INTERNATIONAL STANDARD

ISO 22006

First edition
2009-12-15

Quality management systems — Guidelines for the application of ISO 9001:2008 to crop production

Systèmes de management de la qualité — Lignes directrices pour l'application de l'ISO 9001:2008 pour la production des récoltes

Reference number
ISO 22006:2009(E)

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Published in Switzerland

Contents

Page

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/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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 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, *Food products*.

Introduction

This International Standard gives guidelines to assist crop-producing farm operations in the application of ISO 9001:2008[1].

In the context of this International Standard, a quality management system (QMS) is about how a farm operation is managed. The ultimate goal of implementing ISO 9001:2008[1] in a farm operation should be a combination of improved performance, financial results, and customer confidence and satisfaction. Farmers should focus on what is practical and work to implement a QMS with these results in mind. QMSs are built from existing activities and should not cause excessive paperwork or lack of flexibility. QMSs are not just for large farm operations. The guidelines given in this International Standard are also relevant to small farm operations. Adjustments in implementation and interpretation of this International Standard may be needed in small farm operations. While there may be effort involved in the implementation of ISO 9001:2008[1], the ultimate goal is to achieve net benefits.

This International Standard specifies a set of activities that need to be included; however, it does not specify how to carry them out. Listing all of the farm operation activities on a flow diagram aids in determining whether they fit together well or whether some aspects need to be changed to make the processes work better. ISO 9001[1] and ISO 9004[3] are based on eight management principles — customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision-making, and mutually beneficial supplier relationships — all of which can be used to improve the performance of the farm operation.

This International Standard does not include requirements specific to other management systems such as those particular to food safety, the environment or occupational health and safety, and does not imply that a farm operation is obliged to implement management systems for food safety, the environment or occupational health and safety.

The complexity of documents, records, training, etc. depends on:

a) the number of people working or involved in the farm operation, both on a permanent and seasonal basis;

b) necessary skills or competencies to perform tasks;

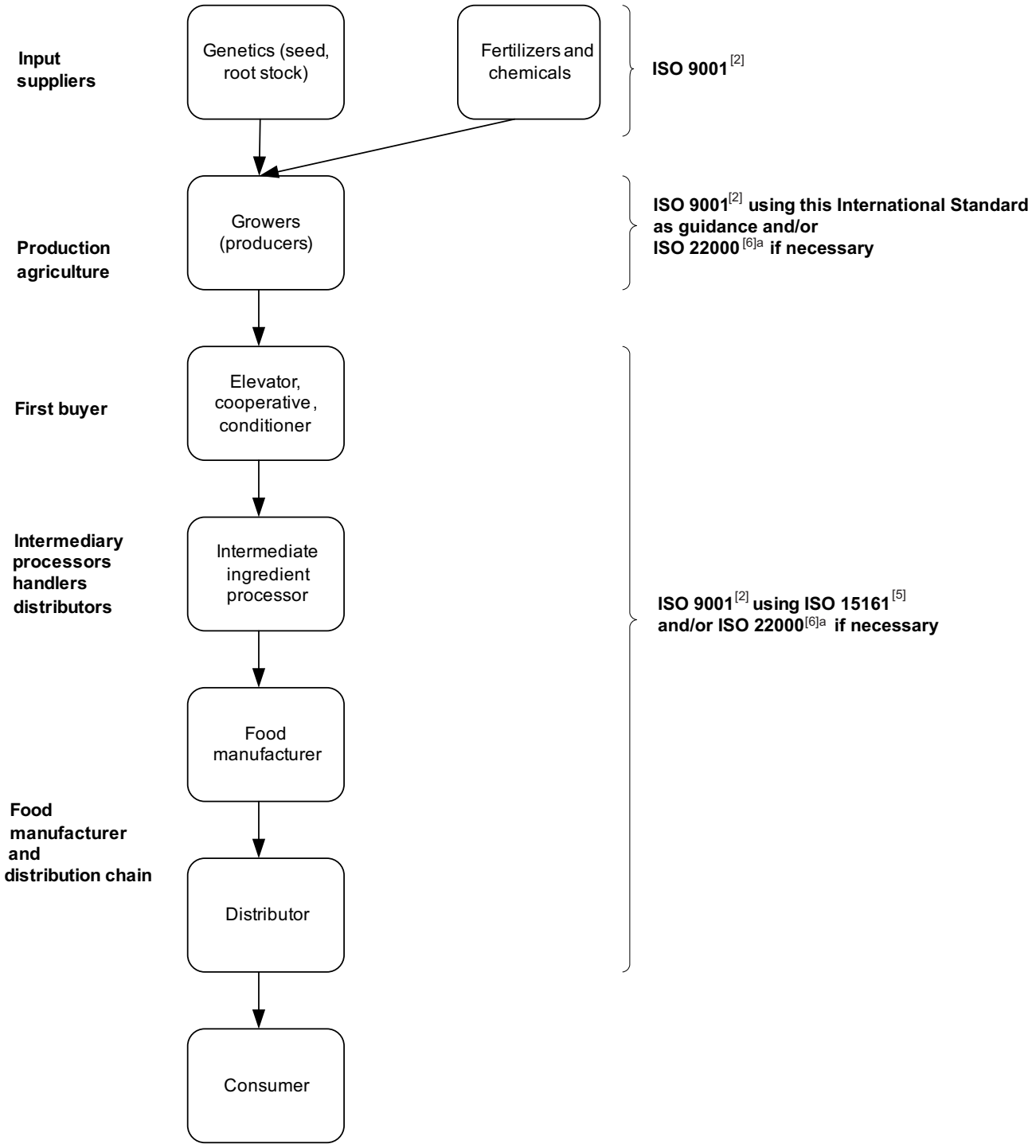
c) complexity of processes;

d) number of distinct processes;

e) types and complexity of tools and equipment used.

A QMS on its own does not lead to improvement of work processes or product or service quality. It is a means to achieve the objectives of the farm operation.

A schematic diagram of QMSs in food supply chains is given in Figure 1.



NOTE ISO 9001:2008[1] and ISO 22000:2005[6] can be used for certification. This International Standard and ISO 15161:2001[4] are not intended for certification purposes.

[a] The requirements specified in ISO 22000[6] include those of a hazard analysis critical control plan (HACCP).

Figure 1 — Example: quality management system in food supply chains

The guidance provided clarifies the clause of the International Standard which it follows.

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

When reading ISO 9001:2008[1], certain words and phrases have particular significance or meaning. Explanations of some of the more important of these are given below.

shall — Whenever this word occurs, there is an obligation to fulfil a requirement in order to demonstrate an effective QMS.

should/may — These words are not to be interpreted as requirements, but as recommendations or permissions.

appropriate — This word means that the organization can decide how the requirements apply to the farm operation. In some cases, the organization may decide that the guidance does not apply to the farm operation (see the exclusions in 1.2).

NOTE In this International Standard, "appropriate" and "suitable" are also used to indicate where such decisions are necessary. Also, "adequate" is used to indicate that the actions, decisions, etc. are fully sufficient to fulfil requirements.

The ISO 22000 family of documents focuses on food, feed and related supply chains, and at the time of publication includes:

— ISO 22000[6], which is a food safety management system standard for the food manufacturing and distribution industries which was developed using HACCP and its prerequisites as a base. ISO 22000 covers the critical control points in the processes of food production, manufacture, and delivery relating to food safety;

— ISO 15161[4], which is a guidance document for the application of ISO 9001:2000[1] for the food and drink industries;

— ISO/TS 22003[7], which is a requirement document for organizations that provide food safety audit services;

— ISO/TS 22004[8], which gives guidance on the implementation of ISO 22000:2005;

— ISO/TS 22005[9], which is intended to be a tool for traceability that can be coordinated within the context of a broader management system (such as ISO 9001:2008[1]);

— ISO 22006 (this International Standard), which is not intended to duplicate the requirements of ISO 22000.

