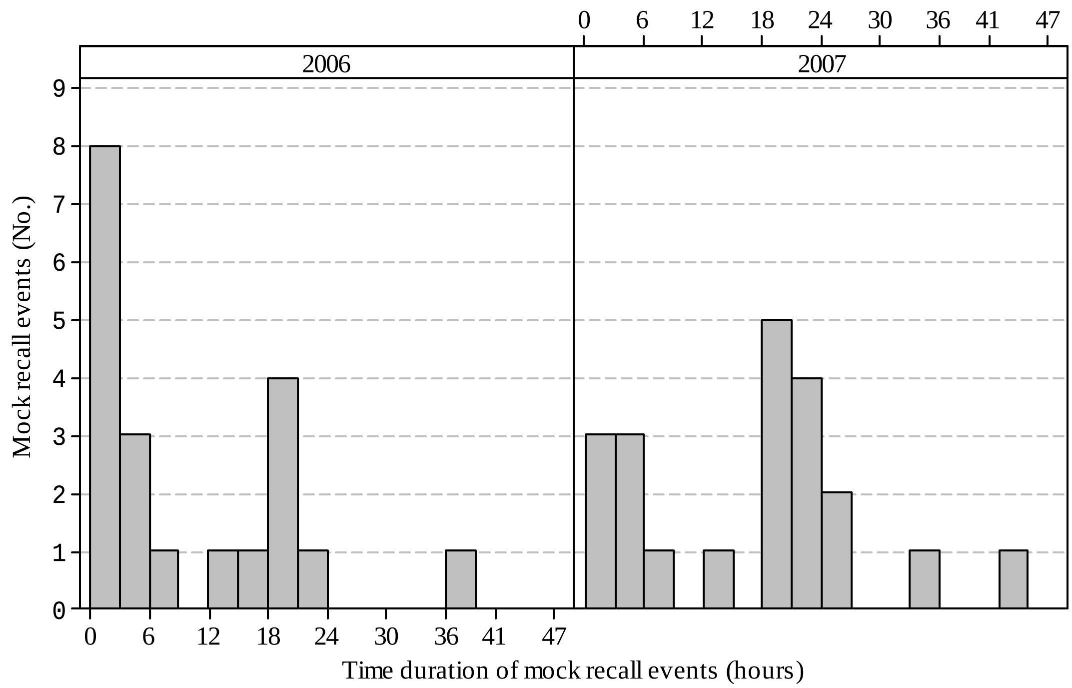

Figure 1. 2006 and 2007 distribution of time results

As shown in figure 2, there was no significant relationship between the time required for the recall event and the precision of grain traceability (TI). The length of time of the traceability processes was not impacted by their tracking precision. The majority of locations reported results, no matter how well defined their inventory control. Since time is the only FDA requirement of grain elevators, then reporting results, no matter how accurate, would be expected.

If grain handlers expect to manage an actual FDA event, specifying a level of traceability would be good practice. For example, simply presenting a list of suppliers and customers of an elevator cooperative to FDA upon request will not meet the requirement of the Act (FDA, 2002a; 2002b). FDA is letting the industry progressively set standards as it improves compliance.

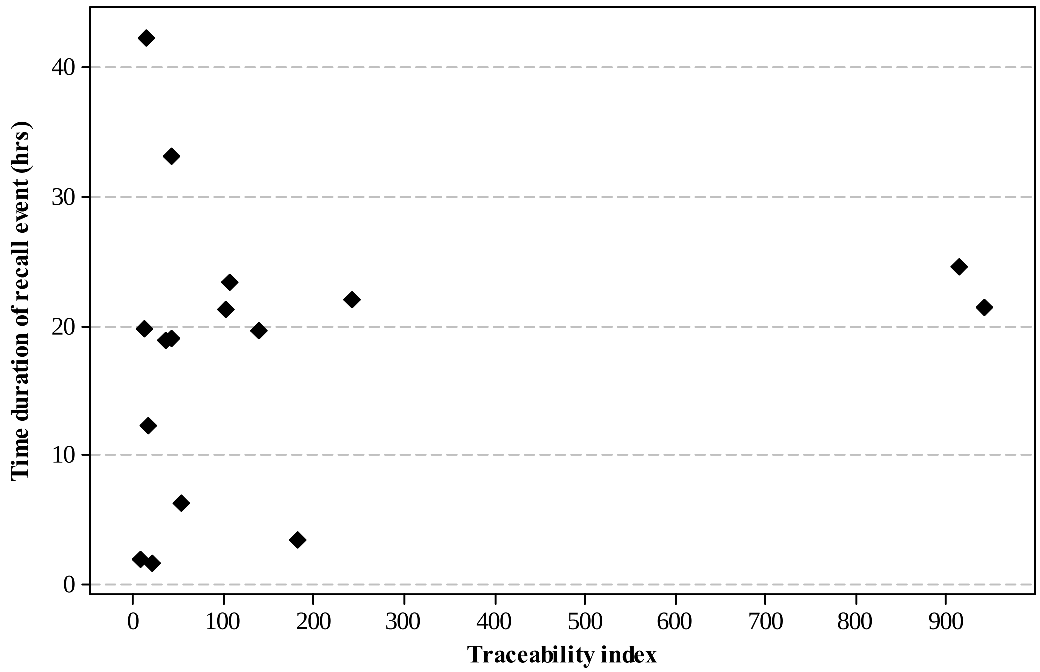

Figure 2. Traceability index and time duration of mock recall events

The results in Table 3 demonstrate that there was a significant difference in the amount of time required to report elevator recall results between the flows (backward and forward). Of the total 41 recalls accomplished, there were 14 elevator locations which did two recalls: one forward and one backward.

For significance testing of a skewed distribution, a Kruskal-Wallis test of the recall time and information flow data was done. The time required to report results took significantly longer in a backward event. This is because tracing suspect material back to the origin also required tracking forward to identify where that material subsequently went. Both backward tracing and forward tracking were required in backward recall events.

Table 3
Time duration of repeated mock recall exercises at FC grain elevator locations

Mock Recall Description	Time duration (hours)		
	n	Mean	SD
Forward (First recall)	14	7.9[a]	8.4
Backward (Second recall)	14	18.4[b]	10.2

[a,b]Means with different letters significantly different at $p = 0.05$

As shown in Table 4, the precision of traceability (TI) was not significantly impacted by the flow of the event (backward and forward). In 2007, the set of mock recalls included both forward (N=3) and backward (N=17) events. The backward events reported less precise TI's than locations doing forward events. But the sample size of events in Table 4 is small. The mean difference in TI's was lessened by the large standard deviation. Grain elevators should conduct both types of recalls to test a traceability system since forwards and backwards recalls are different in nature.

Table 4
Traceability index of 2007 mock recall exercises at FC grain elevator locations

Mock recall description	Traceability Index				
	n	Mean	SD	Min	Max
Backward	17	215	324	8	942
Forward	3	25	15	13	42

There was no relationship between the suspect bushels being tracked (lot size) and the amount of time required to provide data (figure 3). The volume of recalled material was not arbitrarily assigned; mock recall events began with the amount of bushels that were on a single scale ticket, or load of grain.

Minimizing the amount of suspect material should be the goal of a commodity grain handler because in the event of an actual FDA recall, suspected product could be destroyed per FDA regulations (FDA, 2002a). The tracking process is more important in

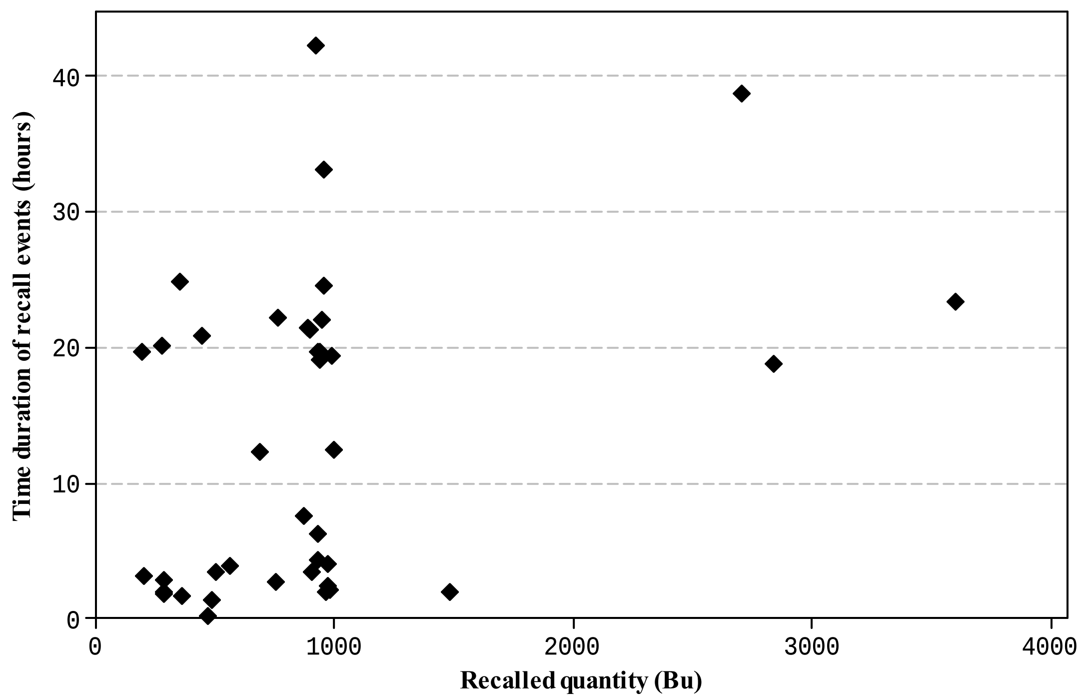

Figure 3. Time duration and lot size of 2006 and 2007 mock recall events

response to an FDA event; not how large the triggering event.

In figure 4, the amount of grain traced (lot size) did not have a significant impact upon the precision of the traceability index. Most of the data were clustered together with a few locations reporting large TI's. Both of the locations reporting the largest TI's conducted backward events. This could be evidence that backward events are harder to manage. There were also two elevators with larger than the average lot size (approximately 1,000 bu) and low TI's at 36 and 107. These elevators demonstrated average grain traceability precision, even though the lot sizes were larger. The process of traceability was more important than how much suspect material was at stake. This was also the second time that these elevators had done mock recalls. The impact of improvement from the first round of events is unknown.

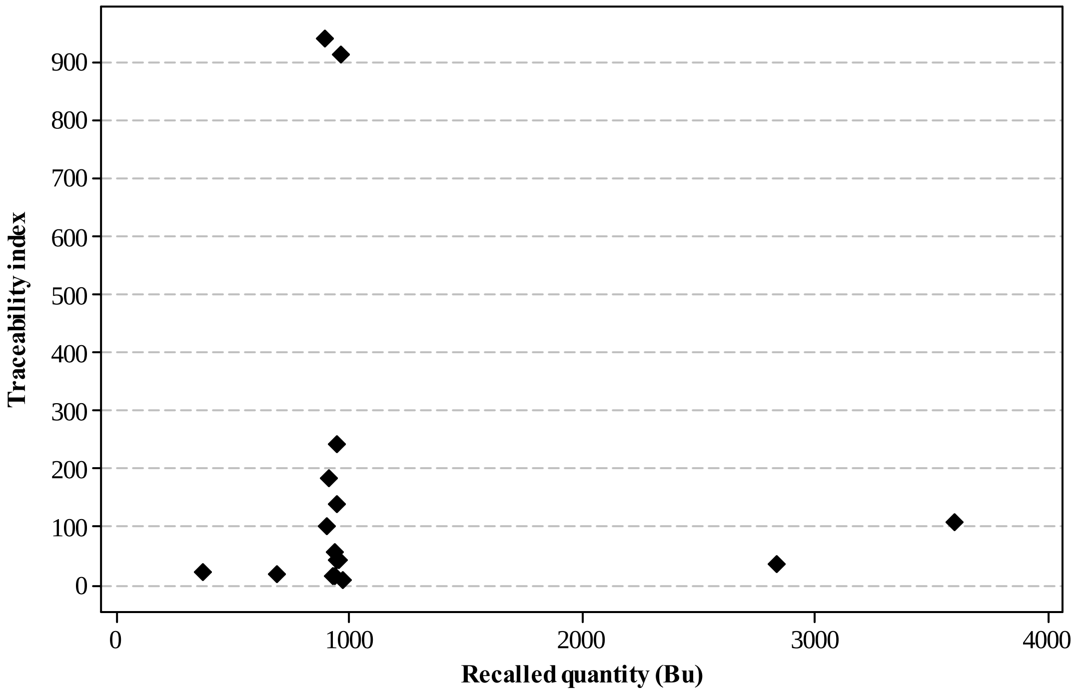

Figure 4. Traceability index and lot size of 2007 mock recall events

Discussion and Conclusions

Farmers Cooperative Co. implemented quality management system grain traceability processes at 27 elevator locations. The results of the mock recall study demonstrate that the QMS provided a benchmark for improvement. FC initially designed and implemented a QMS to meet external goals. Its subsequent focus on internal improvements enabled the organization to meet new, unforeseen government regulations.

FC was able to produce results within the 24 hour timeframe required by FDA. Timeliness of recall could prevent the closing an entire elevator operation in the event of an actual recall. The flow of recall event was significant. A backward event took significantly longer than a forward event. But the process flow of an actual recall event is not within the control of the grain industry. By definition, an FDA recall would be backward due to the nature of tracing backward from a triggering event.

The ability to meet the 24 hour deadline was not related to the lot size of grain traced in the facility, demonstrating that the QMS processes of traceability were robust. Grain elevator operations handle large volumes of grain and the commingling of different sources of grain can result in large lot sizes. The time required by FC to produce results was not effected by the lot size.

The precision level, or TI, of recall event was not related to the time required to produce results. In the event of a recall, identification of suppliers and customers requires precision. More precise levels of grain traceability apparently will not require more time.

The traceability index did not change significantly with regard to a backward or forward elevator recall event. While a backward event takes longer, the level of precision did not change significantly.

The interaction between lot size and the traceability index was not significant. During an actual event, the amount of suspect grain could be large. The FDA would likely quarantine suspect material at quantities greater than the original lot size. This was demonstrated in the spinach recall of 2006 by the FDA (Cuite et al., 2007). Following the QMS traceability processes could minimize the need to destroy large amounts of suspect grain.

An organization that meets the ISO 9001:2000 quality standard also incorporates traceability processes. QMS adoption by FC enabled the company to meet the unanticipated regulation of the Bioterror Act at nominal additional effort. A QMS system requires continuous improvement of quality related activities. It is possible that a more precise level of grain traceability will occur through the ongoing use of a quality management system. This study provides benchmark data on which to evaluate improvement.

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CHAPTER 5. IMPROVED INVENTORY MANAGEMENT: A GRAIN ELEVATOR CASE STUDY USING QUALITY MANAGEMENT SYSTEMS

A working paper to be submitted to the *International Journal of Agribusiness and Management Review*

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Abstract

The agriculture sector is the fastest growing sector of ISO 9001:2000 quality management systems certifications. There is little literature about the impact of quality management system implementation upon operational performance in agriculture. This case study examines the impact of implementing a quality management system based upon ISO 9001:2000 upon inventory management practices at Farmers Cooperative, Farnhamville, IA. The results demonstrated an improvement in inventory control that resulted in $240 extra dollars earned per railcar per train of shipped corn.

Introduction

Quality management systems (QMS) adoption in the food industry is growing. A QMS is a management system to direct and control an organization with regard to quality, requiring participation from the entire organization (ASQ, 2000; Garvin, 1987). The International Organization for Standardization (ISO) created the ISO 9001 standard to provide a global format for QMS, thereby reducing trading barriers (ISO, 2005). It sets specific minimum requirements for the management of a QMS in any organization

(ASQ, 2000). Since its, ISO 9001 has become the de facto language of quality management worldwide (ISO, 2005).

Adoption of a QMS based upon ISO 9001 is voluntary but the benefits of ISO 9001 recognition has resulted in worldwide growth. From the most recent survey of ISO adoption, over 770,000 individual certificates were issued as of 2005 (ISO, 2005). In the five year period between 2000 and 2005, the overall growth of ISO certificates was approximately 1,800 percent (ISO, 2005). Most of the growth was in China and India, demonstrating how quality management, and specifically, ISO 9001:2000 certification, is being utilized for global competitiveness as nations rise in economic stature (ISO, 2005).

There have been few studies of QMS implementation focus on the cereal grain market. There is a need since this sector alone demonstrated with a 50 fold increase in the number of certificates over a five year period (ISO, 2005).

The food industry may be defined by input suppliers, production agriculture (growers), first buyers (elevator cooperatives), processors, food manufacturers, and retail (distribution). The area of interest in this paper is the first buyer (grain handlers), incorporating grain elevator handling operations.

The grain handling industry is the first operation after producers in the food supply chain. Different levels of grain quality are consolidated and delivered to customers in an undifferentiated manner. Grain elevators take advantage of consolidating large volumes of grain to gain efficiencies by blending and creation of larger trade units (Barton, 1989).

As a customer-owned cooperative, Farmer's Cooperative Co. of Farnhamville, IA (FC) is the largest in Iowa with over 300 employees serving over 4000 members. Since

1944, FC has grown through merger and acquisition that now encompasses 49 locations covering a trade territory of approximately 19,000 square miles (Farmers Cooperative, 2005). Organized under a Chief Executive Officer, FC has four distinct divisions based on typical grain elevator operations: Grain and Agronomy, Administration, Sales and Marketing, and Feed (Farmers Cooperative, 2005). The Grain department, excluding Agronomy, was the first area to develop a quality management system at their location in Odebolt, Iowa. FC's development concept was to learn and develop a quality management system at a single location, and then replicate the development and implementation process at all strategic FC facilities (Hurburgh, 2003).

FC's quality policy is total customer satisfaction through operational excellence (Farmers Cooperative, 2004). FC initially implemented a quality management system to create additional opportunities for the marketing arm of the company's grain department. However, during the process of implementation, the immediate benefits of the quality management system seemed to be through improvements to operations management (Hurburgh, 2003).