Additional documents in the ISO 22000 family are planned.

This International Standard has been designed to explain how ISO 9001:2008[1] applies to crop production (food, feed and non-food crops). This International Standard does not set any requirements, nor does it add to or otherwise change the requirements of ISO 9001:2008[1]. It is intended to provide help in the application of ISO 9001:2008[1]. This International Standard contains ISO 9001:2008[1] requirements in framed boxes. Guidance paragraphs specific to agricultural crop production follow the requirement boxes and are not intended to be requirements nor are they expected to be applicable to all farm operations. In addition, help boxes (see example below), highlighted by a grey tint, contain guidance or suggestions and are included in places where they are deemed appropriate.

HELP The clauses of ISO 9001[1] are written to be adapted to a wide range of organizational activities and sizes. To aid in the understanding of ISO 9001:2008 [1] within the context of crop production, help boxes have been created. These help boxes are specifically designed to help with selected clauses throughout this International Standard. Help boxes may be of particular value when relating the ISO 9001:2008[1] requirements to a wide variety of farm operations including those that are large, small, mechanized or labour intensive. Help boxes are highlighted by a gray tint to differentiate them from other text used in this International Standard.

This International Standard is consistent with ISO 22000[6] and ISO/TS 22005[9] requirements; it is not intended to duplicate the requirements of these published documents. This International Standard is not a guidance document for the application of ISO 22000[6] or ISO/TS 22005[9].

This International Standard provides guidance to crop producers to aid in the preparation for ISO 9001:2008[1] certification or for self-declaration to ISO 9001:2008[1]. Text that is unique to this International Standard does not contain requirements associated with certification and registration. This International Standard is not intended to replace ISO 9004:2009[2] which addresses performance improvement. The use of this International Standard does not require the implementation of ISO 9004:2009[2].

0.1 General

ISO 9001:2008, *Quality management systems — Requirements*

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

a) its organizational environment, changes in that environment, and the risks associated with that environment,

b) its varying needs,

c) its particular objectives,

d) the products it provides,

e) the processes it employs,

f) its size and organizational structure.

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, statutory and regulatory requirements applicable to the product, and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004[2] have been taken into consideration during the development of this International Standard.

Guidance: ISO 9001:2008[1] specifies requirements for a QMS. When implementing ISO 9001:2008[1] using the guidelines in this International Standard, the organization should consider and utilize appropriate information [e.g. statutory and regulatory requirements, customer requirements, recognized guidelines, Codex Alimentarius Commission (Codex) principles and codes of practices including national, international or sector standards].

Processes employed may include: good agricultural practices (GAP) as well as good hygiene practices (GHP) as appropriate to the needs of the farm operation 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

ISO 9001:2008, *Quality management systems — Requirements*

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 determine and manage numerous linked activities. An activity or set of activities 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 to produce the desired outcome, 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.

Guidance: A process approach is a way of organizing and managing activities to create value for the customer and/or interested parties. Customers and interested parties may be either internal or external to the farm operation.

Each process has customers and/or other interested parties that are affected by the process and who define the required outputs according to their needs and expectations. Many of these processes are farm operation activities (see Annex A) while others provide support to these farm operation activities, such as inspection and employee training.

For example, in cases where customers expect crops to be produced organically, the specific processes to analyse soil, select crop varieties, choose cropping season, etc., may be an “input” of the next process in the process approach. Inputs and intended outputs may be tangible (such as equipment, facilities) or intangible (such as energy or information). Outputs can also be unintended; such as waste or pollution.

All processes should be aligned with the objectives of the farm operation and be designed to add value, relative to the scope and complexity of the farm operation.

At the heart of ISO 9001:2008[1] is a conceptual model shown in Figure 2, which explains a process-based QMS including the main processes that are integral to its success.

The process approach allows management to identify the steps involved in an activity, devise a control strategy, and implement a system of continuous improvement. The driver for each process is the recognition of the customer's requirements, and their fulfilment. [The process approach is customer driven.] Note in Figure 2 that the customer is shown on both the left and the right. Figure 2 shows that what the customer wants enters on the left, and the crop that meets those requirements exits on the right.

The process flow that produces the crop is shown across the lower part of the figure (product realization). This box covers the various activities that the farm operation needs to do to produce a crop. Crops are the output from the farm operation.

In addition, Figure 2 shows 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 the performance of a farm operation.

The “management responsibility” box is there to explain the importance of the leadership role in the QMS. 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 help 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.