Since initial implementation, the initial goals of external benefits changed to an internal focus. The objectives of quality management system became customer specific inventory management, traceability, and better quality control of stored commodity grain (Hurburgh, 2003). Additionally, the process control utilized better documentation, process consistency, and performance evaluation that implementation of quality management system supported (Hurburgh and Lawrence, 2003; Sullivan and Hurburgh, 2002). On the customer side, improving the precision of inventory management would allow the company to revise the process of targeting grain quality characteristics to better meet customer specifications (Sullivan and Hurburgh, 2002). In summary, the benefit for implementing a quality management system was based upon internal improvements. The application of the QMS was used to capture increased operating efficiencies, and not market premiums (Hurburgh, 2003).

This study is a series in a project to determine the impact of quality management systems in grain elevator operations. The first study demonstrated the significant improvement in the quality control of grain. The second study demonstrated the feasibility of grain traceability in elevator operations. This study focuses on the impact of QMS upon inventory management practices.

In general, grain sold on the open market has variations which result in quality uncertainty for grain handlers, processors, and end-users. Wilson and Dahl (1999) describe how measurement error, the variety of genetics involved, environmental effects, the use of grades and standards, and trade practices all contribute to uncertainty in quality of grain as received. Grain handlers must manage two types of risks: the possibility of grain not meeting contract specifications, resulting in price discounts, and the risk of selling premium grain at a lower value.

Grain is traded on contract and may be discounted if the product does not meet specified targets, or grades. Measured on a number of physical characteristics, such as moisture content, percent of damaged grain, percent of foreign material present in grain, and test weight, quality grades are utilized in assessing the quality of material (USDA, 1997). Administered by the USDA, these range from number one, or the highest grade material, to sample grade, the lowest. Grain that is lower than number two is generally considered ‘discounted’ due to its lower value in trade terms (Hurburgh and Brumm, 1994).

Discounts may come from variation in storage, preservation, and handling processes required to keep the grain at the required condition. Grain defects not only reduce the value of grain but also make it unstable in shipment and/or storage as well. If the grain is of low quality, there are risks to the receipt of lower quality grain, namely, the grain decomposes at a higher rate than higher grain grades (Hurburgh and Brumm, 1994). Grain quality uncertainty is important because variation can impose additional costs on the grain trade by increasing storage and inspection costs (Wilson and Dahl, 1999).

The management of grain inventory is crucial to the success of an elevator since grain is a biological material that degrades over time. To manage and control grain degradation, elevators operate preservation and storage processes to minimize the effect (Hurburgh and Brumm, 1994).

Essential to preservation and handling activities is the blending of grain for shipping and handling for meeting customer specifications. Through blending, multiple sources of grain, varying in quality, are blended together to create a homogenous, undifferentiated product (Sivaraman et al., 2002).

Grain blending is also a preservation method tool for grain defects. The ability to fashion higher grade quality grain from lots of material at lower levels enables the grain elevator to generate revenue in handling and storage operations. Through this process, an elevator operation may receive grain at a lower quality and purchased at a discount; blend it with a higher quality amount of grain to create lot of material at a new, different quality level for sale (Hennessy and Wahl, 1997; Hurburgh and Brumm, 1994).

FC's existing blending program was incorporated into the quality management system. The QMS was utilized to better quantify blending opportunities by managing defective grain through an inventory management record keeping and reporting system (Farmers Cooperative, 2006).

The system of train blending monitoring was established to provide regular updated inventory grain quality information. It begins with inbound sampling and grading of grain for segregation of grain the four USDA quality factors. After inbound grain is stored in bins, the grain is monitored and preserved through techniques such as moisture removal and chemical application until delivery. At customer delivery, grain may be blended by grade to produce a consistent level of grain quality. Procedures relevant to grain preservation and handling at FC are given in Table 1.

Table 1. FC quality management system inventory management procedures

ISO Number	**Relevant QM System Process**	**FC Procedure Objective**
7.5	Grain Inventory and Train Blending Program	Provide a system for regularly updated inventory quality information for quantifying blending opportunities at rail load out
7.5.5	Preservation of grain and grain handling	Provide a system for grain handling and storage activities for the preservation of grain quality and quantity
8.2.4	In-process Inspection	Provide a system, instruction, and responsibility for in-process inspection of stored grain quality and quantity

Table 1. FC quality management system inventory management procedures

ISO Number	Relevant QM System Process	FC Procedure Objective
5.6.1	Management Review	Forum to review grain quality and quantity information, and corrective action, as needed
8.2.2	Internal Quality Audits Procedure	Provide a system, instructions, and assign responsibilities for conducting internal quality audits

The impact of ISO 9001:2000 certification upon operational performance has been widely studied. These studies focus on the impact of ISO certification upon quality and performance factors such as product quality, process performance, and customer satisfaction. In some studies, the impact of certification upon company performance is marginal (Mahadevappa and Kotreshwar, 2004; Singels, et al., 2001; Romano, 2000; Jones et al., 1997; Terziovski et al., 1997) Other studies note the significant organizational benefits of ISO certification (Capmany et al., 2000; Sun, 2000; Gotzamani and Tsiotras, 2002). Quality certification qualifies that an organization meets the minimum requirements of the quality standard, such as ISO 9001. Certification by an independent body may represent a significant event in the development of a quality management system. However, achieving internal benefits from QMS certification often depends upon the motivations of the company. If certification is sought for internal company benefits, then company performance improves afterwards. This was demonstrated in comparing the process performance of certified and non-certified companies in Taiwanese, Greek, and Dutch industries (Chang and Lo, 2005; Gotzamani and Tsiotras, 2002; Singels, et al., 2001). However, if outside recognition from external pressure is the main reason for ISO certification, then organizational improvement may not occur at all (Gotzamani and Tsiotras, 2002; Singels et al., 2001).

In this case study, FC was motivated by internal improvements for outside certification. FC incorporates the ISO QMS into one elevator. It also operates another quality management system developed by the American Institute of Baking (AIB) (AIB, 2006). Less comprehensive than ISO, the Quality System Evaluation (QSE) has been adopted across FC as the initial QMS the company implemented. This study measured the effect of certification (ISO and QSE) upon process performance, in the area of inventory control. This paper is one of the first studies of the impact of quality management system adoption in this field. It is unique because it is based upon performance information and not the perception of benefits.

Materials and Methods

Data collected for this study is based upon the train blend program of FC. The train blend program is an electronic spreadsheet program for the record keeping and reporting of regularly updated grain quality inventory information (Farmers Cooperative, 2006). The spreadsheet maintains constantly updated inventory information about grain quality and quantity that is reviewed during monthly QMS management reviews. When a train to be loaded, the beginning inventory information is utilized by the local management to create a grain blending profile for three goals: (a) meet customer product specifications, (b) blend off the maximum allowable amount of discounted grain, and (c) maximize the value of discountable grain on-train (Farmers Cooperative, 2006). Using these criteria, a manual blend setting is done by the elevator superintendent to estimate the amount and quality of grain to be blended and loaded on the train. This forecast is compared by a computer calculation that uses the linear solver function of Microsoft Excel. A computer macro is done to verify the best possible blend of grain at load out. If this comparison is feasible, then the train is loaded according to the train blend load out plan (Farmers Cooperative, 2006). After rail load out, the inventory of stored grain is rechecked per the ISO 8.2.4 in-process inspection procedure.

Several output measurements are taken to evaluate process performance. One output is the amount of discountable bushels loaded on a train without penalty. This reflects the blending ability of the organization, and more importantly, the understanding of quality and quantity stored in-house.

Six FC locations operating the QMS inventory procedures over four years were used as the case study. These locations were using these processes during QMS certification. The FC elevators in this study shipped grain by rail, on 3500 bu railcar lots, 50-120 cars per train. 153 trains were sampled during the time frame. Corn was used as the test grain as corn represents 60-70% of an FC elevator’s volume. The statistical software packages, SPSS 14.0 and Minitab Release 14.20, were utilized in all the results shown below in this study.

We were able to assess the impact of the quality management and inventory management control in the following way:

$$\frac{\text{Discount Bushels Loaded}}{\text{Inventory Discount Bushels}} = \text{\% Discount Grain Removed at FC location}$$

Ideally, the elevator should move its poor quality grain as questionable and capture any pending gains as soon as possible. In this equation, the numerator was defined by adding the discounted grain inventory in storage bins. The train is loaded and another measurement is taken of the storage bins where grain was removed. By quantifying the change in inventory of discounted inventory, the result is the percent of discounted grain removed at the grain elevator location.

In the inventory management and blending process, discount grain is assigned a value per market prices at the time. The percent of the value of the actual train load from actual weights and grades was compared to what was could potentially have been loaded given the computer solution. Per FC QMS guidelines, the actual train blend value should not be less than 60 percent of the manually calculated train blend value (Farmers Cooperative, 2006). This is represented by the following:

$$\frac{\text{Actual Discount Grain Value Loaded on Train}}{\text{Manually Estimated Discount Value of Train}} = \text{\% of Target Discount Achieved}$$

While a minimum target of 60 percent is set, the percent value may exceed 100 percent since the potential train value is a forecast number. The accuracy of a forecast number may change when the actual train loading occurs, and when a new inventory assessment is done. For example, the elevator may find it has to more mold damaged grain on hand than the original inventory had estimated. The target number allows management to monitor QMS elevator location’s ability to create and apply an effective blending strategy. The ending inventory evaluates conformance with estimates and becomes the start for the next train load out.

The result of the inventory management and train blend process is the train blend value at rail load out. The discount grain blend value per car is defined below:

$$\frac{\text{Discount Grain Value Loaded on Train}}{\text{Number of Railcars per Train}} = \text{Discount Blend Value per Railcar}$$

Accounting for the size of the train, the numerator is divided by the number of railcars to produce a dollar figure of grain value, per railcar, per train. The result estimates added value of the QMS processes of inventory management and train blending at FC elevator locations.

The research questions of this project are noted below:

1. What are the benchmark values for each of the following grain blending performance metrics?
    - % discount grain removed?
    - % target of discount grain achieved?
    - discount blend value per railcar?
2. Do QMS locations differ significantly in grain blending performance?
3. Does QMS outside certification have a significant impact upon grain blending performance?

Results and Discussion

Control of inventory is an important business process. Carrying inventory is inherent to a grain elevator. Elevators carry large amounts of inventory to create value through consolidation, blending, and delivering a uniform product. The consequences of large inventory may add waste. Ohno (1988) defined waste as adding activity adding costs without adding value. The costs of managing grain include storage, inspection, and preservation to maintain product quality. Without measurements to describe the quality and quantity of grain, managing grain becomes problematic due to the natural degradation of grain over time.

Table 2 describes inventory management benchmark metrics for measuring future inventory performance. Important to inventory management is the removal of defective grain. FC removed approximately 20 percent of on-hand defective inventory each time a train was loaded. Eliminating defective product reduces quality costs such as preservation of grain quality, grain inspection, and segregation of poor quality material.

To measure quality performance, FC management set a target for blending performance. Table 2 demonstrates that locations loaded an average of 100 percent of the manually calculated train blend estimate each time a train was loaded. There were few instances (n=5) of individual trains falling below the minimum threshold of 60 percent. The frequency of exceeding the target may reflect a lack of knowledge: there may have been more defective grain in storage than was initially thought. Regardless, since the target has been exceeded frequently, FC management may want to increase the minimum threshold to continually improve the process.

The impact of the QMS on grain inventory management may be defined fiscally. The most important number is the added value a location generates at rail load out. As an output measure of inventory management, it is the validation of quality performance. Table 2 accounts for the size of trains loaded trains (the most frequent size was 110 car trains). On average, FC locations added approximately 220 dollars per railcar, per train.

Ohno (1988) declared that the reason to control inventory is to add value by reducing quality costs. Rather than generate revenue through added sales, the proper control of inventory can generate extra revenue to the company by eliminating waste. The waste that an elevator can generate can be very large due to the amount of inventory carried.

Table 2: Summary results of performance data per train at Farmers Cooperative QMS elevator locations

	Discount Grain Removed (% of location inventory)	Discount Value of Target Achieved (% per train)	Train Blend Discount Value/Railcar (USD)
n (all trains)	153	125	95
Mean	21.5	100.0	222.0
High	92.5	180.0	719.7
Low	0.0	36.0	52.7
Std Dev	22.4	30.0	123.3
Time Period	4/2004-4/2007	4/2004-4/2007	4/2004-4/2007

The performance of inventory management at QMS elevators was not uniform. Table 3 describes the inventory performance measurements by location. Significance testing demonstrated the ability of management to control inventory was inconsistent across elevator locations.

The location operation a QMS based upon ISO 9001 standard exceeded the performance of other locations. It demonstrated the largest percent of discount grain removed (54 percent), and the most added railcar value ($454). However, it was not the most consistent in meeting discount targets (Std Dev=69 percent) from train to train.

There is potential for quality improvement by demonstration of low performers in specific measures. Location 2 was lowest in removing discount grain (mean=9 percent) and among the lowest in added value to individual railcars (approximately $155). To identify gaps in performance, the use of railcar value is useful with the discrepancy of reported results by location.

The use of an arbitrary target appears to be less useful in managing individual locations. None of the locations reporting data differed significantly in achieving discount targets. There is not much use in a goal that is continually exceeded. To be useful, it should be moved up if continual improvement is sought.

Table 3: Summary results of performance data per train by FC QMS Location

	Discount Grain Removed (% of location inventory)			Discount Value of Target Achieved (%)			Train Blend Discount Value/Railcar (USD)		
Loc.	n (trains)	Mean	Std Dev	n (trains)	Mean	Std Dev	n (trains)	Mean	Std Dev
1	68	19.1	20.7	59	98.2	29.3	54	205.9[a]	88.9[a]
2	6	11.3	12.1	4	94.0	37.1[a]	2	155.6	30.7
3	40	9.1	9.3[a]	30	103.5	33.5	13	316.4[b]	197.3[b]
4	7	54.2[a]	17.2	7	118.3	31.5	4	454.3[c]	135.6[c]
5	9	53.2[b]	17.8	9	93.4	68.9[b]	8	133.8	16.2
6	23	30.2[c]	25.3	16	99.1	31.1	14	189.7	63.6

[a,b,c]Values with different letters significantly different at $p = 0.05$

The next thee tables (Tables 4, 5, 6) concern QMS certification and inventory quality performance. The event of certification was the primary event analyzed so both ISO and QSE data points were included in the certified train data set.

Based upon Table 4, QMS certification resulted in significant additional operational performance benefits. Outside certification is an arbitrary event. All of these elevators were utilizing a QMS. More importantly, all utilized the relevant inventory control processes noted in Table 1. However, certification may be used as a measurement of quality improvement since our group of elevators significantly improved their ability to remove defective grain inventory.

Table 4: Percent of total discounted grain inventory blended off at rail load out

QMS Comparison	Discount Grain Removed (%)		
	n (trains)	Mean	Std Dev
Trains from Certified Locations	91	24.7[a]	24.4
Trains from Non-Certified Locations	62	16.8[b]	18.3

[a,b]Means with different letters significantly different at $p = 0.05$

The percent of target grain captured at rail load out again did not display significance in measuring quality performance at FC. Based on the results in Table 5, certification was irrelevant. The ability of local management to meet an arbitrary target did not significantly change after the location received a QMS certificate. The standard deviation confirms a stable, predictable process. In a process in control statistically, the variation displayed will be inherent, or common, to the process. Deming (2000) states that taking action to improve a process based on normal randomness results in tampering. To improve the process of local management using targets, then the company should 'raise the bar' of quality performance.

Table 5: Percent of target discount grain value captured at rail load out

QMS Comparison	Target Grain Value Captured (%)		
	n (trains)	Mean	Std Dev
Trains from Certified Locations	77	98.5	3.3
Trains from Non-Certified Locations	48	103.0	4.6

The event of certification did not significantly impact the overall value demonstrated by the Table 6 results. Comparing QMS certification by railcar, the difference of discount grain value was less than 26 dollars. While ISO and QSE standards do not have a financial requirement, it is recommended that fiscal data be collected and closely measured. Monitoring the financial health of the organization is central to FC. As an operational measure, it may be the most important: a change in the financial picture could signal a change in operational performance. It should at least result in management investigation of what is occurring in the business.

Certification was inconsequential to the added value of railcar results. However, the amount of money could be used to measure the costs and benefits of QMS adoption. Even without certification, implementing a QMS requires resources. Whether that number is $214 or $240, justifying that added cost of QMS adoption is what Table 6 is about.

Table 6: Train blend discount grain value per railcar at load out

QMS Comparison	Discount Grain Railcar Value (USD)		
	n (trains)	Mean	Std Dev
Trains from Certified Locations	66	214.1	108.0
Trains from Non-Certified Locations	29	240.0	153.1

Conclusions

Quality management system requires company resources to for operation. The overall impact of the QMS resulted in FC’s ability to improve the management of inventory, resulting in added value generated through operational improvement at train blending. Company benchmarks were created to use to gauge future quality performance.

Certification of the QMS was a significant event in inventory management. It was not a ‘hollow achievement’ as is reported in other studies (Terziovski et al., 1997; Allan, 1993). FC demonstrated the value of QMS adoption and certification in a commodity business.

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CHAPTER 6. GENERAL CONCLUSIONS

Quality management systems are a collection of practices that together, form the basis for managing a business according to the principles of quality. Formal quality management systems (QMS) are becoming widely adopted. Due to changes in technology, global competitiveness, and biosecurity, agriculture is an emerging area for QMS adoption.

This research concerned the adoption of a quality management system (QMS) based on the ISO 9000 standard for quality management at Farmers Cooperative Co., Farnhamville, IA, (FC) a multi-site grain elevator cooperative. As a case study, this research was the result of working in coordination with the organization to determine the operational impacts of QMS adoption. This research utilized a business process management (BPM) approach to develop measurement indicators based upon the internal improvements sought by FC.

In the first study, the impact of QMS was measured on meeting product customer specifications at FC. The measurement variation of the grain grading was quantified by the difference between FC personnel and official graders. The results demonstrated that QMS adoption had a significant impact upon the quality of measurement data. QMS adoption significantly reduced the measurement error across the four primary grades, resulting in a more accurate account of grain quality and quantity in inventory management.

The second study examined how FC utilized the QMS, to create and implement a traceability system that met the requirements of the Bioterrorism Act of 2002. The results demonstrated that FC met the time requirement of the FDA. Benchmark indicators were created for use as guidelines for the grain handling industry. The QMS enabled the elevator to meet an added, regulatory requirement through little additional cost.

The third paper studied the impact of QMS on inventory management at FC. The management of grain inventory is a large cost item in elevator operations. The results of the study demonstrated that QMS adoption significantly improved the blending operations at FC through more significant reduction of discounted grain. In addition, the fiscal benefits of QMS adoption resulted in an additional $240 per railcar per train at load.

The ISO 22006 standard is currently in draft form and a few years away from publication. A draft version of the standard is in the appendix of this dissertation. The work on the standard by Iowa State personnel was significant. The use of the standard in production agriculture would fill in a gap of QMS adoption in the food supply chain. A strategy for implementation of ISO 22006 by the Grain Quality Initiative is recommended to facilitate the use of QMS in the food industry.

Recommendations for Future Research

Following are several recommendations to researchers that will continue studying the applicability of quality management systems in the agriculture sector:

1) The process of implementation of a quality management system is a topic that is reviewed in the general literature. The uniqueness of QMS adoption in

agriculture is unknown. The development of indicators to determine the impact of QMS in other agriculture sectors, such as biofuels, is recommended.

2) The continuous improvement of grain traceability is unknown. The further development of a traceability system in grain commodity elevator operations is recommended.

3) The use of the BPM instrument has use outside of production agriculture. The practical nature of BPM in other areas of food production and processing are unknown. The development of this measurement device in other areas of the food chain is recommended.

4) The use of ISO 22006 in production agriculture is unknown. The standard is currently in development and the use of ISO 22006 in a business setting is recommended.

APPENDIX

ISO TC 34/WG 12 N0006
Date: 2007-3 - 08

ISO/CD1 22006
proposed version with changes recommended in on Feb 13

ISO/TC 34

Secretariat: MSZT

Quality management systems – Guidelines for the application of ISO 9001:2000 in crop production

The International Organization for Standardization

ISO is the International Organization for Standardization. Because this name would have different abbreviations in different languages ("IOS" in English, "OIN" in French for *Organisation internationale de normalisation*), it was decided at the onset to use a word derived from the Greek isos, meaning "equal". Therefore, whatever the country, whatever the language, the short form of the organization's name is always ISO. It is made up of national standards institutes from countries large and small, industrialized and developing, in all regions of the world. ISO develops voluntary technical standards which add value to all types of business operations.

They contribute to making the development, manufacture and supply of products and services more efficient, safer and cleaner. They make trade between countries easier and fairer. ISO standards also serve to safeguard consumers, and users in general, of products and services - as well as to make their lives simpler.

ISO develops only those standards that are required by the market. This work is carried out by experts on loan from the industrial, technical and business sectors that have asked for the standards, and which subsequently put them to use. These experts may be joined by others with relevant knowledge, such as representatives of government agencies, consumer organizations, academia and testing laboratories.

Published under the designation of International Standards, ISO standards represent an international consensus on the state of the art in the technology concerned.

Contents

About this Standard

This Guidance Standard is designed for crop producing organizations to assist in the application of ISO 9001:2000, *Quality management system - Requirements.*

It is not expected that this Guidance Standard would be read in one sitting. It is broken up into the following sections to be read and used separately and to be referred to as the need arises.

Quality Management System	This section gives an overview an ISO 9001 quality management system.

Application of ISO systems in the food/fiber chain	This provides an initial overview of ISO in the food/fiber chain
How to Start	This section gives some practical advice on different options, for introducing a quality management system into a farming business.
Guidance on what the standard means	This provides general background on ISO 9001:2000

Many organizations encounter some problems when putting a quality management system in place. In a farm these problems are potentially greater due to:

- minimal available resources,
- potential costs involved in setting up and maintaining a quality management system, and
- difficulty in understanding and applying the requirements to crop production.

It may be helpful to understand that there can be key differences in implementing ISO 9001:2000 for crop production than would be found when implementing in another type of organizations, say for example, a manufacturing company. Key characteristics driving these differences may include;

- number of employees, (combine this with the bullet points immediately above
- business philosophy,
- communications (in a small farming operation communication can often be simple and direct),
- individuals in a farm operation are often expected to undertake a wide variety of tasks rather than having a single discretely defined role as might be found in other types of organizations,
- decision making may be confined to a few people (or even one)

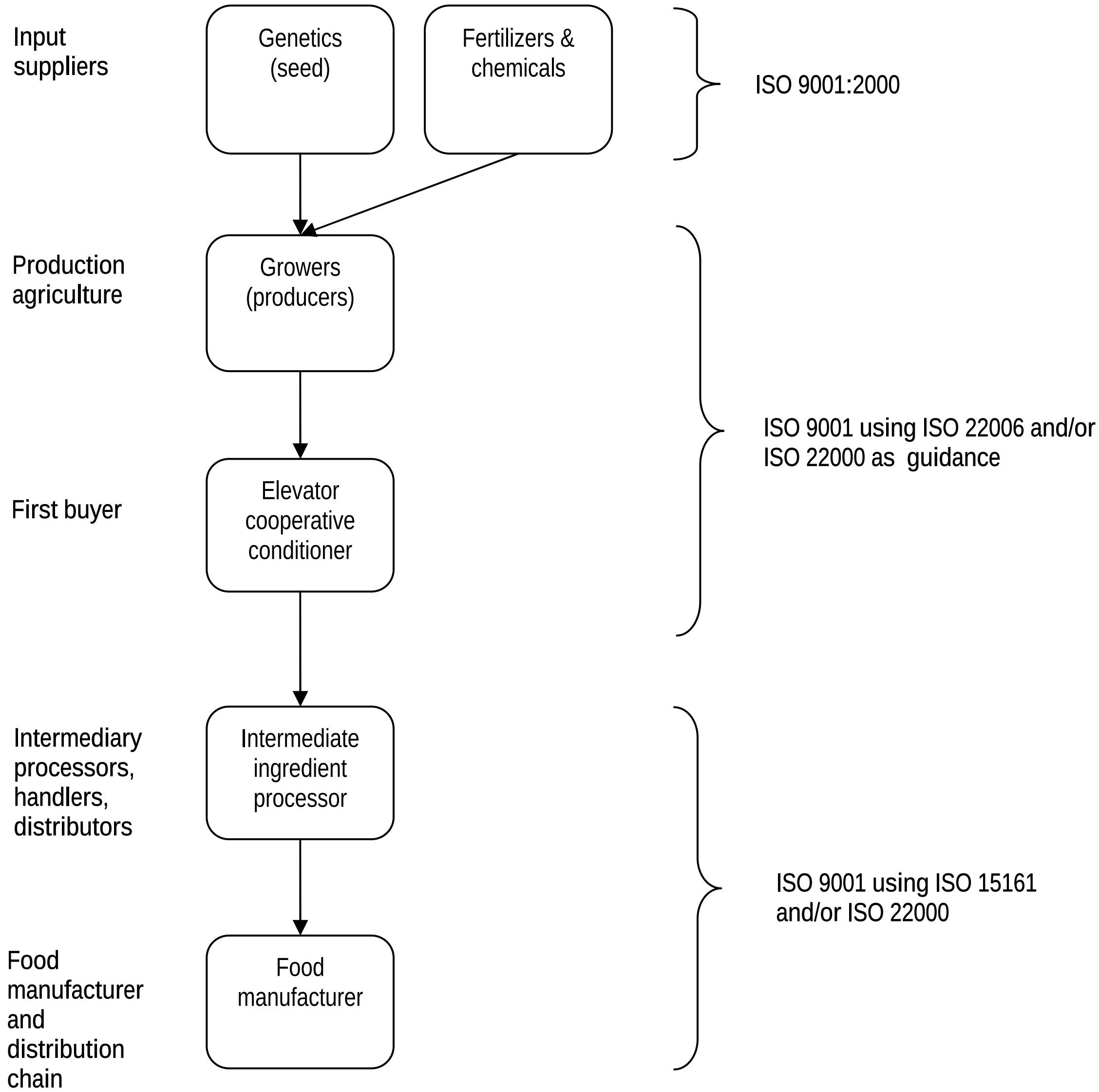
Guidance given in this International Standard is relevant to both large and small farms.

Managers of farm operations should be aware that the ultimate goal of implementing ISO 9001:2000 into their businesses should be a combination of improved performance, financial results and customer satisfaction. To achieve this result, farm managers should keep an eye on what is practical and work to implement their quality management system with these results in mind. While there may be costs, time and efforts involved in the ISO 9001:2000 implementation effort, the ultimate goal is to achieve results that outweigh these initial costs.

Application of ISO systems in food/fiber supply chains

It is anticipated that ISO 22006 will be applied in crop production at the beginning of crop based supply chains, where producers and in some cases first buyers of crops are still considered as "bulk commodities" are involved. Further into the supply chain, in manufacturing processes the language of ISO 9001:2000, ISO 15161, or ISO 22000 may be considered more appropriate. The need for an ISO 9001:2000 based system containing "crop" language evolved when it became apparent that the language of ISO 9001:2000 was difficult to interpret in crop production applications. ISO 22006 is a guidance document similar to ISO 15161 (ISO 15161 covers the application of ISO 9001 in the food and drink industry) see figure 1 below.

Figure 1 Example application of ISO systems in food/fiber supply



Note ISO 9001:2000 is a quality management system
ISO 15161 is an ISO guidance document for the application of ISO 9001:2000 for the food and drink industry
ISO 22006 is a guidance document for the application of ISO 9001:2000 for crop production and initial buyer/handlers of agricultural production
ISO 22000 is a food safety management system (HACCP)
ISO registration of all users of ISO 9001:2000, ISO 15161, and ISO 22006 will be ISO 9001:2000. ISO 22000 registrations will be ISO 22000.

The guidance provided clarifies the clause of the international standard which it follows.

Examples have been used wherever possible as an aid to understanding the requirements. Effective communications and familiarity with all parts of the farm may be all that is needed.

When reading ISO 9001:2000, note that certain words and phrases have particular significance or meaning. Some explanation of the more important of these is given below. (check the definitions below to ensure they match 9004

Shall	Whenever this word occurs in the standard, it is used to indicate a requirement that must be fulfilled in order to demonstrate an effective quality management system.
Should/may	These words are used to suggest a course of action. They are never used to indicate a requirement that must be fulfilled.
Appropriate	This word means that the organization needs to decide how the requirements apply to the farm. In some cases the organization may decide that the guidance may not apply to the farm (see exclusions clause 1.2)

NOTE: In this Guidance Standard, "appropriate" and "suitable" are also used to indicate that you need to make such decisions. Also, "adequate" is used to indicate that the actions, decisions, etc. are fully sufficient to fulfill requirements.

What is the "ISO 22000 family of standards"? The ISO 22000 family of ISO standards focuses on food and related supply chains. The ISO 22000 family of documents currently includes published standards or those under development:

- ***ISO 22000 Food safety management systems – requirements for organizations throughout the food chain*** is a food safety management system standard for the food manufacturing and distribution industries which was developed using the HACCP system as a base. ISO 22000 looks at the critical control points in the processes of food production, manufacture and delivery relating to food safety.
- ***ISO 22002 Guidelines on the application of ISO 9001:2000 for the food and drink industry*** (currently ISO 15161) is a guidance document for the application of ISO 9001:2000 for those industries.
- ***ISO 22005 Traceability in the feed and food chain – General principles and basic requirements for system design and implementation.*** This document is intended to be a tool for traceability that can be coordinated within the context of a broader management system (such as ISO 9001:2000).
- ***ISO 22006 Guidelines for the application of ISO 9001:2000 in crop production*** (this document). ISO 22000 and ISO 22005 support ISO 22006. ISO 22006 is not intended to duplicate the requirements of these standards.
- ***Additional standards in the ISO 22000 family will be published over time.***

What is ISO 22006? ISO 22006 (this document) has been designed to explain how the ISO 9001:2000 quality management system standard applies to crop production. This Standard does not set any requirements, nor does it add to or otherwise change the requirements of ISO 9001:2000. It is simply intended to be helpful. The guidance section of ISO 22006, which begins on page 6, contains the ISO 9001:2000 requirements in the solid boxes (numbered clauses and sub-clauses from 0.1 through 8.5.3). Guidance on the application of each clause specific to agricultural crop production follows the requirement box. In addition, Help Boxes (illustrated below), with dashed lines, contain Guidance or "suggestions" and are included in places where these are deemed appropriate.

HELP BOX: The clauses of ISO 9001 are written to be adaptable to a wide range of organizational activities and organizational and sizes. To aid in the understanding of ISO 9001:2000 within the context of crop production, HELP BOXES have been created. These HELP BOXES are specifically designed to help with selected clauses throughout ISO 22006. HELP BOXES may be of particular value when relating the ISO 9001:2000 requirements to smaller operations or to operations using hand labor rather than machine operations. HELP BOXES are outlined in dashed lines and have a different font style to differentiate them from other text used in this standard.

ISO 22006 supports ISO 22000 and ISO 22005 requirements; it is not intended to duplicate the requirements of these published standards.

ISO 22006 provides guidance to crop producers to aid in the preparation for ISO 9001:2000 certification or for declaration of conformance to ISO 9001:2000. Text that is unique to ISO 22006 does not contain requirements associated with certification/registration. ISO 22006 is not intended to replace ISO 9004:2000 which addresses performance improvement. The use of ISO 22006 does not require the implementation of ISO 9004:2000.

Guidance on ISO 9001:2000

ISO 9001:2000 Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/TEC Directives, Part 2.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance,* Subcommittee SC 2, *Quality systems.*

Annexes A and B of this International Standard are for information only.
Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 22006 was prepared by Technical Committee ISO/TC 34/WG 12, Guidelines for the application of ISO 9001:2000 in crop production.

Guidance: Besides listing technical details about the standards writing and approval processes of ISO, the Foreword states that the quality management system fulfilling ISO 9001:2000 requirements has two major aims, namely

- achieving quality assurance of the crop, and
- enhancing customer satisfaction.

0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.
The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

Guidance: The standard specifies requirements for a quality management system which have been recognized as being aligned with internationally accepted good practice for any organization. When implementing ISO 9001:2000 using ISO 22006 as guidance, the organization should demonstrate consideration and utilization of appropriate information (e.g. statutory and regulatory requirements, customer requirements, recognized guidelines, Codex Alimenarius Commission (Codex) principles and codes of practices including national, international or sector standards).

Processes may include for example; Good Agricultural Practices (GAP) as well as Good Hygiene Practices (GHP) as appropriate to the needs of the farm and its customers. This is particularly important for those practices that are generally acceptable for the specific crop, international, national, local regulations or specific customer needs.

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and meeting requirements,

b) the need to consider processes in terms of added value,
c) obtaining results of process performance and effectiveness, and
d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 2 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 2 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

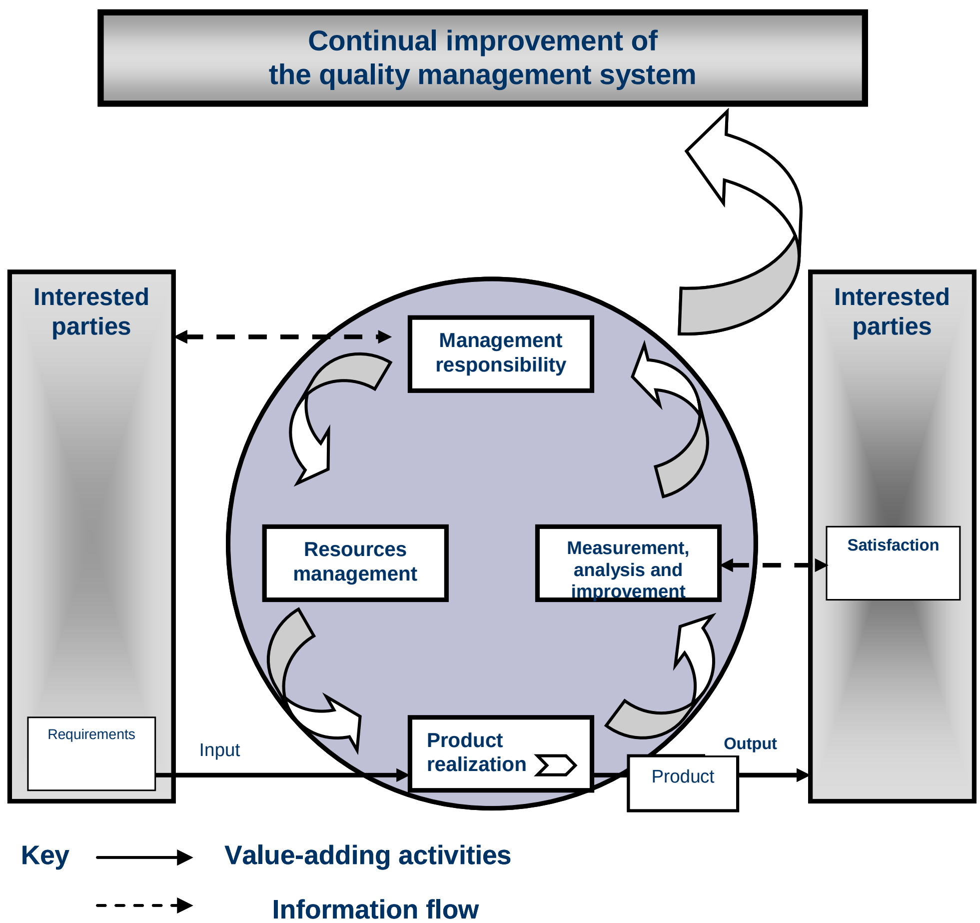
Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

Figure 2 – Model of a process-based quality management system



Guidance: At the heart of ISO 9001:2000 is a conceptual model shown in Figure 2. Figure 2 shows what is called the *process approach.* *It* explains a process-based quality management system including the main processes that are integral to success of the quality management system.