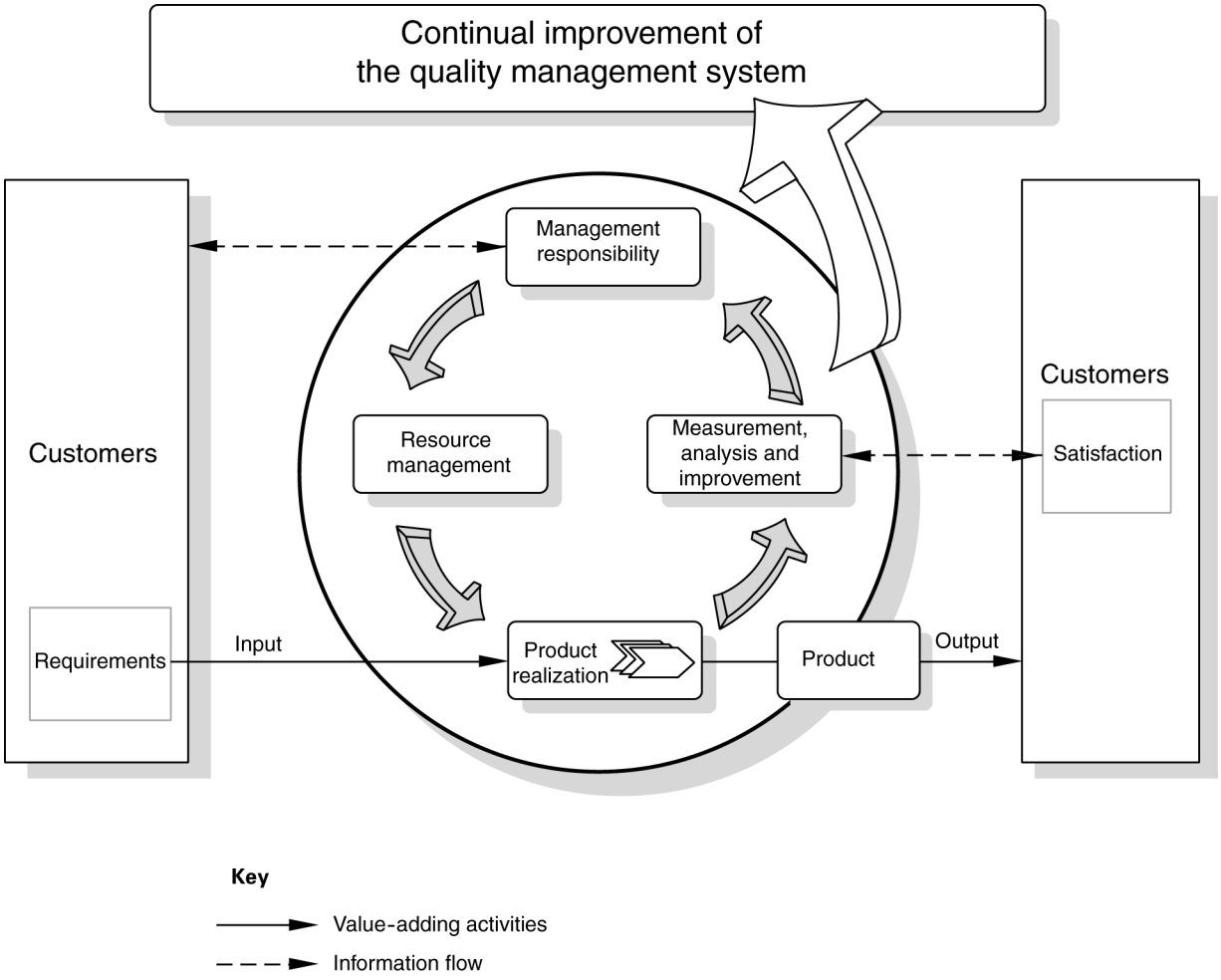


Figure 2 — Process-based QMS

0.3 Relationship with ISO 9004[2]

ISO 9001:2008, *Quality management systems — Requirements*

ISO 9001[1] and ISO 9004[2] are quality management system standards which have been designed to complement each other, but can also be used independently.

ISO 9001[1] 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.

[The following paragraph has been updated as ISO 9004:2009[2] was published after ISO 9001:2008[1].]

ISO 9004:2009[2] provides guidance to management for achieving sustained success for any organization in a complex, demanding, and ever-changing environment. ISO 9004[2] provides a wider focus on quality management than ISO 9001[1]; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use.

0.4 Compatibility with other management systems

ISO 9001:2008, *Quality management systems — Requirements*

During the development of this International Standard, due consideration was given to the provisions of ISO 14001:2004[3] to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between ISO 9001:2008[1] and ISO 14001:2004[3].

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.

Guidance: 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 operation and stakeholders or by contractual requirements. These management systems may include, for example, ISO 14001[3], ISO 22000[6] 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[1] clauses, document control, record keeping, management review, employee training, internal audits, corrective action and preventive action may provide the greatest cost and operational savings.

Quality management systems — Guidelines for the application of ISO 9001:2008 to crop production

1 Scope

This International Standard gives guidelines to assist crop producers in the adoption of ISO 9001:2008[1] for crop production processes. The term "crop" includes seasonal crops (such as grains, pulses, oilseeds, spices, fruit and vegetables), row-planted crops that are cultivated, perennial crops that are managed over a period of time, and wild crops that are not formally planted or managed. Horticultural crops provide an even broader range of types from annual and perennial fruits, vegetables, and ornamental flowering plants, to perennial shrubs and trees, and root crops. These diverse crops require a broad range of planting, cultivating, pest control, and harvesting methods and practices. Decisions regarding planting, growing, and harvesting activities can be similar, although specific steps can be quite different when considering the range of crops.

This International Standard gives guidelines on the use and application of ISO 9001:2008[1] to the establishment and management of a quality management system (QMS) by an organization involved in crop production.

This International Standard is not intended to change, add or reduce the requirements of ISO 9001:2008[1], nor is it intended for certification.

Further down the supply chain, in manufacturing processes, the language of ISO 9001:2008[1], ISO 15161[4], or ISO 22000[6] is considered more appropriate. The need for an ISO 9001:2008[1]-based system containing agricultural terminology became apparent due to difficulties in the interpretation of the language of ISO 9001:2008[1] for crop production applications.

1.1 General

ISO 9001:2008, *Quality management systems — Requirements*

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 statutory and 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 statutory and regulatory requirements.

NOTE 1 In this International Standard, the term "product" only applies to

— a product intended for, or required by, a customer, and

— any intended output resulting from the product realization processes.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

1.2 Application

ISO 9001:2008, *Quality management systems — Requirements*

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 statutory and regulatory requirements.

Guidance: A farm operation can exclude some requirements from Clause 7, when the activities related to these requirements are not performed. When an exclusion occurs, the details and the justification for the exclusion are to be described in the quality manual (see 4.2.2).

2 Normative references

ISO 9001:2008, *Quality management systems — Requirements*

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

Guidance: The reference to ISO 9000:2005 directs readers to the source of terms and definitions used in ISO 9001:2008[1] and ISO 9004:2009[2].

3 Terms and definitions

ISO 9001:2008, *Quality management systems — Requirements*

For the purposes of this document, the terms and definitions given in ISO 9000:2005 apply.

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

Guidance: In this International Standard, it is important to understand the use of the three terms: supplier (3.18), organization (3.13), and customer (3.5).

For the purposes of this document, the terms and definitions given in ISO 9000:2005 and the following apply.

3.1
application
〈crop production〉 treatment of the crop, soil or other medium with an input designed to aid in meeting requirements

EXAMPLE Treatments include fertilizers, insecticides, or fungicides.

3.2
applicator
⟨crop production⟩ person involved in application process

3.3
characteristic
attribute
⟨crop production⟩ distinctive trait that defines the crop

NOTE A characteristic is an identifiable hereditary property, such as a specific component, a structural detail, a colour or pattern, or resistance to pests. The synonym “attribute” is used especially when the trait is measurable.

3.4 Crop

3.4.1
crop
⟨1⟩ plants cultivated collectively

3.4.2
crop
⟨2⟩ product of a particular kind or geographical location which is an element in the definition of the product

EXAMPLE Crops “of a particular kind” include maize and wheat.

3.4.3
crop
⟨3⟩ growing season or year which is an element in the definition of the product

3.4.4
crop
⟨4⟩ wild harvest not formally planted or managed

3.5
customer
⟨crop production⟩ party that receives the output(s) of the product(s) [crop(s)] or services of farm operations

NOTE The customer can be internal or external to the farm operation and may include the end-user of the product(s) of farm operations. Other bodies, such as government or industry organizations, when they stipulate product or process requirements, can be considered to be customers.

3.6
farm
tract(s) of land or facilities under a farm management system devoted to agricultural or horticultural production

3.7
farm management
person or group of people that manage a farm on a day to day basis

3.8
farm operation
farm and the activities used by the farm to produce crops

NOTE A farm operation refers to all of the management and physical activities related to the production of various crops.

3.9
farming plan
plan for crop production on a specified farm

NOTE A farming plan is a set of instructions or activities to be implemented and intended to lead to the production of a crop. The farming plan normally defines the application of the components necessary to produce the crop, e.g. land use, resource management and application of best farm management practices. A farming plan may consist of procedures, flow diagrams, field maps, manuals or outlines.

3.10
harvester
⟨crop production⟩ person involved in harvesting a crop

3.11
input
⟨crop production⟩ product or service used by crop production processes to achieve intended results

NOTE Inputs in crop 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. Labour, custom work, and crop consultants, for example, can also be considered as inputs.

3.12
infrastructure
infrastructure organization
⟨crop production⟩ system of facilities, equipment and services needed for the operation of a farm

NOTE 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.

3.13
organization
⟨crop production⟩ farm operation or farm cooperative implementing a quality management system

3.14
post harvest
any handling activity that may be necessary for the delivery or sale of the product that does not alter the natural state of the crop

EXAMPLE Trimming, cleaning, washing, conditioning, drying, and packing.