The process approach shows that everything to do with quality starts and ends with the customer – making the process approach customer driven. Note in the diagram that the *customer* is shown on both the left and the right. The diagram shows that specifications from the customer – what the customer wants enters on the left and the crop that meets requirements exits on the right.

The main process flow that enables the crop to emerge is shown across the lower part of the figure, as *Product realization*. This box covers the various activities that the farm needs to do to produce a crop. Crops are the *output* from the farm.

In addition, the process approach notes the importance of obtaining information on customer satisfaction (the dotted arrow on the right points back to measurement, analysis and improvement). This and other measurements and evaluations become vital to an organization's performance. These measurement systems are shown as the box entitled *Measurement, analysis and improvement*.

The *Management responsibility* box is there to explain the importance of the leadership role in the quality management system. Action is required on the information and data that show how well or poorly the system is working, and provides or adjusts the resources needed to maintain and improve it.

Resources are represented by the box at the left of the circle. Adequate resources will assure the quality of crops. Resources include for example; land, workspace, equipment, materials (inputs) and people. Assurance that people are trained and competent to do the tasks required of them is also part of providing resources.

Figure 3. Quality management system clauses with descriptive overview

4 Quality management system
- 4.1 General requirements
- 4.2 Documentation requirements
  - 4.2.1 General
  - 4.2.2 Quality manual
  - 4.2.3 Control of documents
  - 4.2.4 Control of records

Clause 4, notably sub-clause 4.1, provides an overview of the entire quality management system. The remainder of clause 4 lists the documents that need to be included in the plan and how to control those documents and records generated by your quality management system. It should be noted that the clauses following clause 4 all relate to one another and in turn, provide sequential steps in the process.

5 Management responsibility
- 5.1 Management commitment
- 5.2 Customer focus
- 5.3 Quality policy
- 5.4 Planning
  - 5.4.1 Quality objectives
  - 5.4.2 Quality management system planning
- 5.5 Responsibility, authority and communication
  - 5.5.1 Responsibility and authority
  - 5.5.2 Management representative
  - 5.5.3 Internal communication
- 5.6 Management review
  - 5.6.1 General
  - 5.6.2 Review input
  - 5.6.3 Review output

Clause 5 points out that management has made a commitment to the quality management system. Even in a small organization typical of many farming operations, someone must make decisions to insure that processes are completed, that these processes are reviewed to see that goals are accomplished, and that requirements are met.

6 Resource management
- 6.1 Provision of resources
- 6.2 Human resources
  - 6.2.1 General
  - 6.2.2 Competence, awareness and training
- 6.3 Infrastructure
- 6.4 Work environment

Clause 6 refers to providing and managing resources required for operation of the quality management system. Management commitment in clause 5 requires the commitment of time to effectively carry out the goals of the quality management system. A quality management system should not require a large capital investment, but does require a commitment of time which may initially add cost until the greater benefits are achieved.

7 Product realization
- 7.1 Planning of product realization
- 7.2 Customer-related processes
  - 7.2.1 Determination of requirements related to product
  - 7.2.2 Review of requirements related to the product
  - 7.2.3 Customer communication
- 7.3 Design and development
  - 7.3.1 Design and development planning
  - 7.3.2 Design and development inputs
  - 7.3.3 Design and development outputs
  - 7.3.4 Design and development review
  - 7.3.5 Design and development verification
  - 7.3.6 Design and development validation
  - 7.3.7 Control of design and development changes
- 7.4 Purchasing
  - 7.4.1 Purchasing process
  - 7.4.2 Purchasing information
  - 7.4.3 Verification of purchased product
- 7.5 Production and service provision
  - 7.5.1 Control of production and service provision
  - 7.5.2 Validation of processes for production and service provision
  - 7.5.3 Identification and traceability
  - 7.5.4 Customer property
  - 7.5.5 Preservation of product
- 7.6 Control of monitoring and measuring devices

Clause 7 describes and controls the processes associated with producing products to meet the requirements that the organization has put in place to meet customer requirements. This clause begins with the planning stages of crop production and how this relates to the customers' needs. The design and development (clause 7.3) may not relate to most farming operations and may be excluded when appropriate by statements referencing this point.

8 Measurement, analysis and improvement
- 8.1 General
- 8.2 Monitoring and measurement
  - 8.2.1 Customer satisfaction
  - 8.2.2 Internal audit
  - 8.2.3 Monitoring and measurement of processes
  - 8.2.4 Monitoring and measurement of product
- 8.3 Control of nonconforming product
- 8.4 Analysis of data
- 8.5 Improvement
  - 8.5.1 Continual improvement
  - 8.5.2 Corrective action
  - 8.5.3 Preventive action

Clause 8 describes the processes for planning, and implementing the monitoring, measurement, analysis and improvement processes needed by the quality management system. This includes the activities of analyzing what this data tells us. Are there trends in this data? Are the trends consistent with what is expected? How can we continually improve?

Figure 3 provides the overview of the entire quality management system and shows the relationship of the various clauses within ISO 22006 (ISO 9001:2000).

0.3 Relationship with ISO 9004

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

0.4 Compatibility with other management systems

This International Standard has been aligned with ISO 14001:2004 in order to enhance the compatibility of the two standards for the benefit of the user community.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

Quality management systems — Requirements

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

NOTE: In this International Standard, the term “product” applies only to the product intended for, or required by, a customer.

1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided. Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion. Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

Guidance: The numbered clauses above set the breadth of application within an organization. It answers the question "where does ISO 9001:2000 fit and how does it apply?" Only the crop(s) that a farming operation intends to sell to customers are intended to be included in ISO 22006, however, users will likely find value for all crops.

The scope of ISO 22006 is to provide assistance to crop producers for the adoption of ISO 9001:2000 to crop production processes. Crops can range from broadcast-seeded annual grains and pulses, to row-planted crops that are cultivated, and perennial crops that are managed over a period of time. Horticultural crops provide an even broader range of types from annual fruits, vegetables, and ornamental flowering plants; to perennial shrubs and trees; and root crops. This vast range of crops provides a broad range of planting, cultivating, pesticide and insect control application, and harvesting equipment. The fundamental decisions, planting, growing, and harvesting activities are similar, although specific steps might be quite different when considering the range of crops. It is hoped that users will find the basics of management principles for all crops in this standard.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9001:2000 *Quality management systems – Fundamentals and vocabulary.*

Guidance: The reference to ISO 9000:2000 directs readers to that standard as a source for definitions of terms used in ISO 9001:2000 and ISO 9004:2000.

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.

The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:

supplier → organization → customer

The term “organization” replaces the term “supplier” used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term “supplier” now replaces the term ”subcontractor”.

Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

Guidance: In this document it is important to understand the use of the three terms; supplier, organization, and customer.

- **supplier** – people and organizations that provide (supply) the inputs used in crop production – this might include other crop producers, seed companies, fertilizer dealers, equipment dealers, chemical dealers, applicators, and others providing inputs to crop production processes
- **organization** – the farm implementing the quality management system
- **customer** – people or organizations that purchase the farm’s products (crops)

Additional guidance:

Definitions in ISO 9000:2000 apply. Additional terms and guidance to ISO 9000:2000 definitions used in this standard are shown below:

application	treatment of the crop, soil or other medium with an input designed to aid in meeting requirements
	Guidance: treatment can be for example, with fertilizers, insecticide, fungicide etc.
applicators	person or organization involved in the application process
attribute	a measurable characteristic or trait that differentiates one crop from similar products/crops
	Guidance: Where used in this Standard, it is intended to mean specific traits that can be measured, such as low linolenic soybean (soybeans with lower than normal linolenic acid content)
characteristic	a distinctive trait that sets something apart
	Guidance: An identifiable hereditary property, such as a specific component, a structural detail, a color or pattern, or resistance to pests. Sometimes used interchangeably with attribute.
crop	a) cultivated plants collectively;
	b) a product/crop of a particular kind (maize, wheat),
	c) place (geographical location of production),
	d) season (for example one year)
farm	A tract(s) of land or facilities under a management system devoted to agricultural or horticultural production.
Farm management	person or group of people that manage the farm on a day to day basis
farm operation	The activities involved in producing crops
	A farm operation refers to all of the management and physical activities related to the production of various crops.
farm plan	the plan for crop production on a specified farm

Guidance: Where used in this Standard, the term refers to a set of instructions or activities to be implemented and intended to lead to the production of a crop. The farm plan normally defines the application of the components necessary to produce the crop for example; land use, resource management and application of best management practices. A farm plan may consist of procedures, flow charts, field maps, manuals, or outlines.

farming plan	see farm plan
FSMS	food safety management system (usually referring to ISO 22000)
GAP	good agricultural practices (GAP)
GHP	good hygiene practices (GHP)
input	a product or service used by crop production processes to achieve the intended results
	Guidance: Inputs in agricultural production systems are the "ingredients" for the crop(s) produced. Soil amendments (fertilizers), seed or rootstocks, crop protection chemicals, and fuel are examples of direct inputs into the crop production system. Labor, custom work, crop consultants for example, can also be considered as inputs.
infrastructure	(organization) system of facilities, equipment and services needed for the operation of an organization
	Guidance: This term includes for example; equipment, facilities, agricultural land, buildings, vehicles, computers, communication systems, hand tools, production machinery and utilities needed to produce a crop.
operation	see farm operation
product	result of a process
	Guidance: The results of farm processes is the crop
scouting	a specialized type of field inspection
	Guidance: In the context of production agriculture, this term refers to a method of inspecting a field for pests or other production problems during the growing season. Farm management or farm employees may perform this activity or they may hire a qualified individual to conduct scouting activities, depending upon the skills required and level of expertise available. Fields may be scouted several times during the growing season, or at specific times to identify pests or to assess crop conditions.
SOP	Standard Operating Procedure(s)
top management	person or group of people who directs and controls an organization at the highest level
	Guidance: Where it is used in this Standard, it is intended to mean, as appropriate, any of the following: Farm Management, Single Owner, Owners, Proprietor, Partners, President, Chief Executive Officer, Managing Director, Chairman, Board of Directors, Executive Directors, Managing Partner(s), or third party advisors that provide high level control over the farm operation by establishing policy and setting objectives for the organization.
work environment	set of conditions under which work is performed
	Guidance: This term refers to those environmental factors in the work-place that can affect the quality of a product (see 6.4 for examples). This document does not include requirements specific to other management systems such as those particular to environmental management or occupational health and safety management, and does not imply that a farming operation must implement an environmental management system or an occupational health and safety management system.

4 Quality management system
4.1 General requirements

The organization shall establish document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a. identify the processes needed for the quality management system and their application throughout the organization (see 1.2),
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.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE: Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

Guidance: This clause is intended to cover the requirement for the organization to actually develop and implement a quality management system, and broadly lists the activities associated with this action. These activities are described in greater detail in the remainder of the standard.

To meet the requirements of ISO 9001:2000, the organization will need to ensure that the activities described in a) to f) have been addressed in the quality management system. The activities required are described in greater detail in the remainder of the standard.

a) Processes may include for example; planning process, planting process, harvest process, etc. The organization may want to refer to other sub clauses as the planning process proceeds, for example; 5.4.1 (Quality objectives), 5.4.2 Quality management system planning, 7.1 (Planning of product realization), and 7.2 (Customer-related processes).
b) General planning for crop production operations are normally documented depending on the needs of the farm and its customers. A documented farm plan would be particularly important in larger farms or on farms with complex or significant customer or regulatory requirements. A documented farm plan may include for example; flow charts, standard operating practices, crop production plans, farming plan, operational plan or other methods deemed relevant by the organization. In a large farm the farm plan may include an updated field map to define what will be planted, where to plant, planting schedule, crop input application schedule and other activities that are to be performed to support the quality objectives and achievement of customer, contract and regulatory requirements. Farm plans should take into account that many or all farm process may be

connected and the sequence, interaction and interdependence between these processes should be considered at all stages of planning and when changing plans

c) General planning for crop production should include as appropriate the criteria for the individual operations that make up the plan.
d) Resources used in agricultural production may include for example; the land, labor, tools equipment, buildings, and other consumable inputs such as seed, crop protection products, fertilizers, and herbicides. See Clause 6 (Resource management)
e) Measurements, monitoring activities and analysis can have a significant impact on some farm processes. Clause 8 covers collection of data to be used to measure success and to track improvement.
f) Once farm management determines what is to be done, these activities must be done as a means of ensuring results.

The farm plan provides controls that ensure that organizational activities, subcontracted activities, and the responsibilities and interactions related to contracted activities and supporting services are undertaken and are effective.

Other management systems activities and processes may be associated with the paragraphs listed above. Wherever practical these other Management Systems should be considered for integration whenever integration provides benefits to the farm and stakeholders or by contractual requirements. These Management Systems may include for example; ISO 14001 (Environmental Management Systems), ISO 22000 (Food Safety Management Systems) and other Management Systems that may be relevant such as Occupational Health and Safety. While opportunities for integration may occur in several numbered ISO 9001 clauses, document control, recordkeeping, management review, employee training, internal audits, corrective action and preventive action may provide the greatest cost and operational savings.

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,
b) a quality manual,
c) documented procedures required by this International Standard,
d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and
e) records required by this International Standard (see 4.2.4).

Note 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

Note 2 The extent of the quality management system documentation can differ from one organization to another due to

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

Note 3 The documentation can be in any form or type of medium.

Guidance:

a) The quality policy represents top managements commitment to the quality management system. These should be stated and communicated to personnel. Quality objectives may be different for various processes within the farm operation. Objectives need to be reviewed and updated as change takes place over time.

b) The quality manual is covered in detail in sub clause 4.2.2.

c) A *documented procedure* is a procedure which is *"written down"* and available in a reproducible form and which is controlled as indicated in 4.2.3. The organization is responsible for ensuring that the requirements described in the following six clauses are included in documented procedures
   - 4.2.3 Control of documents
   - 4.2.4 Control of records
   - 8.2.2 Internal audits
   - 8.3 Control of nonconforming product
   - 8.5.2 Corrective action
   - 8.5.3 Preventive action

   Note: These six are the only clauses where the existence of a *documented procedure* is a specific requirement. It is entirely up to the organization whether it will be helpful to have other documented procedures.

d) This requirement specifies that the organization have the means ***"to ensure effective planning, operation and control … of processes".*** These may or may not be documented. The organization is responsible for determining how this control is undertaken. The important issue is that workers have the information they need to do their job. Some common methods for providing this control include;
   - work practices, work procedures or work instructions,
   - operating practices, operating instructions or operating procedures,
   - production schedules, farm plan, farm map
   - preferred supplier lists (people from whom inputs are purchased)
   - specifications, (grain grade standards), and
   - production contract specifications
   - it is important to note that small farms performing simple operations may require no documented procedures beyond the 6 stipulated by the requirements.

e) A record of processes related to quality may be important to customers. In addition, records may provide a trail of evidence for traceability or records of quality testing. These records may be any type or format developed to fit the needs of the farm or the customer.

Guidance related:

The notes associated with this clause provide important guidance for the development of the quality management system documentation. This clause gives a broad overview of required documentation and the notes provide an idea of what these expectations are.

Note 2

a) Smaller, simpler organizations may not need as much documentation as a larger one. A one person organization may not need documentation to guide other employees but may just need to write things down as an aid to memory.
b) A simple process may require little documentation on what is being done compared to a complex process that may require extensive written instructions.
c) Competent personnel may require little or no documented procedures depending on the needs of the farm.

Note 3

Documentation can be in any form or type of medium for example; paper, electronic, photographs, drawings etc. As an alternative a video showing the correct methods and the exact steps of the operation may work well in describing the instructions for some tasks.

Documentation is the written material that describes the various parts of the quality management system as listed above. The extent to which processes need to be documented depends on the complexity and stability of the process activities, the degree of risk associated with the activity and the competence of personnel.

Documentation should indicate, to the extent necessary, who does it, what is being done, and should include as appropriate answers to; where, when, why and how. It should not be a wish list of what the organization would like to happen, but should clearly and accurately reflect what is really intended to happen. For example, it is not necessary to have a formal document on how to keep farm equipment safe – simply including a term such as *"replace shields after maintenance"* may adequately describe the outcome intended.

Management, working with employees should decide how much detail is needed. This will depend largely on the methods used, the skills of personnel, the training undertaken and the extent of supervision required. Excessive detail does not necessarily provide more control nor ensure better results. Good documentation is often brief, to the point and applied where needed. Training can often replace the need for written instructions. Farm managers should understand that existing documentation might be adequate in its current state.

The quality management system and the preparation of documentation may involve many people who work for the farm. Involving people can help ensure that details in the documents reflect actual work practices. Because of this, the earlier people become involved and the more people included may provide a better understanding, involvement, and sense of ownership in the quality management system.

Documents associated with crop production may include:

- Documents provided by the customer that outline customer requirements
- Documents created by the organization used to gather customer specific requirements
- Checklists or other evaluation tools used to assess capability of input suppliers
- Requirements for seed/root stock, soil amendments, and other inputs
- Documents relating to equipment operation and maintenance
- Procedures or instructions to control field scouting activities, testing, field inspection activities, identity preservation, traceability, equipment cleanout, storage cleanout and bin preparation, crop verification, transport, and storage of crop and inputs

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes:

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),
b) the documented procedures established for the quality management system, or reference to them, and
c) a description of the interaction between the processes of the quality management system.

Guidance:

A quality manual should clearly describe the structure of the quality management system and serve as a "road-map" through it. All associations and links to other systems or documents which the organization may be required to meet should be detailed within the quality manual.