3.15
product
⟨crop production⟩ end result of farm processes

3.16
field observation
specialized type of field inspection

NOTE In the context of production agriculture, this term refers to a method of inspecting a field for pests or other production problems before or during the growing season. It is possible for farm management or farm people to perform this activity themselves or to hire a qualified individual to conduct field observation activities, depending upon the skills required and level of expertise available. Fields can be scouted several times during the growing season, or at specific times to identify pests or to assess crop conditions.

3.17
segregation
separation of nonconforming products from products that conform to the customer's order

EXAMPLE Separation of different quality types or varieties.

3.18
supplier
⟨crop production⟩ provider of inputs used in crop production

EXAMPLE Crop producers, those supplying seed and plant material, fertilizer, equipment, chemicals, and others providing inputs or services (including consultants and advisors) to farm operations.

3.19
top management
⟨crop production⟩ single person or group of people who directs and controls farm operation or farm cooperative operations at the highest level

EXAMPLE Farm management, single owner, owners, proprietor, farm coop management board, 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 farm operation.

NOTE In small organizations, farm management and top management may be the same person.

3.20
work environment
⟨crop production⟩ set of conditions under which work is performed

NOTE 1 Farm operations may want to refer to ISO 14001[3] as appropriate.

NOTE 2 The term covers environmental factors in the workplace that can affect the quality of a product (see 6.4 for examples). This International Standard does not include requirements specific to other management systems such as food safety management, environmental management or occupational health and safety management, and does not imply that a farm operation is under an obligation to implement a food safety management system, environmental management system or an occupational health and safety management system.

3.21 Abbreviated terms

FSMS food safety management system (usually referring to ISO 22000[6])

GAP good agricultural practices

GHP good hygiene practices

HACCP hazard analysis critical control plan (see ISO 22000[6])

QMS quality management system

SOP standard operating procedure(s)

4 Quality management system

4.1 General requirements

ISO 9001:2008, *Quality management systems — 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) determine 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 where applicable, and analyse 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 to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.

NOTE 2 An “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

— the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,

— the degree to which the control for the process is shared, or

— the capability of achieving the necessary control through the application of 7.4.

Guidance: The intention of 4.1 is to cover the requirement for the farm operation to actually develop and implement a quality management system (QMS), and specifies generic requirements for the basis on which to plan the QMS (see 5.4.2).

To meet the requirements of ISO 9001:2008[1], the farm operation should ensure that the activities described in a) to f) have been addressed in the QMS. The activities required are described in greater detail in the remainder of this International Standard.

a) Processes may include, for example, planning process, planting process, harvest process, soil management, water management, nutrition, and pest management (see Annex A) The farm operation may want to refer to other subclauses as the planning process proceeds, e.g. 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 operation and its customers. A documented farming plan is increasingly important on farms with complex or significant customer or statutory and regulatory requirements. A documented farming plan may include, for example, flow diagrams, standard operating practices, crop production plans, farm layout, operational plan or other methods deemed relevant by the farm operation. Farming plans may include: an updated field map to define what is to be planted and where it is to be planted; planting schedule; crop input application schedule; and other activities that support quality objectives and the achievement of customer, contract, and statutory and regulatory requirements. Farming plans should take into account that many or all farm processes may be connected and the sequence, interaction and interdependence between these processes should be considered at all stages of planning and when changing plans. See Annex A.

c) General planning for crop production should include, as appropriate, the criteria for the individual operations that constitute the plan.

d) Resources used in crop production may include, for example, the land, labour, tools and equipment, water, buildings, and other consumable inputs such as seed, crop protection products, fertilizers, and herbicides. See Clause 6.

e) Measurements, monitoring activities and analysis can have a significant impact on some farm operation processes. Clause 8 covers collection of data to be used to measure success and to track improvement.

   The farming plan and crop are often affected by various changes including, for example, the environment, weather or the business situation. Therefore, management should specify, as appropriate, the processes for monitoring, measurement, and analysis in order to ensure actions for continual improvement are taken.

f) Once farm management determines what is to be done, these activities should be carried out as a means of ensuring results and continual improvement (see 8.5.1). Farm management should specify the processes for monitoring and measurement, analysis and improvement to achieve continual improvement of a QMS.

HELP For small farm operations, the planning can be limited to activities related to the crop areas, provisions, and salaries.

To achieve the farming plan (see ISO 9001:2008[1], 5.4), farm management determines and implements actions necessary to support continual improvement. Actions should be based on the results of monitoring, measurement and analysis (see ISO 9001:2008[1], 8.2 and 8.4). As necessary, farm management may need to consider changing and improving the system, processes or the farming plan (see 8.5.1).

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

4.2 Documentation requirements

4.2.1 General

ISO 9001:2008, *Quality management systems — Requirements*

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures and records required by this International Standard, and

d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

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

— the size of organization and type of activities,

— the complexity of processes and their interactions, and

— the competence of personnel.

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

Guidance: Note that documents may already exist to meet customer requirements, other certification programmes, or statutory and regulatory requirements. As long as these documents meet the requirements of ISO 9001:2008[1], they may be referenced and used in the farm operation's QMS.

a) The quality policy (5.3) represents top management's commitment to the QMS. These should be stated and communicated to personnel. Quality objectives (5.4.1) may be different for various processes within the farm operation. Objectives need to be reviewed and updated as change occurs over time.

b) The quality manual is covered in detail in 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 farm operation is responsible for ensuring that the requirements described in the following six clauses are included in documented procedures. It is not required to have the six required procedures in six separate documents. They may be included in the quality manual or in other documents as determined by farm management:

    1) control of documents (4.2.3);

    2) control of records (4.2.4);

    3) internal audits (8.2.2);

    4) control of nonconforming product (8.3);

    5) corrective action (8.5.2);

    6) preventive action (8.5.3).

A farm operation may determine whether additional procedures require documentation.

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 operation or the customer.

d) This requirement specifies that the farm operation is able "to ensure effective planning, operation and control of processes". These may or may not be fully or formally documented. The farm operation is responsible for determining how this control is undertaken. It is important that workers have the information they need to do their job. Some common methods for providing this control include:

    1) work practices, work procedures, work instructions, flow diagrams, process diagrams, process steps, checklists;

    2) operating practices, operating instructions or operating procedures;

    3) production schedules, farming plan, farm map;

    4) preferred supplier lists (people or organizations from whom inputs are purchased);

    5) specifications, (grain grade standards);

    6) production contract specifications;

    7) list of statutory and regulatory requirements.

Guidance on the notes to 4.2.1: These provide important guidance for the development of the QMS documentation. A broad overview of required documentation and the associated notes is given in 4.2.1 to provide some clarity regarding what the expectations are.

Simple processes may require little documentation related to what is being done compared to a complex process that may require extensive written instructions. 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.

Competent personnel may require little or no documented procedures depending on the needs of the farm operation.

Documentation can be in any form or type of medium, for example, paper, electronic, photographs, and drawings. 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 QMS 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.

Documents should appropriately answer the questions: "Who?" "What?" "Which?" "When?" "Where?" "Why?" "How?" For example, it is not necessary to have a formal document on how to keep farm equipment safe — simply including a phrase such as "replace shields after maintenance" may adequately describe the outcome intended.

Management, working with people involved, should decide how much detail is needed. This depends 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 or 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.

The QMS and the preparation of documentation may involve many people who work for the farm operation. This ensures that details in the documents reflect true work practices. The earlier people become involved and the more people are included in this activity provide a better understanding, greater involvement, and a sense of ownership in the QMS.