The organization should consider documenting its specific quality management system requirements following the sequence of the process flow or the structure of the selected standard or any sequencing appropriate to the organization. This may be achieved by means of flow charts, schematic representations, a cross-reference matrix, etc. In many agricultural market systems there may be several organizations involved in the delivery of a product to customer. For example, a soybean grower may deliver a crop to a soybean conditioning plant that cleans the soybeans before delivering them to an ingredient manufacturer that dehulls, roasts, and grinds the whole soybeans into another product. This product is then delivered to the soy food manufacturer that makes soymilk or tofu. In the case of this example, there is interaction between production activities within each of the entities involved in this system, as well as between the entities themselves. If the interactions between entities can be seamless (almost as if it was one and the same), value will be added and the end-user will benefit from the credibility of the system.

Guidance:

The requirements listed below may be considered for inclusion in the manual based on the needs and intentions of the organization.

- the activities of the farm,
- the principal characteristics of the quality management system,
- the quality policy (clause 5.3) and associated quality objectives (clause 5.4.1),
- statements on responsibility and authority (clause 5.5.1),
- a description of the organization, such as an organizational chart,
- how the documentation works and where people should look to find the procedures on how to do things (clauses 4.2 and 4.2.3), or
- definition of any terms having a unique meaning to the farm.

Formatting of the quality manual is left to farm management. As these decisions are made, farm management should consider the different readers of the quality manual. It can also be helpful to understand that the manual could be shown to outsiders. The quality manual should be a real working document and not just a showpiece to impress customers.

The ISO 9001 requirements that do not apply to the farm and are not included in the quality management system should be identified. The reasons for this exclusion should also be given. There may be few requirements that will qualify for exclusion with clause 7.3 (Design and development, under product realization) being the most common.

HELP BOX: A small organization may find it appropriate to include the description of its entire quality management system within a single manual, including all the documented procedures required by ISO 9001. Large, multinational organizations may need several manuals at the global, national or regional level, and a more complex hierarchy of documentation.

In addition to the requirements stated in 4.2.2, the quality manual may contain the points described below,

- Table of contents – the table of contents of the quality manual should list the number and title of each part of the manual and its location.
- Review, approval and revision – evidence of the review, approval, revision status and date.
- The nature of any change to the manual could be identified in the document or the appropriate attachments.
- Quality policy and objectives may be included.
- The quality manual may provide a description of the structure of the organization. Responsibility, authority and interrelation may be indicated by such means as organization charts, flow charts and/or job descriptions.
- References – the quality manual may contain a list of documents referred to but not included in the manual.
- Appendices containing information supportive of the manual may be included.

See Annex F for additional guidance on writing a quality manual.

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

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

Guidance:

The term *document* is used to cover the information contained in various media, such as written documents, computer hard disks, diskettes or CD-ROM, video, audio tapes or graphic posters.

This requirement ensures that someone in the organization determines that all documents are adequate and controlled and that they are available to people as a means for adequately controlling operations. In other words, does the document fit what the organization does and the way it is done? Someone should be assigned the responsibility of making this determination and giving final approval to original or modified documents before they are used.

Some documents may have a predetermined review and modification schedule (such as annually for each production contract), while others may require less frequent review and modification.

A clear document identification and tracking system should be considered to ensure that the current version of documents are identified and used, for example, equipment-cleaning checklists might be kept near where the equipment is cleaned.

Ensure that readable, clean, and current documents are available. For example, directions for cleaning equipment or tools might be laminated to protect them from grease and dust.

Documents of external origin should also be identified and controlled. For example an equipment operation manual provided by the manufacturer may be identified as part of the documentation. Text that is important to the quality management system may be highlighted and a notation made both on the operator's manual and in other instructions to help ensure that obsolete documents are identifiable and removed from use as appropriate.

Farm management should be reminded that controls needed (and the extent of control required) might be different from document to document.

This clause makes it clear that records are a special type of document (see 4.2.4). Records are generated as a result of some activity and are a statement of the facts existing at the time and cannot be revised. Superseded documents (or revised documents) can become records.

With the rapid development of computer networks, it has become relatively easy to comply with the requirements of document control. If electronic methods are available, these can provide effective means of controlling documents.

Attempt to keep the number of copies of documents to an absolute minimum. Access to common documentation is much simpler in a small farm where there is less formality, fewer potential users and smaller, often single, sites. If everybody has easy access to one central copy, the need for complex controls can be eliminated and arrangements for controlling changes simplified.

HELP BOX: Where there are relatively few employees, a list could be kept of who has what documents. If there is a change, one person could be assigned to collect the old document and issue the new one. A suitable note to this effect could be made in an appropriate log book or computer record.

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

Guidance:

Records exist in all organizations. These records can provide information to help manage the farm effectively. Records provide evidence that the farm has actually done something, or met a particular requirement. This clause deals with how to manage those records. Throughout the standard there are references to the need for records and these are identified in all clauses where the phrase, *see 4.2.4,* is found.

Records demonstrate the effectiveness of the quality management system. Retaining appropriate records for a specified period of time, under controlled conditions, is a critical activity that may be important to the farm, customers and appropriate regulatory bodies. If an organization were challenged at a later date about a product or process, which had occurred previously, records may be the only way to provide proof.

Records should be compiled, for example, in a hard copy file or on a computer. Each record should be rigorously classified and protected insofar as it constitutes:

- a history of the results
- the proof that necessary quality is reached,
- the proof of the effective application of pre-established controls or requirements,
- the demonstration that the farm is organized according to the quality system.

Examples of records associated with crop production (see examples below) can be grouped into several categories as follows:

- Input records may include incoming inspection records, crop protection chemical labels, and analysis of fertilizer, storage location and suitability, equipment maintenance records, proof of competency of organization and contract personnel, compliance with customer and or regulatory requirements date, time and weather conditions during different activities or processes of crop production.
- Crop amendment application and planting records might include for example; identification of the field, dates and persons performing activities, specific seed/root stock used, pre-planting records (seed tags, field location etc.), planting log (including date, conditions, inspection, test, equipment cleanout, storage cleanout, equipment type and unique identification), and records of application (including date, rate, and weather conditions, crop isolation, and abnormal conditions during planting).
- Growing and growing activity records might include crop verification, identity preservation, crop history, land history, field maps, rental agreements, cultural practices, conservation compliance, historical test data, process validation, updates to farm plan, updates to field plan, changes to contracts, field Isolation, yield estimates, crop observation notes, scouting reports,
- Harvest preparation and harvesting records might include for example; harvest, transport, unique identity, traceability, crop attribute testing, equipment calibration, records of adjustment to harvest timetable.
- Storage and handling records might include transportation and storage, including storage conditions,
- Delivery records might include unique identification of bin, truck, railcar, etc., settlement sheet, scale ticket, bills of lading, transport documents, delay or down time during shipment that impacts product quality
- Overall management system records would include internal audit records and records of management reviews.

When records are no longer useful, they should be identified and destroyed. Only keep what is needed. Records should not be kept merely to satisfy an auditor.

Record retention requirements may be determined by farm management, customers or regulatory authority. Production contracts may dictate how long records need to be kept. If there is a chance of product liability claims or questions pertaining to meeting customer requirements the records may provide valuable information.

Methods for generating and retaining quality management system records can be incorporated as appropriate with systems used for financial, payroll, and personnel records as appropriate. A backup system should be considered for both electronic and paper records. Extremely important records should be protected from fire and other risks. If records are stored electronically, copies should be held in more than one location.

HELP BOX: It is important that a small farming operation does not burden itself with large quantities of paper that serve no purpose. Decisions as to what records are required in relation to the farm as well as what is required by the quality standard must be made. Identify how long each type of record needs to be kept, where it will be found, and how it is to be disposed of in the future. Only keep what needs to be kept. Records should not be kept just to satisfy an auditor.

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
b) establishing the quality policy,
c) ensuring that quality objectives are established,
d) conducting management reviews, and
e) ensuring the availability of resources.

Guidance: For any organization to function effectively a single person or group of people should assume responsibility for providing direction and for decision making. This person or group of people is designated as top management.

Without top management's solid commitment to the quality management system in the beginning and throughout its use, it is difficult to generate, implement and maintain the system.

Top management is responsible for every aspect of the quality management system, since the quality management system impacts the quality of the crop produced to meet all customer requirements. In addition, statutory and regulatory requirements need to be considered at this point especially if these impact the customer and/or the end user of the product.

HELP BOX: In a small farm, top management may include the owner, in a sole operator farm, owners or partners and a few key people who report directly to them. Requirements that presume communication among a number of people can be simplified or even omitted in very small organization where communication may be inherently obvious.

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

Guidance: This clause is designed to ensure that top management is responsible for ensuring both requirements are met. To do this, top management needs to define the customer as well as their requirements (7.2.1) and the customers' perception that their needs have been met (8.2.1).

The customer is usually the immediate customer, but may be the end user or whoever utilizes the product after the producer. Customer requirements such as: delivery time, crop type, volume, product specifications or grade, etc. should be part of this process. It should be noted that the customer may not be the entity that takes immediate possession of the crop when it is sold or transferred; in many circumstances the quality management system may place an inherent responsibility on understanding the full chain of use for products. Once the customer(s) is identified, the customers' perception of whether these requirements have been met should be determined.

5.3 Quality policy

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,
b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
c) provides a framework for establishing and reviewing quality objectives,
d) is communicated and understood within the organization, and
e) is reviewed for continuing suitability.

Guidance: It may be useful to develop the overall policy as the first step of developing a quality management system. Be sure to include policies for marketing/sales, finance, etc. where these are appropriate. The quality policy should be a short summary statement that describes the operation's overall vision and commitment to quality. The quality policy should lead the organization/operation to meet requirements and to demonstrate continual improvement.

Employees should be familiar with the quality policy so they are able to talk about what the quality policy means to them and how they help the organization achieve it.

Attainment of the quality policy is demonstrated through achievement of quality objectives.

As stated in 5.6.1, the quality policy is periodically reviewed for suitability by management.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

Guidance: Quality objectives are those strategies that the organization intends to accomplish. They may be outlined within the operation's farm plan or by other means. Quality objectives may be based on or related to customer requirements, input requirements, product quality and crop attributes or measurement factors chosen by the organization or specified by customers.

In order to put the quality policy into effect, top management needs to establish clearly defined objectives that the organization can aim for. This does not need to be performed personally by top management, rather, top management is responsible for ensuring it happens..

Relevant objectives (e.g. process performance, continual improvement, achievement of unique customer requirements) are established within appropriate parts of the organization (e.g. human resources, production, sales). It is important that each individual in the organization is aware how they contribute to the achievement of the quality objectives.

This clause also requires that quality objectives be measurable. The organization will need to be able to verify that they are achieving the objective and, if not, determine what steps the organization will take to meet it.

5.4.2 Quality management system planning

Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented

Guidance: At the planning stage it is appropriate to refer to clause 4.1 (the general requirements for a quality management system). The quality policy and objectives help determine the goals of the operation. Planning describes the actions necessary to meet the objectives and ensure that the operation has clarified its requirements. Requirements occur at multiple levels and come from multiple sources. A well developed and detailed management plan will allow operational changes to be introduced without compromising the quality system.

Thorough planning ensures that all activities within the operation from the beginning to end of crop production are completed as required. This may include, but need not be limited to planting, crop care, harvest, storage, and transport. Each plan relies on tools, methods and models which orient the operation and the customer in their decision-making. Each plan is reasoned and optimized based on the needs of crop production.

In order to meet its objectives, the farm can establish and maintain one or more programs. This program or these programs should include for each function and each relevant level of the operation, the designation of the persons responsible for meeting these objectives, and the means and the timetable for achievement and monitoring.

Proper planning helps manage any changes to the operation that affect the quality management system. With proper planning the quality management system should continue to be effective during and after the changes.

Planning activities may include integrated planning with other Management Systems such as ISO 14001 (Environmental Management Systems), ISO 22000 (Food Safety Management Systems), or other Management Systems determined by farm management.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

Guidance: Everyone needs to know their job duties and authority level. This can often be done through formal job descriptions or informal discussions.

Special consideration should be given to joint decision makers (equal authority level)

HELP BOX: Small Operation
The descriptions do not have to be elaborate or complex. It is important that the descriptions clearly reflect the actual situation and allow for flexibility.

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented and maintained,
b) reporting to top management on the performance of the quality management system and any need for improvement, and
c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

Guidance: In a small operation such as an individual owner operator this person will be the management representative. In a larger operation the management representative is the primary individual for ensuring the quality management system is implemented, effective and maintained. This person has a requirement to communicate effectively, at all levels of the organization and be aware of the performance of the system. If multiple sites exist, it is possible for each site to have its own management representative.

HELP BOX: Small Operation
The management representative is often an owner or farm manager but this person could be supported by other people in the day to day management of the operation. Whether this person is an owner operator or a management representative in a larger organization, this is the person who looks after the quality management system.

5.5.3 Internal communication

Top management shall ensure that appropriate communication channels are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

Guidance: Internal communication addresses whether communication is taking place between people, activities and processes within the quality management system regarding the overall effectiveness of the system. It may be a good idea to make a record of communication regarding the quality management system as it occurs.

HELP BOX:
Communication takes many forms, including: charts, graphs, notes, letters, emails, photographs, samples, and conversations with neighbors, employees, and customers.

5.6 Management review

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained. (see 4.4.2)

Guidance: The goal of the management review is to step back and look at the quality management system in a more structured manner than daily assessments may allow. Specific reviews should take place at planned intervals.

The results of the management review should be a clear determination of three key factors regarding the quality management system. This review should ask:

1) Suitable – Does it still fit its purpose?
2) Adequate – Is it still sufficient?
3) Effective – Does it still achieve the desired results?

Management reviews are used to determine if the direction of the quality management system is well defined and being achieved, and if not, what needs to be done to get there.

5.6.2 Review input

The input to management review shall include information on

a) results of audits,
b) customer feedback,
c) process performance and product conformity,
d) status of preventive and corrective actions,
e) follow-up actions from previous management reviews,
f) changes that could affect the quality management system, and
g) recommendations for improvement.

Guidance: Various sources of materials, including documents and records are incorporated in the management review:

a) Audits are often self assessments by the owner or manager. Information on results of audits includes any audit findings or reports from internal and external audits. Other audits can be customer audits, supplier audits, and producer audits. This information should be reviewed to find trends and opportunities for improvement.
b) Customer feedback is often by personal contact or may be more formal
c) Information on process performance and product conformity may include for example; crop yields, crop grades, equipment function, labor allocation, employee training and competency, timeframes, etc.
d) Information on the status of preventive and corrective actions assess whether or not these are being completed and in a timely fashion.
e) Have follow-up actions from previous management reviews been completed?
f) Changes that could affect the quality management system include changes in staff, changes in product, changes in customer requirements, changes in regulation, etc.
g) Recommendations for improvement from customers, employees, or management.

Key factors that may be considered as part of the management review inputs may include information that indicates;

- the relevance of quality policy and objectives to current needs;
- whether objectives are being met and if they need to be changed;
- analysis of the operation's performance;
- quality problems and actions taken (including customer feedback and complaints).

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes,
b) improvement of product related to customer requirements, and
c) resource needs.

Guidance: The output or written record of management reviews is vital to the future of a quality management system since these outputs allow the organization to track progress. Consider decisions and actions related to:

a) improvement, over time (since the last review) of the effectiveness of the system and of the sub-processes within the system (does the system work better?)
b) improvement of product related to customers' requirements (what is customer response?)
c) resource needs (were needs addressed from the last review? what are new needs?)

Any actions indicated from the review need to be prioritized and plans made to implement changes that are necessary.

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and
b) to enhance customer satisfaction by meeting customer requirements.

Guidance: The intent of this clause is to make sure the organization has the resources needed to implement, maintain and improve the quality management system and also to carry out the work to satisfy customer and regulatory requirements. This should include the prioritized use of available resources as well as planning to acquire resources that are needed but not currently available.

The organization should identify and/or review resource needs on a regular basis. This review may be undertaken under a number of circumstances and may include for example:

- At the time customer requirements are identified
- As part of management review process
- When customer requirements are changed
- When crop or growing conditions change

The output of the resource review process may result in a list of resources which may be included in the farm plan. As part of this activity, the organization may want to refer to customer and/or regulatory requirements. Resources may include for example; qualified personnel, tools, equipment, finance, materials, facilities, timely scheduling, instructions, supplies, repair parts etc.

HELP BOX:
Resources for small organizations or organizations using extensive manual labor may include, for example, the availability of labor including work performed by animals, hand tools, containers to be used during harvest, and containers to be used for transport to storage
In addition to the resources listed above, resources for large and/or mechanized crop operations may include for example; Resources necessary for soil testing including the availability of a suitable

laboratory; crop testing to customer, regulatory and organizational requirements; crop or field applications; equipment maintenance activities including cleaning and calibration; resources to provide for identification, transportation, segregation, handling and storage of seed/root stock; scouting activities; crop and field maintenance activities; testing and field inspection activities; crop attribute testing; inspection of storage facilities; resources as necessary for re-verification of labor and equipment at appropriate stages of the crop production cycle; transportation, and handling of product; identification and segregation; storage cleaning activities; and security.

6.2 Human resources

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

Guidance: People who are assigned to carry out activities should be competent to do them. An initial determination of the availability of competent personnel (employees or subcontracted personnel / labor) should be made at the beginning of the crop production cycle. Further determination of resource needs may be made at each stage of the crop cycle.

Competence is understood to be a combination of appropriate education, training, skills and experience that can be demonstrated. Note that there is no requirement for a person to have all four attributes, only those that are necessary for the particular task.

6.2.2 Competence, awareness and training

The organization shall

a) determine the necessary competence for personnel performing work affecting product quality,
b) provide training or take other actions to satisfy these needs,
c) evaluate the effectiveness of the actions taken,
d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
e) maintain appropriate records of education, training, skills and experience (see 4.2.4)

Guidance: Producers may need to consider additional training to develop competencies associated with customer or regulatory requirements. This clause provides a logical process for:

a) determining the necessary competence of specific personnel affecting product quality – are personnel currently available for the required tasks?
b) after the needs are determined what training or other action is needed to satisfy the needs?
c) after the indicated action is taken are the competency requirements met? Testing may be required.
d) some employee education about the tasks and competencies required may be needed. Employees need to understand or be aware that the farm expects certain levels of competence for specific tasks. In some cases activities may be regulated requiring training and testing (some chemical applications).
e) records, which may include licenses or copies of licenses need to be maintained as appropriate.

The knowledge of Good Agricultural Practices and Good Hygiene Practice for the farm of the organization as applied to the types of operation and products may be important. New employees and seasonal employees may require the same screening, training and testing as experienced employees.

HELP BOX: For small farms, competence may be demonstrated by means that are practical for the specific needs of the farm and its customers, for example, by direct observation of employee knowledge and understanding. As needed, a more formal review of records associated with training or education may be required.

Competence can be demonstrated as determined by the organization. The crop producer may not need to provide evidence of competency in all circumstances, for example; for employees performing tasks by rote or tasks that are culturally imbedded.

The records that show the successful completion of a training program and that competence has been demonstrated can be as simple or as complex as necessary. This may include for example whether employees can use certain equipment, carry out specific processes or follow certain procedures. Records of these qualifications should become part of the farm's records. Competency records for example may include as appropriate Commercial Drivers License and Chemical Applicator's license or certificate.

HELP BOX: In a small farm, records may consist of a simple checklist to confirm that personnel are capable of doing their job.

In addition, re-verification of the availability of competent personnel may be conducted as appropriate throughout the crop cycle or as needed.

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

a) buildings, workspace and associated utilities,
b) process equipment (both hardware and software), and
c) supporting services (such as transport or communication).

Guidance: An initial determination of infrastructure requirements should be made during the initial planning process. This may include;

a) "permanent or non-movable" parts of the operation. This would include land (including isolation requirements for the crop being produced), buildings used for work and storage, and associated utilities, maintenance buildings for field equipment, etc.
b) all equipment used in the field and for processing (crop drying equipment). The broad meaning would also include computers and computer software.
c) transportation and handling equipment to deliver inputs in and product out and communication equipment (cell phones, radios, computers and the related services). Equipment or instruments for product testing would be included in this area.

Infrastructure needs may be provided by farm management, by the customer or may be provided, leased or rented as appropriate. All infrastructure needs including land productivity need to be evaluated to achieve conformity to product requirements. Re-verification of infrastructure requirements should be considered at appropriate stages of the production cycle to ensure ongoing capability to meet organizational, contract and regulatory requirements.

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements

Guidance: This clause can be interpreted as meaning the work environment for people, equipment inputs, and outputs that are necessary for the successful production of a crop that meets requirements. To a large extent the work environment is also the growing environment for crop production. This environment is not always controllable or manageable, for either working or growing. The organization should adequately review its work environment and were appropriate ensure its ongoing ability to meet product requirements.

This control should include all stages of crop production from purchasing inputs to product delivery. This may include as appropriate; environment, buildings, and equipment. Worker safety should be considered as part of the work environment considerations. Workers may be outside, in equipment (such as tractors and combines), and inside buildings. All of these environments need to be evaluated to see that they are adequate for crop production and worker safety.

7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;
b) the need to establish processes, documents, and provide resources specific to the product;
c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1: A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2: The organization may also apply the requirements given in 7.3 to the development of product realization processes

Guidance: *Product realization* is the term used to cover the activities associated with the delivery of a service or product to a customer. In crop production these activities would include planting, growing, harvesting and all of the other processes associated with the delivery of a crop that meets customer required specifications. At the planning stage it is appropriate to refer to clause 4.1 (the general requirements for a quality management system). In crop production, planning for product realization needs to be completed for each new crop cycle.

a) Quality objectives should be reviewed or determined based on customer requirements for the products that will be grown. Changes from the last crop cycle should be noted and plans made to include any different or additional requirements.
b) As new technologies are put into practice any changes in processes, documentation, and resources required need to be planned for and implemented.
c) As new technologies are employed and new crop specifications set by customers, any requirements for verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance need to be determined and initiated.
d) Record keeping requirements and methods should be reviewed and necessary changes made to provide the evidence that the realization processes meet specifications

The planning for these production activities may be one of the most important activities in the farm operation. The output of the planning process can be in any form that is suitable for the farm operation, as long as it meets the needs of the operation and its customers. Note 1 refers to this as a quality plan (farm plan).

Planning for crop production could be in the form of a crop season (cycle) operating plan, such as a farm plan. Development of a farm plan should consider (for example):

- **Contract requirements** – including customer and product specifications
- **Production environment –** including infrastructure (land), multi-year crop history, isolation
- **Production Inputs –** including seed/root stock, crop protection inputs, equipment, personnel
- **Management Inputs –** including a quality policy, measurable objectives, and customer satisfaction measurement (scouting, documentation, competency, internal audits), identity preservation)
- **Harvest –** including handling, storage, and transportation

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,
b) requirements not stated by the customer but necessary for specified or intended use, where known,
c) statutory and regulatory requirements related to the product, and
d) any additional requirements determined by the organization

Guidance: This clause focuses on defining and understanding all requirements for the crop to be provided to the customer. It should be remembered that additional factors, such as regulatory or legal requirements, delivery schedules, and conditions of payment or unspecified customer expectations must be taken into account at this point.

a) In crop production this might include an understanding of, for example, the need for on farm storage or perhaps delivery at a specific location and/or time.
b) Where there are underlying product specifications that are not spelled out in the contract that the farm is expected to know, these may need to be defined.
c) This may include for example; food safety, industry, or government standards.
d) Product requirements that the farm sets for itself for example use of a particular type of equipment.

A brief list of contract and regulatory requirements may include for example; land, seed/root stock, food safety requirements, field isolation, crop protection restrictions, identity preservation requirements, equipment, outsourced labor, technology, crop segregation, contamination control, handling and storage requirements, etc. Conditions of payment need to be clearly understood.

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) product requirements are defined,
b) contract or order requirements differing from those previously expressed are resolved, and
c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues, or advertising material.

Guidance: Product requirements were determined in clause 7.2.1. At this point these requirements need to be reviewed prior to any commitment to supply the crop to the customer(s). This review is intended to ensure that any commitment that follows can be met. In cases where there is no written contract or agreement with the customer, for example on a small farm, specifications need to be clarified, understood, and confirmed prior to any oral agreements. All parts of a customer’s order or contract should be reviewed on a regular basis during the production season to ensure that they can be met as conditions change. Any changes should be communicated to the customer as soon as possible.

Customer and regulatory requirements are normally included in the farm plan. The completed farm plan should be reviewed to ensure that:

- All requirements are clearly stated in the farm plan
- Prior differences and changes that may have occurred may be resolved and that the farm plan is current and meets customer requirements
- The farm has the capability of meeting defined requirements. This capability review may consider requirements associated with field history, size, availability of seed/root stock, facilities and equipment as well as availability of qualified personnel, etc.
- It should be noted that a farm plan that has been reviewed and approved will help provide confidence that all requirements can reasonably be met prior to acceptance of the contract. The farm plan normally includes requirements for delivery including dates when dates are specified by the customer as well as requirements for transportation and storage especially when these are defined by the customer.

- All leases, whether written or oral, should be reviewed to assure that lease terms are consistent with contract requirements.

7.2.3 Customer communication
The organization shall determine and implement effective arrangements for communicating with customers in relation to

a) product information,
b) enquiries, contracts or order handling, including amendments, and
c) customer feedback, including customer complaints.

Guidance: There needs to be open communication with the customer before the contract is finalized, during crop production, and after crop delivery. Product information can sometimes be changed by the customer after an agreement on specifications. If new specifications can be met this communication needs to flow both ways between the organization and the customer. Customer feedback, including complaints is valuable for continual improvement. Any changes that impact meeting requirements especially any changing conditions and customer notifications are important.

Review and re-confirm crop, soil and other conditions prior to harvest as a means of ensuring customer, regulatory and other specified requirements can be met. This review should start with contract requirements and should confirm as appropriate, the current status with regard to meeting requirements. This confirmation should include consideration of all specified contract and appropriate regulatory requirements. Where conditions are found to be inconsistent with the fulfillment of requirements, the customer should be notified and a record of this notification should be kept. Conditions may include for example: crop suitability for harvest; environmental conditions related to planting or harvest, availability of handling and storage facilities; identity preservation protocols are in place; changes, weather or crop conditions, or any other conditions which may require notification or reconfirmation with the customer. Open and early communication with the customer is important when these circumstances appear.

The farm operation should consider having established methods for soliciting and dealing with customer feedback including customer complaints. It is important to the quality management system that this feedback be captured and noted as a means of correcting problems and to make improvements. Records of customer feedback and complaints may become part of this process to aid in tracking these issues and to identify trends.

7.3 Design and development

7.3.1 Design and development planning

The organization shall plan and control the design and development of product.

During the design and development planning the organization shall determine

a) The design and development stages
b) The review, verification and validation that are appropriate to each design and development stage, and
c) The responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

Guidance: It is important to analyze and determine if this clause is applicable to the farm operation. It is relevant only to those organizations that actually carry out design and development.

In a farm operation a design could be considered as any unique changes to genetics, inputs, outputs, growing conditions or any process associated with farm processes which impart a unique characteristic or attribute of the crop that is desirable to current or future customers.

Many farms do not design crops, but apply, modify or adapt proven designs and processes to meet various customer requirements. These activities should not be considered as part of design.

If the farm does not perform design and development, and is not responsible for these processes, the "exclusion" provisions of 1.2 (additional information is given in *Guidance on ISO 9001:2000, clause 1.2 "application") apply.*

HELP BOX. Design and development applies to those farms that choose to devise a new product to meet known or anticipated customer or marketplace needs. For example this might include a unique combination of inputs or methods that result in a newly devised product with unique characteristics or attributes.

Additional guidance is provided in Annex E, step 2.

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall 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 shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

Guidance: Inputs to the design process should be considered as any input that uniquely changes the required characteristic or attribute(s) of the crop delivered to the customer. These inputs are therefore critical to meeting customer requirements and should be identified and managed as inputs to the design process as listed in 7.3.2.

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,
b) provide appropriate information for purchasing, production and for service provision,
c) contain or reference product acceptance criteria, and
d) specify the characteristics of the product that are essential for its safe and proper use.

Guidance: Required or expected outputs associated with the design process should be considered as any output that uniquely characterizes or supports the characteristic or attribute of the crop to be delivered to the customer. In addition, any output associated with maintaining the desired output, for example; defined storage conditions, should be included. These outputs are therefore critical to meeting customer requirements and should be identified and managed as outputs from the design process as listed in 7.3.3.

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1).

a) to evaluate the ability of the results of design and development to meet requirements, and
b) to identify any problems and propose necessary actions.

Participants in such reviews shall 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 shall be maintained (see 4.2.4).

Guidance: Design and development activities associated with crops may in some circumstances require one or more growing seasons to confirm the attribute and the inputs, outputs and controls necessary to achieve the desired attribute. Therefore it is important to understand that progress toward meeting the desired characteristic or attribute should be tracked during a formally defined Design and Development review process. During this review inputs, outputs and other conditions or processes can be reviewed and as necessary formally changed as a means of assuring that the requirements associated with the crop characteristic or attribute are ultimately achieved.

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) 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 shall be maintained (see 4.2.4).

Guidance: Design and development verification is used in the design of unique crop characteristic or attributes to provide the farm with information related to progress on design and development activities. This should be a formal process that determines that design inputs, outputs and other aspects associated with these activities are occurring in a manner that helps ensure the achievement of the desired crop characteristic or attribute.

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, when known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

Guidance: Design and development validation is the process of confirming that the crop characteristic or attribute is actually present and meets the stated requirements. Crop characteristic or attributes that do not meet requirements may under some circumstances be considered as adequate if customers are provided with information that accurately describes the actual characteristics or attribute of the product and determine them to be acceptable.

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

Guidance: From time to time during the design process it may become necessary to make a change to the various components of the design process. This may include changes to inputs, outputs, conditions or even the characteristics associated with the crop attribute. This clause is intended to ensure that these changes are controlled, readily apparent to farm management and are approved.

7.4 Purchasing

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

Guidance: The organization needs to identify those materials and services purchased which can affect the quality of the crop(s). The farm then needs to select suppliers capable of meeting the requirements for the relevant materials and services to be purchased. In the assessment of suppliers for the inputs and services purchased from a third party, the farm may:

- make provision for supplier assessment and monitoring procedures based on methods deemed suitable for the operational needs of the farm.
- Past performance of the suppler may meet this need in some circumstances

HELP BOX: For small farms, previous history with labor, service provider, or material supplier may be sufficient to meet to fulfill this evaluation. In some circumstances this same approach may also apply to large farms.

This requirement applies to any process, product or service purchased by the farm that can have an impact on meeting customer or regulatory requirements. The organization should clearly describe the expectations associated with suppliers as the first step in insuring that the supplier can meet stated requirements.

When the farm needs to rent land this should be considered as an input purchased from a supplier. Arrangements need to be made that ensure that rented land provides conditions that enable customer and regulatory requirements can be met. Considerations may include as appropriate, an evaluation of soil type, moisture, cleanliness of irrigation water,, field isolation, etc as a pre-condition to any agreement that commits the farm to using the land. When the farm rents property from a supplier, it is responsible for ensuring that the supplier (or owner) of the land is capable of fulfilling requirements. This may require an examination of the land and associated conditions by farm management.

As part of this process be sure to consider all purchased inputs necessary to meet requirements including for example; equipment (including types, quantity and availability), technology, personnel availability, and personnel qualifications. In addition it is important to consider as appropriate the capacity of personnel and organizations with consideration given to timing and availability of the contracted service. Externally provided services for crop production may include for example: soil testing, fertilizer application, crop protection application, planting, field scouting, custom applications, yield estimation services, harvesting, inspection and testing services, laboratory testing, crop attribute testing, and transportation and storage.

When externally purchased services are obtained care should be taken to ensure: The provider is capable of conducting the activity to meet established criteria; Clear communication takes place ensuring that the provider understands the requirements including any appropriate records that are required; Appropriate verification of completed activities takes place as suitable.

The type and extent of control applied to the labor and outsourced services should be dependent on the impact of the service provided on the ability of the farm to meet contract and regulatory requirements. Due consideration can be given to past history when determining the capability or qualifications associated with a purchased input.

HELP BOX: Externally provided services should be taken to include exchanged or bartered services between crop producers, as well as purchased services.

7.4.2 Purchasing information

Purchasing information shall describe the product 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.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

Guidance: The operation will need to determine the level of formality of the purchasing system that is appropriate. When outsourced services are purchased, the farm is responsible for communicating approval requirements for the service, procedures, processes, equipment, facilities, and work environment, etc. as appropriate to the supplier operation. Purchase instructions should leave no doubt about the quality and quantity of what is required. Where reasonable, this communication should be in writing.

Producers should give consideration to documenting rental agreements for land. Rental agreements should outline all purchasing information associated with the requirements of the organization including appropriate, customer and regulatory requirements.

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

Guidance: Specific methods of inspection or verification should be initiated where appropriate for each type of purchased input or service. Examples could include: if genetic purity and crop attributes are important to the product the label of each seed container should be inspected to see that the seed variety and lot number match what was ordered; Pesticides should be checked to see that formulation and strength are appropriate.

The operation may choose to re-verify the availability and capability of suppliers to meet requirements as necessary to ensure operational, regulatory and contract requirements can be met. This re-verification may include confirmation of availability in a timeframe that meets requirements, qualification of personnel and equipment, and verification of other inputs such as seed/root stock and applications remain available.

7.5 Production and service provision

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

a) the availability of information that describes the characteristics of the product,
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 measurement, and
f) the implementation of release, delivery and post-delivery activities.

Guidance: This clause describes the various types of controls that may be needed to actually produce and deliver the crop to the customer. It follows from clause 7.1 a) and b), where it is stated that the objectives, product requirements, processes and other resources should be identified and planned to achieve intended results. Understanding how all of this comes together to impact the final crop is important. This clause directs the organization to initiate controls for the conditions listed in a) through f) as applicable.

Crop processes may be divided as shown below. Each of these processes (or others identified by farm management) should be adequately controlled with due consideration given to all internal and external requirements. These processes can be controlled by providing work instructions, representative samples, providing direction or training to personnel or other means determined by farm management. It should be noted that each of the example processes listed below may require significantly different methods of control than the other example processes listed.

1. Farm Planning
2. Land allocation
3. Allocate/purchase/procure inputs
4. Field preparation
5. Field planting
6. Field activities
7. Pre harvest and storage activities
8. Harvest
9. Transportation and handling
10. Crop storage
11. Distribution and delivery

Farm management should understand and manage appropriate activities within each farm process that can affect the product. It can be helpful to begin this with a description of the crop(s) and crop attributes being produced, the requirements necessary for establishing and verifying quality (e.g. moisture, firmness, organic, purity etc), and the contractual/legal requirements that apply. Farm management should consider documenting the results of this to provide a record, to ensure continuity over time and to ensure results are achieved.

HELP BOX: All farms and especially small farms should pay particular attention to the definition of the word "procedure" provided by ISO 9000:2000 where it is stated that procedures can be documented or not. Based on this definition, procedures may be communicated verbally, provided by example, pictures/drawings, or other actions that meet the needs of the farm.

Many processes from the list above may assign or require specific acceptance criteria (e.g. planting depth, population, fertilizer application, product traits, etc.). For each of these processes, the important indicators should be measured if possible or monitored in cases where physical measures might not be possible. Measuring methods should be verified for accuracy and consistency where practical. Knowledge of the quality of the product, and the relationship to customer acceptance requirements and how transportation or storage may affect product quality may be important to achieving success.

Remember that the farm's customer may not be the final customer for the product and that appropriate steps may need to be taken in consideration of these intermediate and final customer needs. ISO 9001:2000 focuses on the customer. Intermediate and final end users of agricultural crop products may be important as part of this process.