Documents associated with crop production may include:

a) documents provided by the customer that outline customer requirements;

b) documents created by the farm operation used to gather customer specific requirements;

c) checklists or other evaluation tools used to assess capability of input suppliers;

d) requirements for seed and root stock, soil amendments, and other inputs;

e) documents relating to equipment operation and maintenance;

f) procedures or instructions to control field observation activities, testing, field inspection activities, identity preservation, traceability, equipment clean-out, storage clean-out and bin preparation, crop verification, transport, and storage of crop and inputs;

g) regulatory requirements.

4.2.2 Quality manual

ISO 9001:2008, *Quality management systems — Requirements*

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 QMS and serve as a “road-map” through it. All associations and links to other systems or documents which the farm operation may be required to meet should be detailed within the quality manual.

The scope of the QMS should specify the crops, processes, customers and production sites where the QMS applies as appropriate to the farm operation.

The quality manual may reference documented procedures that already exist to meet customer requirements, other certification programmes, or statutory and regulatory requirements. As long as these procedures meet the requirements of ISO 9001:2008[1], there is no need to rewrite these procedures. However, it remains a requirement that these procedures be referenced in the quality manual.

The farm operation may chose to use flow diagrams, drawings and diagrams, to document the sequence and interrelationships of individual processes of its operations. The quality manual may contain or reference the points described below.

a) A description of the structure of the QMS including, for example: a brief description of the farm operations documents, the location of the documents, how the documentation works, an organizational chart or diagram, and a description of the activities of the farm operation.

b) A contents list of the number and title of each part of the manual and its location.

c) The quality policy (5.3), quality objectives (5.4.1) and statements on responsibility and authority (5.5.1).

d) A reference to all documented procedures required within the QMS.

e) Definition of any terms having a unique meaning to the farm operation.

The format of the quality manual is to be determined by 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 ISO 9001[1] requirements that cannot be applied to the farm operation and are not included in the QMS should be identified as exclusions (see 1.2). The reasons for each exclusion should also be given. However, few requirements qualify for exclusion with the possible exception of design and development (see 7.3).

HELP A small farm operation may find it appropriate to include the description of its entire QMS within a single manual, including all the documented procedures required by ISO 9001[1]. Large, multinational farm operations may need several manuals at the global, national or regional level, and a more complex hierarchy of documentation.

4.2.3 Control of documents

ISO 9001:2008, *Quality management systems — Requirements*

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 determined by the organization to be necessary for the planning and operation of the quality management system 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: “Controlling documents” means that one or more people are assigned the responsibility for ensuring that only the most current documents are used. This includes giving final approval to original or modified documents before they are used. This requirement ensures that one or more people in the farm operation 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 farm operation does and the way it is done? 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.

Documents of external origin should also be identified and controlled. For example, an equipment operator's manual provided by the manufacturer may be identified as part of the documentation. Text that is important to the QMS 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.

In 4.2.3, it is made clear that records are a special type of document (see 4.2.4). Records are generated as a result of some activity, are a statement of the facts existing at the time, and cannot be revised. Obsolete documents (or revised documents) can become records.

With the rapid development of computer and electronic storage of information, 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 operation 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. Ensure that current documents are readable, and clean.

Documents should be retained under the control of the farm operation.

HELP In a small organization, a list could identify the holders and location of the document. If there is a change to a document, one person should be assigned to collect the old document and issue the new one. A suitable record to this effect may be made using hand-written notes or other methods.

4.2.4 Control of records

ISO 9001:2008, *Quality management systems — Requirements*

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records shall remain legible, readily identifiable and retrievable.

Guidance: Records provide evidence that the farm operation has actually met a requirement of the QMS. Risk management is a major factor in determining what records are needed and how long they should be kept. Examples of records include:

a) mandatory QMS records (see 4.2.1);

b) planning records;

c) planting and growing activity records;

d) field activity records;

e) harvest, storage, and handling records;

f) traceability or food safety records (if required by contract or if statutory and regulatory);

g) supplier declarations.

Computer and electronic storage of information need backup. When records are no longer required by the farm operation, they may be destroyed as outlined in the quality management plan.

HELP It is important that a small farm 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 shall be made. Identify how long each type of record needs to be kept, where it is to be found, and how it is to be disposed of in the future. Only keep what needs to be kept.

5 Management responsibility

5.1 Management commitment

ISO 9001:2008, *Quality management systems — Requirements*

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: A person or group of people should have responsibility for providing direction and decision-making. This person or group of people is designated as top management. They are responsible for the QMS. Management should commit to meet statutory and regulatory, contract or customer requirements.

HELP In a small farm operation, top management may be the owner, partnership, or a few designated individuals. The amount of internal communication is determined by the complexity of the farm operation. For example, a single person farm operation may not require any lines of internal communication.

5.2 Customer focus

ISO 9001:2008, *Quality management systems — Requirements*

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: Customer requirements may include:

a) actual crop status (planting through harvest and storage);

b) contract specifications;

c) planned crop quantity compared to actual quantity;

d) crop storage conditions;

e) planned crop delivery time compared to actual crop delivery time;

f) intended use.

The farm operation should determine how the customer perceives customer satisfaction, and these may include:

1) meeting contract specifications;

2) customer feedback;

3) other specifications.

5.3 Quality policy

ISO 9001:2008, *Quality management systems — Requirements*

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: The quality policy should be a short summary statement that describes the farm operation's overall vision and commitment to quality. People involved in the farm operation should be familiar with the quality policy. Top management should review the quality policy annually.

5.4 Planning

5.4.1 Quality objectives

ISO 9001:2008, *Quality management systems — Requirements*

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], 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 specific measurable outcomes within a specific timeframe that the farm operation intends to accomplish. They should be clearly defined by farm management. The objectives may be included within the farm operation's quality plan. The farm operation should verify that it is achieving the objective(s). Measurables can include timeframe, amounts, dimensions or other means determined appropriate by farm management. Some examples include:

a) reduction in the number of deliveries that do not meet customer specifications;

b) reduction in pesticide applications;

c) reduction of soil erosion;

d) improvement in the document control system.

Objectives should not be a wish list of what the organization would like to happen, but should clearly and accurately reflect what is intended to happen.

HELP Quality objectives do not have to be elaborate or complex. It is important that quality objectives clearly reflect the intent of the farm operation. Contracts with customers may contain clear objectives that are suitable quality objectives.

5.4.2 Quality management system planning

ISO 9001:2008, *Quality management systems — Requirements*

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: Top management is responsible for this critical planning process. The quality policy and objectives should relate to the farm operation's goals. Planning describes the actions necessary to meet the objectives.

A requirement of 5.4.2 is that top management of the farm operation ensure planning of the QMS to achieve quality objectives which are specified by the farm operation, and to satisfy the requirements of 4.1. The farm operation needs to establish its QMS based on this plan of “entire QMS”. When planning the QMS, the farm operation should consider compatibility with other management systems such as those for the environment and labour.

If the farm operation needs to change or modify the QMS, 5.4.2 b) requires that the farm operation also plans changing or modifying the QMS to ensure ongoing effectiveness and consistency.

Confusion between 5.4.2 and 7.1 frequently occurs. The purpose of 5.4.2 is to plan the entire QMS. During this planning stage, it is appropriate to refer to the general requirements for a QMS (4.1), as well as the individual farm operation processes. An approach to planning that may be useful follows:

a) identify processes within the organization that comprise the QMS;

b) identify all of the procedures related to each process;

c) analyse the connections between the processes identified;

d) determine the procedures used when implementing the processes;

e) identify which areas should be or shall be monitored or measured;

f) use date to make preventive and corrective actions.