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish 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 (see 4.2.4), and
e) revalidation.

Guidance: Processes requiring validation are those processes where it is difficult to determine the outcome until it is too late. In addition there may be some processes that are important where verification of results can be uneconomical or impossible.

An example would be in the control of the uniformity of chemical application where it would not be feasible to measure the application of the chemical; rather the control would be better monitored by properly calibrating the application equipment. Other types of control that may be appropriate activities requiring verification could be performance of a task by qualified personnel or in the use of capable, well maintained equipment.

Reliance on end of season inspection and testing to serve the verification needs of the organization should be minimized since this is usually too late to take corrective action. Farm processes should be planned, and implemented to ensure that all possible inputs are well defined and controlled.

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).

NOTE: In some industry sectors, configuration management is a means by which identification and traceability are maintained.

Guidance: Identification is knowing what it is. Traceability is knowing where it came from, where it is now and, in the case of services, what stage it is now.

Identification and traceability may include records which identify and/or trace not only the product but also the inputs involved in the production processes. This may mean recording the amount and type of input applied. A paper or electronic trail may be required to follow the processes and necessary inputs.

Some examples of identification and traceability activities:

- Seed/root stock should be clearly identified to preclude mix-ups with other genetic materials.

- Traceability should follow customer requirements or code requirements as appropriate. At a minimum, lot information should be retained unless lot identity information is retained by the customer for confidentiality purposes. Traceability should be maintained as specified by the contract or when determined that this provides assurance of confidence for any stakeholder in the seed/root stock.
- Inputs should be clearly identified, as appropriate, by a means that is suitable and precludes mix-ups. Traceability of inputs should be maintained per customer agreement.
- Identification and as appropriate, traceability during crop verification should be considered.
- Identification and as appropriate, traceability during transport should be considered.

The facilities and equipment used in the production processes will affect the identification and traceability.

- Equipment to be used should be clearly identified, as appropriate, by a means that is suitable and recorded in the farm plan. Traceability including use on other fields and all equipment cleanout activities should be maintained as part of the farm record.
- A clearly defined means for identification of specific storage facilities, sites, containers, etc. to prevent mix-ups and to ensure traceability when required.
- Handling and processing equipment should be clearly and uniquely identified as a means of preventing the inappropriate use of equipment that does not meet requirements. This identification should consider the status of the equipment with regard to the verification of equipment suitability (including cleanout and calibration)
- Clearly defined means for identification of specific storage facilities, sites, containers, etc.
- Transportation equipment should be clearly and uniquely identified as a means of preventing the inappropriate use of equipment that does not meet requirements. This identification should consider the status of the transportation equipment with regard to the verification of suitability including cleanout of meeting requirements specified by OEM, the organization and/or contract requirements.

Traceability is addressed in an ISO standard, ISO 22005. "*ISO 22005 Traceability in the feed and food chain -- General principles and basic requirements for system design and implementation"* is not intended as a broad management system but is intended to be coordinated within the context of a broader system such as ISO 22000:2005 or ISO 9001:2000. If the organization is developing a management system that will incorporate ISO 22005 the traceability aspects with other systems, these should be coordinated as appropriate.

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).

NOTE: Customer property can include intellectual property.

Guidance: Customer property should be clearly identified and controlled according to the requirements of the customer and any requirements in the farm plan. Use of this property and any associated records should conform to the requirements of the customer and farm plan. Customer property that does not meet the operation's requirements or remains unused should be reported to the customer as defined in the contract or as determined by farm management.

Examples of customer property in an agricultural setting may include: seed/root stock, land, inputs such as chemicals, equipment such as applicators, storage facilities, and transportation such trucks, wagons, railcars, etc.

7.5.5 Preservation of product

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

Guidance: The farm is responsible for providing conditions that maintain product integrity, value, effectiveness, and safety in a manner that assures fulfillment of customer and regulatory requirements.

In crop production this clause is especially important in the harvesting, handling, storage and delivery phases of the operation. When on-farm storage is part of the production and delivery processes, frequent or continual monitoring of storage conditions is often extremely important to product integrity. Maintaining the quality level attained during the growing season can mean the difference in premium levels. It is also important to note that segregation of the product from similar products and other products in storage needs to be observed according to contract specifications.

7.6 Control of monitoring and measuring devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall
a) be calibrated or verified at specified 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) be adjusted or re-adjusted as necessary;
c) be identified to enable calibration status to be determined;
d) be safeguarded from adjustments that would invalidate the measurement result;
e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

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

NOTE: See ISO 19011 for guidance.

Guidance: Monitoring and measuring devices that are used to confirm or verify such things as moisture, flow rate, seed counts etc. should provide accurate information. Generally, the manufacturer of every measuring device will have some calibration procedure for maintaining its accuracy and consistency. Records that these calibrations are done at the specified interval should be maintained. Some examples might be:

- Chemical or fertilizer application – flow meters or pressure gauges
- Harvesting equipment monitors, weighing devices, moisture testers and similar equipment
- Storage, conditioning and transport monitoring devices such as thermometers, hydrometers, etc

Handling and processing equipment maintenance and cleanout should be capable of meeting requirements specified by equipment manufacturers, the organization and/or contract requirements

In general, the accuracy and consistency of any data that is used to make decisions should be known, and controlled to the extent possible. This may mean requesting calibration and accuracy records from external suppliers, as well as maintaining internal records. In many cases crop moisture tests by the buyer will prevail and in this case the farm may choose to calibrate their equipment to correspond to the buyer's equipment

HELP BOX: This section is not meant to create more effort than is necessary to meet farm requirements unless customer or regulatory requirements are more rigid. Measurements made when goods are sold or transferred may be subject to government regulation, but measurements to support internal decisions are not. However, it is good practice to compare internal measurements with regulated measurements when possible. Eventually goods will likely be sold based on regulated or standard tests, so a comparison will improve internal decision making.

8 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity of the product,
b) to ensure conformity of the quality management system, and
c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use

Guidance: It should be noted that the control of monitoring devices and measuring equipment is specifically addressed in clause 7.6, whereas this clause addresses the wider monitoring, measurement, analysis and improvement of the performance of the quality management system.

The organization needs to plan how to carry out the monitoring and measuring activities to meet their and their customer needs. The activities to which these will be applied are:

- customer satisfaction (8.2.1)
- quality management system performance (8.2.2)
- process conformance (8.2.3), and
- product and service conformance (8.2.4)

All of the clauses listed above provide the data to be analyzed as per clause 8.4. Clause 8.1 sets the stage and outlines the activities for the measurement, analysis and improvement of the quality management system. This will show how the quality management system is doing (system performance) and how it affects the farm.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

Guidance: The primary customer is the person or organization that purchases the crop. It should be noted that there may be a chain of handlers leading to the end consumer and that all of these may be considered customers based on the needs of the organization. Attempts should be made to understand the end user of the product. If the crop is grown under contract, satisfying the contract requirements may be sufficient.

Examples of methods to measure customer satisfaction are:

- Customer surveys
- Face to face interviews
- Results of delivery of contracts
- Customer complaints/feedback

In agricultural marketing, face-to-face contact with the customer or representative of the customer is common. If there are problems indicated from a customer representative employees should be encouraged to immediately contact farm management to determine what to do. The most serious customer reaction would be the rejection of product at delivery because of quality problems. If the quality management system is working as planned this should not happen.

ISO 9004:2004 has a more extensive discussion of consumer satisfaction.

HELP BOX: Routine conversation with the customer may be sufficient to identify any problems or improvements needed. This may be especially true in the case of small farms or individual producers.

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization,
b) and is effectively implemented and maintained.

An audit program shall be 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 shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall 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) shall be defined in a documented procedure.

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

NOTE: See ISO 19011:2002 for guidance

Guidance: Internal audits are a process of self-evaluation of the effectiveness of the management system as it is being used in practice. This is a very important part of extracting value from a quality management system and in uncovering opportunities for improvements/efficiencies. As part of this clause, ISO 9001:2000 requires that internal audits be objective and impartial. It is stated that an auditor shall not audit their own work. In a small organization this can be challenging. At the very least if auditing their own work and auditor needs to step back and try to look with total objectivity. Internal audits should be done on a regular basis. Clause 8.2.2 outlines the steps to consider in the auditing process and what other clauses need to be considered. The audit should evaluate the farm's quality management system against the clauses of ISO 9001:2000.

Internal audits can be conducted on the entire quality management system at one time, or on selected portions of the quality management system conducted over a designated period of time. Whatever the approach, all internal audits should begin with a determination of how much or what part of the system is to be audited. The second step would be to understand the requirements for the part or parts to be audited, and honestly evaluating whether the requirements are being met. If problems are identified, it is important that they be recorded, and that corrective action is taken where and when appropriate.

A reasonable frequency of audits in crop production where there is one crop per year might be an annual audit. In other regions where there are multiple crops in a year an audit following each cycle might be appropriate. It is important to review the results and corrections (corrective actions Sec 8.5.2) from previous audits as a method of identifying recurring problems.

HELP BOX: Farms can cooperate by exchanging audits with each other. Audits should be scheduled to minimize disruptions to production operations. It is possible for internal audits to be done by an individual operator but small or individual operations might consider having them done by a qualified outside source such as a consultant or perhaps by a government person that may be able to provide this help.

8.2.3 Monitoring and measurement of processes

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

Guidance: Understanding of the critical points of each activity is necessary to achieve good results. The quality system plan should identify these points and show how each is being monitored or measured.

It may be difficult to measure some processes and the organization should take a practical approach with careful consideration given to customer and regulatory requirements. An assessment of product quality (clause 8.2.4) can often provide some guidance on how crop production processes are performing and provide a good indication of which processes should be monitored and/or measured.

HELP BOX: Small farms may find that direct observation and experience sufficient to monitor processes.

8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).

Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

Guidance: Depending on the crop, it may be appropriate to monitor or measure it at several points in the crop production cycle. Problems identified during production (growing) can be monitored and possibly corrected, but the actual final product quality cannot be measured at that point. After harvest and before the product is released for sale or delivery, farm management needs to know that all customer and regulatory requirements and expectations are met (or not met). Appropriate crop measurements and monitoring methods must be selected as appropriate to demonstrate conformance.

Data from production activities may be used in cases where requirements cannot be objectively tested, as for example organic grains. Proof of product conformance should become part of the farm records.

8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

The organization shall deal with nonconforming product 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;
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, shall be maintained (see 4.2.4).

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

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

Guidance: Nonconforming products are crops that either fail to meet customer purchase specifications or that fail to meet production practice or regulatory requirements. When nonconforming crops are identified, they are either not offered for sale or marketing arrangements can be renegotiated. If the nonconformity can be corrected, these products may be offered again for sale. If nonconformities cannot be corrected alternate marketing arrangements should be made. It is important that nonconforming product be identified wherever possible before, during or after crop harvest. Nonconforming product can be identified appropriately by visual inspection or crop testing. Nonconforming product should be immediately segregated and controlled by methods listed in the clause or by other means determined by farm management. The nature of nonconformities and actions taken to control nonconforming product needs to be recorded and maintained. If products containing nonconformities are sent to the customer before detection the organization needs to notify the customer.

One method to control nonconforming product in crop production that is widely used in specialty crops is a “mistake wagon” during harvest. A wagon or other container is designated for use to dump nonconforming product as harvest progresses. If nonconforming product is encountered, either because of poor production areas in the field or from harvesting “errors”, the product is dumped in the mistake container rather than cause potential contamination of good product. Poor crop from around a wet spot in the field or dirty crop caused by personnel or equipment can be dumped without contaminating a larger quantity of product. Harvest equipment may need to be “flushed” after the problem has been identified to ensure future product meets requirements. Precautions need to be taken that the “mistake container” is not mixed with good product. It is important that all employees be aware of established methods.

A key principle of quality systems is the identification of reasons that caused nonconforming crops. Each nonconforming crop should be analyzed (where practical) to identify the reasons for the nonconformity, and actions that are or will be taken to prevent it in the future.

8.4 Analysis of data

The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

a) customer satisfaction (see 8.2.1),
b) conformity to product requirements (see 7.2.1),
c) characteristics and trends of processes and products including opportunities for preventive action, and
d) suppliers.

Guidance: Effective decisions are based on the analysis of data and information. Information and data is continuously gathered during the processes of crop production including an analysis of the crop produced. The analysis of this data to identify any trends will be helpful in planning future production. Customer satisfaction, as measured in clause 8.2.1 needs to be part of the analysis process with results of this process used to prevent future problems.

Previous sub-clauses (particularly 8.2.1 and 8.2.2) require measurement of customer satisfaction and system performance. Turning this data into useful information requires careful analysis. Areas for improvement can be identified from this data: each nonconformity is an opportunity for improvement. This activity is often where the largest benefits from having a quality management system can be captured.

As an example of this process, excessive amounts of broken grains may be indicative of a harvesting or drying problem. This problem can be caused by faulty equipment, inappropriate equipment adjustment, or weather and crop conditions at harvest. Remember to understand that identification of trends not immediately identified during the crop production can help to reduce problems in the future.

8.5 Improvement

8.5.1 Continual improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

Guidance: Continual improvement should be interpreted as a recurring (step-by-step) activity. What it means is when opportunities for improvement are identified and when such improvements are justified; action is taken to make improvements to resolve the problem. Improvements may be initiated by personnel or farm management that identify an opportunity to make things better or they may be triggered by a corrective action. Actions taken to make improvements should be based on the available resources, severity of the problem and the practicality of the situation. Where concurrent opportunities are identified, prioritization may be required before implementation.

Continual improvement is another of the eight quality management principles and should be a permanent objective of the organization. Corrective action is an important component providing feedback into the continual improvement process. Benefits associated with these activities provide performance improvements leading to advantage through improved organizational capabilities; alignment of improvement activities at all levels to an organization's strategic intent; and flexibility to react quickly to opportunities. These benefits are should support the farms quality policies and objectives.

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define 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) records of the results of action taken (see 4.2.4), and
f) reviewing corrective action taken.

Guidance: Both corrective (clause 8.5.2) and preventive (clause 8.5.3) actions are important steps in a quality improvement cycle. Corrective actions seek to eliminate permanently the causes and consequent effects of problems. Corrective action involves finding the cause of a particular problem and then putting in place the necessary actions to prevent it from occurring again reducing negative impacts on:

- Business results,
- The farms products, processes, quality management system, or
- The satisfaction of customers

Corrective action should be taken on:

- Product nonconformities
- Activities that do not meet requirements originally specified.

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) determining and implementing action needed,
d) records of results of action taken (see 4.2.4), and
e) reviewing preventive action taken.

Guidance: This cause is intended to prevent problems before they occur. The steps of analysis are very similar and the potential results can be more beneficial in that nonconforming product is prevented and will not need to be dealt with.

It may become clear in operations and during internal audits that certain conditions may increase the potential for nonconforming products or for individual activities being out of specification, even if these circumstances have not yet occurred. When identified, these conditions should be recorded and plans made to alter them. This is the concept of preventive action. Preventive action is an important improvement activity.

Examples of preventive action include:

- planned preventive equipment maintenance,
- alarms, indicators, and mistake-proofing techniques

Annex I: Example crop processes and sub processes

Eleven example crop processes and associated sub process are listed in the table below. The size and complexity of the farm and associated crop requirements will determine the actual applicability of the processes and sub processes listed. Users of this standard may find it helpful to refer to this list and select the processes, sub process and appropriate tips that may apply to their unique needs. Users of this standard may select their own processes and sub processes or may modify any processes or sub processes suggested by the table as needed by their farm operation.

Suggested Crop Processes listed in the tables below:

1. Planning
2. Land allocation
3. Allocating/purchasing crop inputs
4. Field preparation
5. Field planting
6. Field activities
7. Pre-harvest and producer controlled storage activities
8. Harvest
9. Crop management – transportation and handling
10. Storage
11. Distribution and delivery

#1 Planning

Sub Process	***Tips***
Determine contract requirements (acreage, yield goal, etc.) tied to customer requirements and as appropriate the criteria for the field (land use, history, suitability)	This sub process is often associated with each crop cycle. The purpose is to ensure that customer requirements are determined as the first step in planning for crop production. This sub process should take place in a manner that ensures that customer requirements are identified and translated into a plan (usually a Farm Plan) that is designed to ensure customer and regulatory requirements are met. If this sub process applies look for linkages to clauses; 7.1 and 5.4.2. Quality Objectives may also be established at this point. Remember, quality objectives may be articulated within the Farm Plan. Quality Objectives may consist of customer requirements, input requirements, crop quality standards/test results or certifications associated with the crop. . If this sub process applies look for linkages to clause; 5.4.1
Determine the criteria for any known or anticipated inputs that will be needed (seed, fertilizer, tools, machinery, transportation, purchased services, labor)	Criteria for known or anticipated inputs may be determined by ➢ the historical relationship between the producer and existing or past suppliers ability to meet contract requirements, and/or, ➢ determination of whether the farm has suitable production capabilities, and/or ➢ alignment of existing farm process with crop requirements. If this sub process applies look for linkages to clauses; 4.1, 7.2.2.c and 7.4.1

#2 Land Allocation

Sub Process	Tips
Align the land to the Farm Plan	The land and associated environmental conditions should support the achievement of customer, regulatory and appropriate farm requirements. This alignment activity should help identify potential problems and can help in the creation of a farm plan that ensures results are met. If this sub process applies look for linkages to clauses; 5.4.2 and 7.1

#3 Allocating/purchasing crop inputs

Sub Process	Tips
Allocating/purchasing seed/root stock	Selection of seed/root stock that meets contract requirements is the first step in allocating existing resources or in purchasing resources that are not currently available. If this sub process applies look for linkages to clauses; 7.2.1 and 7.4.2.
Allocating/purchasing production inputs	Production inputs are the inputs (fertilizer, insecticide, etc.) planned or anticipated to be used in the production of the crop. During this process, consideration should be given to the necessary storage and handling of these inputs. In addition, consideration should be given to security, safety, and other requirements necessary for the fulfillment of customer, farm or regulatory requirements. If this sub process applies look for linkages to clauses; 7.2.1 and 7.4.2.
Allocating/purchasing services/labor	Labor includes the work done within the processes of crop production. These can be allocated from existing farm resources or they can be purchased from individual workers or from an organization that provides these services. This labor is used for farm process and may include for example; scouting, planting, etc. If this sub process applies look for linkages to clauses; 7.2.1 and 7.4.2.
Allocating/purchasing custom application services	These include purchased services for applying crop inputs and may include the application of crop protection chemicals, fertilizers, etc. If this sub process applies look for linkages to clauses; 7.2.1 and 7.4.2.
Allocating/purchasing other input purchases	This may include tools, equipment, and transportation. If this sub process applies look for linkages to clauses; 7.2.1 and 7.4.2.