Planning activities may take into account other management systems related to food safety or the environment.

HELP The planning process does not have to be elaborate or complex. It is important that plans clearly reflect the actual intent (contractual obligations) and allow for flexibility. Contracts may contain plans or may be referenced during the planning process.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

ISO 9001:2008, *Quality management systems — Requirements*

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

Guidance: Top management needs to ensure that everyone knows what they are expected to do (responsibilities), what they are allowed to do (authorities), and that they understand how these responsibilities and authorities relate to each other. Special consideration should be given to joint decision makers (equal authority level).

HELP Job descriptions do not have to be elaborate or complex. It is important that the descriptions clearly reflect the true situation and allow for flexibility.

5.5.2 Management representative

ISO 9001:2008, *Quality management systems — Requirements*

Top management shall appoint a member of the organization's 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 farm operation with an individual owner-operator, this person is the management representative. In a more complex farm operation, the management representative is the individual responsible for the QMS. This person has the responsibility to communicate with all people in the farm operation and at all farm operation locations.

HELP The management representative, top management, farm management, and farm owner may be the same person. 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 QMS.

5.5.3 Internal communication

ISO 9001:2008, *Quality management systems — Requirements*

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

Guidance: Internal communication takes place between people in the farm operation. Appropriate internal communication encourages effective operation of the QMS. It may be helpful to make a record of internal communication.

HELP Communication takes many forms, including: charts, graphs, notes, letters, emails, photographs, samples, and conversations with neighbours, people involved, and customers.

5.6 Management review

5.6.1 General

ISO 9001:2008, *Quality management systems — Requirements*

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 periodically assess the QMS in a more structured way than daily assessments. The management review should ask whether the QMS is working and effective. Management review should be used to determine the current status as well as improvements necessary to meet the quality objectives.

HELP In small operations management reviews may simply consist of a list of actions to be reviewed and actions taken.

5.6.2 Review input

ISO 9001:2008, *Quality management systems — Requirements*

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 information including documents and records may be incorporated into the management review:

a) audits: internal or external;

b) customer feedback;

c) information regarding crop yields and quality, process and product performance;

d) status of corrective and preventive action;

e) completion of actions identified during previous management reviews;

f) changes in farm operations that would impact the QMS;

g) recommendations from customers, employees, or management.

5.6.3 Review output

ISO 9001:2008, *Quality management systems — Requirements*

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 written record of management reviews is important to the maintenance of the QMS. Consider decisions and actions related to:

a) improvements made over time;

b) improvement of product related to customers' requirements;

c) resources needed to maintain the QMS, including new or changed resource needs based on decisions made by farm management.

Actions identified during the management review should be prioritized and implemented.

6 Resource management

6.1 Provision of resources

ISO 9001:2008, *Quality management systems — Requirements*

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 6.1 is to make sure the farm operation has the resources necessary to develop, maintain and improve the QMS and also to carry out the work to satisfy customer, and statutory and regulatory requirements. This should include the use of available resources as well as planning for 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 performed under a number of circumstances and may include, for example:

a) at the time customer requirements are identified;

b) at the time statutory or regulatory requirements are changed;

c) as part of farm management review process;

d) when customer requirements are changed;

e) 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 farming plan. As part of this activity, the farm operation may want to refer to customer and/or statutory and regulatory requirements. Resources may include, for example, qualified personnel, tools, equipment, finance, materials, facilities, timely scheduling, instructions, supplies, repair parts.

HELP Resources for small organizations or organizations using extensive manual labour may include, for example, the availability of labour 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 (complex) organizations 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, statutory and regulatory and organizational requirements; crop or field applications; crop security; equipment maintenance activities including cleaning and calibration; resources to provide for identification, transportation, segregation, handling and storage of seed and root stock; field observation activities; crop and field maintenance activities; testing and field inspection activities; crop characteristic testing; inspection of storage facilities; resources as necessary for re-verification of labour 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

ISO 9001:2008, *Quality management systems — Requirements*

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

NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

Guidance: People who are assigned to carry out activities should be competent to do them. An initial determination of the availability of competent personnel (people involved, subcontracted personnel and labour, exchanged labour from neighbouring farm operations) 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, training and awareness

ISO 9001:2008, *Quality management systems — Requirements*

The organization shall

a) determine the necessary competence for personnel performing work affecting conformity to product requirements,

b) where applicable, provide training or take other actions to achieve the necessary competence,

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 relating to customer or statutory and regulatory requirements. A logical five step process is provided in 6.2.2.

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. People involved need to understand or be aware that the farm operation 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 licences or copies of licences, need to be maintained as appropriate.

Competence can be demonstrated as determined by the farm operation. The crop producer may not need to provide evidence of competency in all circumstances, e.g. for people performing tasks by rote or tasks that are culturally embedded.

The involvement of new workers and seasonal workers may require the same screening, training, and testing as for experienced workers. Where necessary, training provided should include subjects such as food safety, and HACCP (ISO 22000[6] may be appropriate when issues of food safety are part of the QMS).

HELP For simple operations, competence may be demonstrated by means that are practical for the specific needs of the farm operation and its customers, for example, by direct observation of employee knowledge and understanding. A more formal review of records associated with training or education may be required. In some cases, records of employee competence may consist of a simple checklist to confirm that personnel are capable of doing a job. A file containing proof of employee qualifications may be a simple approach to providing these records.

The records that show the successful completion of a training programme and that competence has been demonstrated can be as simple or as complex as necessary. This may include, for example, whether people involved or other personnel can use certain equipment, carry out specific processes or follow certain procedures. Records of these qualifications should become part of the farm operation's records. Competency records, for example, may include, as appropriate, a commercial driving licence and a chemical applicator's licence or certificate. External service providers and contractors also need to demonstrate the required competencies and qualifications (see also 7.4.2).

The determination of the availability of competent personnel may be conducted as appropriate throughout the crop cycle or as needed.

6.3 Infrastructure

ISO 9001:2008, *Quality management systems — Requirements*

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, communication or information systems).

Guidance: An initial determination of infrastructure requirements should be made during the initial planning process. This may include items a) to d).

a) "Permanent or non-movable" parts of the operation. This includes land (including any isolation and buffer requirements for the crop produced), buildings used for work, storage, associated utilities and maintenance buildings for field equipment.

b) Water resources.

c) All equipment used in the field and for processing (crop drying equipment). This may also include computers and computer software.

d) Transportation, handling equipment, and communication equipment (mobile phones, radios, computers, and related services). Equipment or instruments for product testing are included in this area.

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

Consideration should be given to permanent or portable hygiene facilities (toilets, hand washing, etc.) when issues of food safety are part of the QMS (food safety management system requirements are specified in ISO 22000[6]). Consideration may also need to include environmental issues (see ISO 14001[3]).

6.4 Work environment

ISO 9001:2008, *Quality management systems — Requirements*

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

NOTE The term "work environment" relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).

Guidance: An interpretation of 6.4 is the work environment for people, equipment inputs, and outputs that are necessary for the successful production of a crop that meets requirements. The work environment is also the growing site for crop production. This environment is not always controllable or manageable, for either working or growing. The farm operation should adequately review its work environment and, where appropriate, ensure its ongoing ability to meet product requirements. Consideration should be given to work environment issues that relate to food safety, whenever food safety is part of the QMS (food safety management system requirements are specified in ISO 22000[6]).

This control should include all stages of crop production from purchasing inputs to product delivery. This may include, as appropriate: environment, buildings, and equipment. Farm management may choose to consider worker safety as part of the work environment to meet statutory, regulatory or customer requirements. In the absence of local or national statutory and regulatory requirements, internationally accepted labour regulations may be considered. Workers may be outside, in equipment (such as tractors and combines), and inside buildings. All of these environments may be evaluated to see that they are adequate for crop production and associated processes as well as worker safety.

7 Product realization

7.1 Planning of product realization

ISO 9001:2008, *Quality management systems — Requirements*

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 and documents, and to provide resources specific to the product;

c) required verification, validation, monitoring, measurement, 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 processes include determining and understanding customer or market needs and expectations, planning to realize these needs and expectations (e.g. see crop processes listed in Annex A), and all other processes associated with the delivery and post-delivery of a crop. The planning process is often an output of the design and development process whenever design and development is within the scope of the farm QMS.

In crop production, these activities 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 4.1. In crop production, planning for product realization, see steps a) to d), needs to be completed for each new crop cycle.

a) Quality objectives for the product and or processes should be reviewed or determined based on customer and market requirements for the products to be grown. Plans should include any amended or additional customer or market requirements.

b) As new technologies and/or new crop specifications set by the customer or market 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/or new crop specifications are set by the customer or market, 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. In the case of sensory analysis, it is important to specify competence of the person (panel) evaluating the product and the evaluation criteria.

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. In 7.1, Note 1, this is referred to as a quality plan (farming plan).

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 operation can establish and maintain one or more programmes, which 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.

Changes in growing conditions may require changes to the farming plan. For example, when growing conditions cause the crop to deviate from customer or market requirements, the farm operation may be able to restore the crop in the later process of crop production.

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

— *contract requirements* — including customer and product specifications, and the organization's specifications and requirements for inputs and outsourced activities;

— *production environment* — including infrastructure (land, fencing, manure management, flooding history, pest control, etc.), multi-year crop history, isolation, previous use of land;

— *production inputs* — including seed and root stock, crop protection inputs, equipment, personnel, compost, water sources, etc.;

— *management inputs* — including a quality policy, measurable objectives, and customer satisfaction measurement (field observation, documentation, competency, internal audits, identity preservation);

— *harvest* — including handling, storage, personnel hygiene, water quality, pest control, and transportation;

— *food safety* — including references to ISO 22000[6] and appropriate statutory and regulatory requirements may be appropriate when issues of food safety are part of the QMS.

HELP Production contracts, technical advice and guides, and analytical results may be used to augment the farming plan.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

ISO 9001:2008, *Quality management systems — Requirements*

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 applicable to the product, and

d) any additional requirements considered necessary by the organization.

NOTE Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

Guidance: The focus of 7.2.1 is the definition and understanding of all requirements for the crop to be provided to the customer. Remember that additional factors, such as statutory and regulatory or legal requirements, delivery schedules, and conditions of payment or unspecified customer expectations, see steps a) to d), should be taken into account at this point.

a) In crop production this might include an understanding of customer requirements related, for example, to the need for on-farm storage or perhaps delivery at a specific location and/or time.

b) These requirements include implied needs and expectations in use of products by the customer. Generally, customers do not state explicitly their requirement that the product is safe for use. The farm operation should determine what the implied needs are as well as the expectations of the customer or the market.

c) This may include, for example, regulatory requirements that cite food safety, industry, or government standards.

d) Product and process requirements that the farm operation sets for itself, e.g. use of a particular type of equipment.

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

Where customer requirements for the environment, health and safety or other working conditions are specified, they should be taken into account in the development of the QMS.

7.2.2 Review of requirements related to the product

ISO 9001:2008, *Quality management systems — Requirements*

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 are determined in 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, e.g. on a small farm operation, 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 statutory and regulatory, requirements are normally included in the farming plan. The completed farming plan should be reviewed to ensure that:

a) all requirements are clearly stated in the farming plan;

b) prior differences and changes that may have occurred have been resolved and that the farming plan is current and meets customer requirements;

c) the farm operation has the capability of meeting defined requirements — this capability review may consider requirements associated with field history, size, availability of seed and root stock, facilities and equipment as well as availability of qualified personnel, etc.

It should be noted that a farming plan that has been reviewed and approved helps to provide confidence that all requirements can reasonably be met prior to acceptance of the contract. The farming plan normally includes requirements for delivery, including customer specifications such as dates and requirements for transportation and storage.

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

7.2.3 Customer communication

ISO 9001:2008, *Quality management systems — Requirements*

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 farm operation and the customer. Customer feedback, including complaints, is valuable for continual improvement.

Review and reconfirm crop, soil and other conditions prior to harvest as a means of ensuring customer, statutory and 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 statutory and regulatory requirements. Where conditions are found to be inconsistent with the fulfilment 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, assurance that identity preservation protocols are in place, changes in 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 QMS 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. Results of customer feedback should become part of farm management reviews.

HELP In a small farm operation, it may be sufficient to retain correspondence from and with the customer.

7.3 Design and development

7.3.1 Design and development planning

ISO 9001:2008, *Quality management systems — Requirements*

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.

NOTE Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.

Guidance: It is important to analyse and determine whether 7.3.1 is applicable to the farm operation. It is relevant only to those farm operations that carry out design and development.

In a farm operation, a design can be considered as any unique changes to genetics, inputs, outputs, growing conditions or any process (such as organic farming) associated with farm processes which impart a unique characteristic to the crop that is desirable for current or future customers or markets.

The application or adaptation of proven designs and processes to meet various customer and market requirements should not be considered as part of design.

Whenever new or modified processes are needed by the farm operation as a means of attaining a crop characteristic that is necessary to meet customer or market requirements, the development of these processes may be assigned to design and development.

If the farm operation does not perform design and development, and is not responsible for these processes, the “exclusion” provisions of 1.2 apply.

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

7.3.2 Design and development inputs

ISO 9001:2008, *Quality managements systems — Requirements*

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.

The 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(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

ISO 9001:2008, *Quality management systems — Requirements*

The outputs of design and development shall be in a form suitable for 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 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.

NOTE Information for production and service provision can include details for the preservation of product.

Guidance: Required or expected outputs associated with the design process should be considered as any output that uniquely characterizes or supports the characteristic of the crop to be delivered to the customer. In addition, any output associated with achieving the desired result, 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.

Where design and development have been applied, outputs from this process should be included in the farming plan.

7.3.4 Design and development review

ISO 9001:2008, *Quality management systems — Requirements*

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 characteristic and the inputs, outputs and controls necessary to achieve the desired characteristic. Therefore it is important to understand that progress toward meeting the desired characteristic 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 characteristics are ultimately achieved.

7.3.5 Design and development verification

ISO 9001:2008, *Quality management systems — Requirements*

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 characteristics to provide the farm operation 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 characteristics.

7.3.6 Design and development validation

ISO 9001:2008, *Quality management systems — Requirements*

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, where 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 required crop characteristics are present and meet the intent of the design objectives. Crop characteristics that do not meet requirements may under some circumstances be considered as adequate if customers are provided with information that accurately describes the characteristics of the product and can determine them to be acceptable. Where the farming plan is the output of the design and development process, validation should also confirm that the inputs (type of seed or propagule, use of pesticide, type of fertilizer) satisfy the requirements.

7.3.7 Control of design and development changes

ISO 9001:2008, *Quality management systems — Requirements*

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. The intention of 7.3.7 is to ensure that these changes are controlled, readily apparent to farm management, and are approved. Consideration should be given to design changes that have the potential to impact food safety.