#4 Field Preparation or suggested title might be Crop Management

Sub Process	Tips
Confirm Field Selection	This process is used to make the final check of the field prior to planting. This process should be undertaken whenever changes may have taken place after any initial considerations with regard to issues that impact requirements such as; field Isolation, field productivity, field border identification, weather damage, etc. If this sub process applies look for linkages to clauses; 7.1, 7.2 and 7.4
Soil testing	Fertility testing may be conducted as confirmation that the field is capable of producing a crop that meets requirements. This testing may include for example; fertility testing, tests for the presence of chemical residue, presence of unwanted genetic material, etc. If this sub process applies look

	for linkages to clauses; 7.1, 7.2, 7.4.1, 7.5.1and 7.6
Soil Amendment	Fertilizer application or other steps may be taken during this process to make changes to the soil prior to planting. These changes/amendments are normally based on the results of the soil testing process. If this sub process applies look for linkages to clauses; 7.1, 7.2, 7.4.1, 7.5.1, 7.5.3, 7.5.4, 7.5.5, and 7.6
Crop protection chemical application	Application of chemicals or other steps may be taken during this process to make changes to the soil, normally with regard to pests, prior to planting. These applications are normally based direct observation of the field the previous year. If this sub process applies look for linkages to clauses; 7.1, 7.2, 7.4.1, 7.5.1, 7.5.3, 7.5.4, 7.6
Equipment management	This process includes a determination of equipment capability including, functionality, set-up, maintenance, clean out, inspected, calibrated including corrective or preventive action as appropriate. This process is normally undertaken to ensure that equipment is ready for use and is capable of meeting requirements associated with delivery of a crop. If this sub process applies look for linkages to clauses; 7.1, 7.2, 7.4.1, 7.5.1, 7.5.3, 7.5.4, 7.6

#5 Field Planting

Sub Process	***Tips***
Equipment management	This sub process ensures that equipment is set-up, cleaned, inspected, calibrated in a manner that ensures that contract and regulatory requirements are met. This sub process usually takes place after the Equipment Management process (above) makes a determination of equipment capability. If this sub process applies look for linkages to clauses; 7.5.1, 7.5.2, 7.5.3, 7.5.4, 7.6
Reconfirm ➢ field plan, ➢ field selection ➢ customer, farm and regulatory requirements	This sub process is a key process that re-confirms that everything is ready prior to planting. While this process may be very informal in a small farm, this step can be very formal and rigorous in larger more complicated farm operations. The result of this sub process is a final determination that contract requirements can be met. Steps in this process may involve a final review of planting conditions or a final review of requirements. If this sub process applies look for linkages to clauses; 7.1, 7.2, 7.4
Identification, transportation, segregation, handling and storage of Genetic material	This step is designed to ensure that genetic material (seed or root stock) that meets all requirements is available for planting. This may include check for the identity of the material, transportation of the material, segregation of the material (particularly when mix ups can occur), handling practices and storage requirements are planned to take place. This may include for example; a check of seed tags with appropriate verification against farm or field plan (Only checking delivery receipts at this point, could cause an irreversible error). Remember that genetic materials must be placed in proper transportation equipment that ensures identity and qualities are maintained. If this sub process applies look for linkages to clauses; 7.1, 7.4.3, 7.5.1, 7.5.3, 7.5.4
Pre-Planting	This sub process, when necessary is intended to ensure the final re-confirmation of contract requirements. If this sub process applies look for linkages to clauses; 7.2, 7.2

Plant	This sub process consists of the actual planting process following all associated plans, procedures and instructions by appropriately qualified personnel. The planting sub process, when properly undertaken, ensures that all requirements that can be impacted by planting are taken. Depending on conditions and requirements this could also include formal or informal verification of soil conditions and genetics. Other key specifications associated with planting such as planting depth and rate and weather conditions may also be part of this sub process. If this sub process applies look for linkages to clauses;7.5, 7.5.3, 7.6
Record unused or nonconforming inputs and disposition action	This sub process is designed to account for inputs that are not used. While this may be important in many circumstances, it is particularly important when inputs are provided by customers. If this sub process applies look for linkages to clauses;7.1, 7.2, 7.4.3, 7.5.3, 7.5.4
Replant	This step is only used when replanting is determined to be necessary to meet requirements. Plans for replanting may be included in the farm plan when this is determined to be appropriate by farm management. If this sub process applies look for linkages to clauses; 7.5, 7.5.3, 7.6

#6 Field Activities

Sub Process	***Tips***
Scouting	The scouting sub process should identify problems or issues that prevent the organization from meeting requirements. When scouting is necessary this activity should be included in the farm plan with timing and appropriate resources allocated. Scouting may identify problems where corrective action can be taken or the customer notified or both. If this sub process applies look for linkages to clauses;7.2, 7.4, 7.5, 7.6
Input application	This sub process may include irrigation, fertilizer, soil amendments, or crop protection chemicals as dictated by the crop plan or the crop scouting report. Equipment associate with input application should be suitable and calibrated as appropriate to ensure proper application. If this sub process applies look for linkages to clauses;7.1, 7.2, 7.4
Crop and field maintenance	This may include as appropriate; mechanical cultivation of the crop, hand cultivation or weed removal and other steps determined as necessary or as designated by the farm plan, customer or regulatory requirements. Use of appropriate tools or equipment with proper adjustments or calibration as required to meet requirements. If this sub process applies look for linkages to clauses;7.1, 7.2, 7.5
Field inspection and testing	This sub process is designed to provide feedback on progress toward meeting requirements. This step may be part of the farm plan or other requirements or may be indicated based on scouting reports. This step may include for example; tissue testing, yield estimates, third party inspections or audits designated by customers. If this sub process applies look for linkages to clauses; 7.1, 7.2, 7.4, 7.5, 7.6

#7 Pre-harvest and Producer Controlled Storage Activities

Sub Process	***Tips***
Contract review	This sub process is intended to be the final review of the crop to verify whether customer requirements will be met. It involves evaluating any changes to the crop caused by growing conditions, disease or other circumstances. Whenever it is found that customer requirements cannot be met, actions may be taken or the customer may be notified as appropriate. If this sub process applies look for linkages to clauses; 7.1, 7.2, 7.2.3, 7.4.1, 7.5.1, 7.6
Crop attribute testing	This sub process is designed confirm progress toward meeting requirements. Rather than evaluating growing conditions or other impacts on the growing crop, this step is an actual check on the crop. When this is undertaken in the absence of formal customer specifications, this sub process may be fairly informal. When customer or regulatory requirements are specific, this sub process may include for example; tissue testing, yield estimates, third party inspections or audits designated by customers. When necessary, this sub process should be built into the farm plan. This step may provide the final indication that harvest conditions have been met. If this sub process applies look for linkages to clauses; 7.1, 7.2, 7.4.1, 7.5.1, 7.6
Yield estimate	This step is designed to indicate the anticipated yield for the crop. Results of this sub process can often trigger notification to the customer when requirements cannot be met, but can also provide an indication of success to farm management. If this sub process applies look for linkages to clauses; 7.1, 7.2, 7.4.1, 7.5.1, 7.6
Final equipment preparation	This sub process is designed ensure that harvest equipment and tools are available and in proper working condition as the crop reaches maturity. This step may provide an indication of the need for maintenance, replacement or calibration. When equipment is found to be unsuitable and this cannot be corrected, this sub process should trigger the initiation of alternate steps such as rental or replacement of equipment as deemed appropriate by farm management. If this sub process applies look for linkages to clauses;7.5.1
Inspection of storage facilities	This important step is used to confirm proper storage is available for harvested crops. This sub process may not be required in all farm operations but should be considered whenever storage and in particular, specific storage conditions are necessary to meet requirements. This step may include an inspection of storage facilities as indicated in the contract or by farm procedure and should determine adequate storage capacity based on the anticipated size of the crop. This sub process may be particularly important when storage facilities are not owned or controlled by the farm. If this sub process applies look for linkages to clauses; 7.1, 7.4.3, 7.5.3, 7.5.4
Final verification of contract labor and equipment availability and suitability	This sub process is intended to confirm necessary resources for harvest activities. This may include an assessment of resources related to labor, equipment, and tools. It may be important to consider weather conditions that may influence availability. Activities associated with this step are

	normally listed in the farm plan. If this sub process applies look for linkages to clauses;
Determine harvest timetable and sequence	This step confirms the harvest schedule in relation to crop conditions, availability of resources including storage facilities and weather conditions. Consideration should also be given to avoiding any cross contamination of crop as appropriate. Careful consideration should be given to all requirements when this step is undertaken. If this sub process applies look for linkages to clauses; 7.1, 7.2, 7.2.2.b, 7.2.2.c, 7.4

#8 Harvest

Sub Process	***Tips***
Adjust harvest timetable and schedule based on actual field, weather and crop conditions	This step is taken whenever adjustments are required to the harvest schedule. These actions ensure final timing and schedule meet contract and yield requirements. If this sub process applies look for linkages to clauses; 7.1, 7.2, 7.5, 7.5.1, 7.6
Harvest equipment cleanout	This sub process may apply to farms that use farm equipment and where cross contamination of crops can occur. When determined necessary, equipment cleanout should be undertaken as required before and during harvest. These activities should take into consideration cross contamination during harvest. If this sub process applies look for linkages to clauses;
Monitoring and adjustment of equipment	This sub process may only apply to farms that use farm equipment. This sub process maybe ongoing as needed during harvest. Should take into consideration of cross contamination. Ongoing adjustment of equipment to optimize crop quality (reduce damage and increase harvestable yield) may also be components of this sub process. If this sub process applies look for linkages to clauses; 7.5.1, 7.6
Harvest Crop	Steps involved with this sub process ensure proper performance of tasks. In mechanized farm operations this will also include proper operation of equipment. Defined steps in this sub process may need to be adjusted based on the conditions of the soil, crop and weather. If this sub process applies look for linkages to clauses; 7.5, 7.5.3, 7.6
Crop testing (quality and condition, etc.)	As appropriate, ongoing crop testing may be required to ensure requirements are met and optimum yield and quality are achieved. When required, this sub process should outline requirements for these activities. If this sub process applies look for linkages to clauses; 7.1, 7.2, 7.4.1, 7.5.1, 7.6

#9 Crop Management - Transportation and Handling

Sub Process	***Tips***
Transportation and Handling	When handling and transportation of the crop need special controls to ensure requirements are met, this sub process should be put in place to ensure these activities take place as determined by the farm. When appropriate this may include maintenance of associated transportation and

	handling records for example; ➢ crop attribute records, ➢ yield monitor records, ➢ crop conditioning, ➢ scale tickets If this sub process applies look for linkages to clauses; 7.4.3, 7.5.1, 7.5.3
Identification and Segregation	When crop identification and/or segregation are issues that need to be managed, this sub process should be used to control these activities. When specified by the farm or other requirements records may be associated with these activities for example; before, during and after transport records may include; ➢ Spill cleanup ➢ Truck cleanout ➢ Border rows ➢ Conveyance equipment ➢ Etc. If this sub process applies look for linkages to clauses; 7.5.1, 7.5.3, 7.5.5
Equipment cleanout	This sub process may apply to farms that use farm equipment and where cross contamination of future crops or other crops may need to be prevented. These requirements may be determined by the farm or by customer requirements. These activities should include as appropriate; transport equipment and handling equipment, etc. If this sub process applies look for linkages to clauses;7.5.1, 7.6
Crop Verification	This sub process is intended to confirm the final characteristics or attributes of the completed crop prior to transport to storage or to the customer. This sub process may be undertaken whenever customer requirements, farm procedures or farm management determine that this is necessary. This step could also be taken as an initial check of quality / condition prior to storage. When this step is taken, records of these activities should be considered as appropriate to the needs of the farm. If this sub process applies look for linkages to clauses; 7.5.3
Transport	This sub process normally takes place unless the customer or end user of the crop assumes responsibility for these transport activities. When required, these steps ensure the quality and integrity of the crop during this stage. If this sub process applies look for linkages to clauses; 7.1, 7.4.3, 7.5.1, 7.5.3

#10 Storage

Sub Process	*Tips*
Maintenance of identity and segregation	This sub process should be considered whenever ay storage activities are the responsibility of the farm prior to delivery of the crop to customers. When these activities take place, maintenance of crop identity may be an important consideration. When appropriate, farm procedures or other requirements may stipulate specific methods that are required. This can be done through bin identification, storage records, etc. If this sub process applies look for

	linkages to clauses;7.5.1, 7.5.3, 7.5.5
Handling / processing equipment	Prior to storage, it may be necessary to confirm any handling/processing equipment as being clean and operational. If farm management determines this is a required sub process, arrangements should be made to ensure these steps take place. This should be done considering contract requirement and according to any procedures that apply. If this sub process applies look for linkages to clauses; 7.5.1, 7.6
Crop handling / processing	When special handling and/or processing of the crop after harvest is determined to be needed to meet requirements, this sub process should be developed to put in place. When applicable to the farm, these processes may include any activity necessary to ensure methods for crop handling or processing are carried out under controlled conditions. Handle and processing activities should minimize nonconforming crop. This sub process may include cleaning and drying, etc. If this sub process applies look for linkages to clauses; 7.5.1, 7.5.2
Cleanliness of storage facilities: (bins, silos, containers, etc.)	After harvest and prior to any storage it may be necessary to re-confirm the cleanliness, functionality and adequacy of any storage facility and conveyance equipment immediately preceding its use. Depending on the needs of the farm and as specified by requirements the farm should consider for example: ➢ Bins / silos ➢ augers / legs / distributors / conveyers ➢ etc. If this sub process applies look for linkages to clauses;7.5.1, 7.5.2, 7.5.3, 7.5.5, 7.6
Control and monitor storage environment and conditions	Whenever crops are stored after harvest it may be necessary to provide control over this storage environment. This may be done as determined by farm procedures or to meet customer requirements. Considerations may include: ➢ monitoring during storage, ➢ bin identification ➢ environmental conditions. ➢ periodic observations ➢ Etc. If this sub process applies look for linkages to clauses; 7.1, 7.4.3, 7.5.3, 7.5.4
Control and monitor crop quality, condition, specifications and characteristics	As necessary to meet farm or customer requirements it may be appropriate to control or monitor the crop in order to identify any deterioration and to enable appropriate actions can be taken to resolve identified issues. Considerations may include as appropriate: ➢ crop monitoring during storage, ➢ Crop identification ➢ periodic sampling and / or observation ➢ Etc. If this sub process applies look for linkages to clauses; 7.1, 7.4.3, 7.5.3, 7.5.4
Crop security	This sub process should be considered whenever farm procedures, customer or regulatory requirements specify these activities or as designated by farm management. This sub process should contain the steps and procedures necessary to provide security over the crop when this is deemed to be necessary. If this sub process applies look for linkages to clauses; 7.1, 7.2, 7.4, 7.5, 7.6

#11 Distribution and Delivery

Sub Process	Tips
Delivery planning	This sub process contains the steps necessary to reconfirm the contract and re-affirm delivery plan with customers. This sub process and associated steps and procedures should be undertaken whenever these added controls aid in the delivery of crops to customers and to meet the needs of farm management. If this sub process applies look for linkages to clauses; 7.1, 7.2, 7.2.3, 7.4
Validation, verification, crop tests	In some crop production situations it may be necessary to validate, verify or confirm in some way, the tests that were used to check the crop. When this sub process is deemed to be necessary, farm management should plan these activities and put in place necessary controls as part of this sub process. If this sub process applies look for linkages to clauses;7.1
Handling equipment	As part of any distribution and delivery activities it may be necessary to re-confirm appropriate handling equipment as being clean and capable of meeting these requirements. When this is determined to be necessary these steps may include equipment owned by the farm, borrowed equipment, equipment provided by customers or equipment that is rented from a third party. If this sub process applies look for linkages to clauses; 7.4.1, 7.6
Transportation equipment	As part of any distribution and delivery activities it may be necessary to re-confirm appropriate transportation equipment as being capable of meeting requirements. When this is determined to be necessary these steps may include transportation equipment owned by the farm, borrowed equipment, equipment provided by customers or equipment that is rented from a third party. If this sub process applies look for linkages to clauses;7.5.1, 7.5.2, 7.5.3, 7.5.4, 7.6
Load and transport	Loading and transport is normally a sub process that applies to all farm crops. When this sub process is to be undertaken, process steps for these activities should give consideration to; proper procedures, maintenance of identity and security. If this sub process applies look for linkages to clauses; 7.5.1, 7.4.3, 7.5.1, 7.5.3, 7.5.5
Post shipment cleanout of storage and handling equipment.	Depending on the needs of the farm and in anticipation of future crops, it is often appropriate to perform checks and appropriate maintenance of storage facilities and equipment. This sub process should be designed to ensure these activities take place to meet the requirement of the farm with due consideration given to future crop and customer needs. If this sub process applies look for linkages to clauses;7.1, 7.2, 7.5.1, 7.5.2
Crop transfer and settlement	This sub process is often conducted as the final step in the crop production cycle. This may include the final closeout and confirmation with the customer relating to requirements that apply and the transfer of ownership of the crop to the customer. This sub process may include any financial transaction that is appropriate with the transfer of the crop to the customer. If this sub process applies look for linkages to clauses; 7.5.1, 7.5.2

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