7.4 Purchasing

7.4.1 Purchasing process

ISO 9001:2008, *Quality management systems — Requirements*

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 farm operation needs to identify those materials and services purchased which can affect the quality of the crop(s). The farm operation 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 operation may:

a) make provision for supplier assessment and monitoring procedures based on methods deemed suitable for the operational needs of the farm operation;

b) deem that past performance of the supplier meets this need in some circumstances.

HELP For small farm operations, previous history with labour, service provider, or material supplier may be sufficient to meet or to fulfil this evaluation. In some circumstances, a similar approach may also apply to large farm operations.

This requirement applies to any process, product or service purchased by the farm operation that can have an impact on meeting customer or statutory and regulatory requirements. The farm operation should clearly describe the expectations associated with suppliers as the first step in ensuring that the supplier can meet stated requirements. The management of agriculture inputs is especially important. For example, soil inputs, pesticide, and fertilizers should be appropriate to the crop being grown and the intended use. This information should be clearly specified within purchasing documents as appropriate.

Rented land should be considered as an input purchased from a supplier. Farm management is responsible for ensuring that the land conditions enable customer and statutory and regulatory requirements to be met. Considerations may include, as appropriate, an evaluation of soil type, moisture, cleanliness of irrigation water, field isolation, etc. as a precondition to any agreement that commits the farm operation to using the land.

As part of this process, consider all the purchased inputs necessary to meet requirements including, for example: equipment (including types, quantity and availability), technology, personnel availability, personnel qualifications, and packaging. In addition, ensure the appropriateness of the capacity of personnel and farm operations 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 observation, custom applications, yield estimation services, harvesting, inspection and testing services, laboratory testing, crop attribute testing, and transportation and storage.

When externally purchased services are retained, care should be taken to ensure:

1) the provider is capable of conducting the activity to meet established criteria;

2) clear communication takes place ensuring that the provider understands the requirements including any appropriate records that are required;

3) appropriate verification of completed activities takes place.

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

Farm management may choose to re-verify the availability and capability of suppliers to meet requirements as necessary to ensure operational, statutory, regulatory, and contract requirements can be met. This re-verification may include confirmation of: availability in a timeframe that meets requirements, qualification of personnel (e.g. licensing or certification of a chemical applicator) and equipment, and other inputs such as seed and root stock and applications.

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

7.4.2 Purchasing information

ISO 9001:2008, *Quality management systems — Requirements*

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 farm operation needs to determine the level of formality of the purchasing system that is appropriate. When outsourced services are purchased, the farm operation is responsible for communicating approval requirements for the service, procedures, processes, equipment, facilities, work environment, etc., 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.

The management of agricultural inputs is often very important. Inputs such as herbicides, pesticides, fertilizer, and composts may need to be evaluated against their intended use and customer requirements during the purchasing process. In addition, producers should give consideration to documenting rental agreements for land. Rental agreements should outline all purchasing information associated with the requirements of the farm operation including, as appropriate, customer, statutory, and regulatory requirements.

As part of the purchasing information, consideration should be given to providing requirements for personnel qualification/competence (see 6.2.2).

7.4.3 Verification of purchased product

ISO 9001:2008, *Quality management systems — Requirements*

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 include: if genetic purity and crop characteristics are important to the product, the label of each container should be inspected to see that the seed variety and lot number match what was ordered and pesticides should be checked to see that formulation and strength are appropriate.

7.5 Production and service provision

7.5.1 Control of production and service provision

ISO 9001:2008, *Quality management systems — Requirements*

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 equipment,

e) the implementation of monitoring and measurement, and

f) the implementation of product release, delivery and post-delivery activities.

Guidance: In 7.5.1 are described the various types of controls that may be needed to actually produce and deliver the crop to the customer. It follows from 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. In 7.5.1, the farm operation is directed to initiate controls for the conditions listed in a) to f), as applicable.

Each of these processes 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 or checklists, representative samples, assigning competent personnel or providing direction or other means determined by farm management. Each process may require unique methods of control. Processes may include but are not limited to:

a) farm planning;

b) land allocation (field selection);

c) allocate/purchase/procure inputs;

d) land and water management;

e) planting;

f) field activities;

g) pre-harvest and storage activities;

h) harvest;

i) transportation and handling;

j) crop storage;

k) distribution and delivery.

To ensure performance within the farming plan, check sheets may be used. Check sheets ensure control and allow competent personnel to acquire experience as operations supervisors.

Farm management should understand and manage appropriate activities within each farm operation process that can affect the product. It can be helpful to begin this process with a description of the crop(s) and crop characteristics being produced, the requirements necessary for establishing and verifying quality (e.g. moisture, firmness, organic nature, and purity), and the contractual or 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 All farm operations and especially small farm operations 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 or drawings, or other actions that meet the needs of the farm operation.

Crop processes may have specific requirements (e.g. planting depth, population, fertilizer application, product traits, compost quality, water quality, and pre-harvest interval). Each of these requirements should be measured or, in cases where physical measures might not be possible, monitored. Measuring methods should be verified for accuracy and consistency where practical.

In the case of growing conditions which cause the crop to deviate from the criteria, it should be noted that the farm may be able to restore the crop in later process of crop production.

When the farm's customer is not the final customer for the product, farm processes should take into account the requirements of intermediate and final users.

7.5.2 Validation of processes for production and service provision

ISO 9001:2008, *Quality management systems — Requirements*

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, 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),

e) revalidation.

Guidance: This requirement ensures that products delivered to the customer or the market completely meet their requirements. 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.

For example, in assessing the uniformity of chemical application where it is not feasible to measure the application of the chemical, the control is effected by proper calibration of the application equipment. Other types of control that may be appropriate could be the performance of a task by qualified personnel or the use of fit for purpose and well-maintained equipment.

Reliance on end of season inspection and testing to serve the verification needs of the farm operation 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, and all intended outputs are achieved to fulfil specified customer requirements.

7.5.3 Identification and traceability

ISO 9001:2008, *Quality management systems — Requirements*

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 throughout product realization.

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (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, at 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 are listed here.

— Seed and 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 and 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 affect identification and traceability.

— Equipment to be used should be clearly identified, as appropriate, by a means that is suitable and recorded in the farming plan. Traceability including use on other fields and all equipment clean-out activities should be maintained as part of the farm operations records.

— A clearly defined means for identification of specific storage facilities, sites, containers, etc. should be in place 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 clean-out 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 clean-out of meeting requirements specified by original equipment manufacturers, the farm operation and/or contract requirements.

Traceability is addressed in ISO/TS 22005[9], which is not intended to be a management system document. It is intended to coordinate ISO/TS 22005[9] with the context of a broader system such as ISO 22000:2005[6] or ISO 9001:2008[1]. If the farm operation is developing a comprehensive management system, then ISO/TS 22005[9] processes should be coordinated with other systems.

7.5.4 Customer property

ISO 9001:2008, *Quality management systems — Requirements*

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, the organization shall report this to the customer and maintain records (see 4.2.4).

NOTE Customer property can include intellectual property and personal data.

Guidance: Customer property should be clearly identified, used, and controlled according to the requirements of the customer and any requirements in the farming 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 and root stock, land, inputs such as chemicals, equipment such as applicators, storage facilities, transportation (such as trucks, wagons, and railcars), and packaging materials (such as labels).

7.5.5 Preservation of product

ISO 9001:2008, *Quality management systems — Requirements*

The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, 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 food safety in a manner that assures fulfilment of customer, statutory, and regulatory requirements.

In crop production, 7.5.5 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 equipment

ISO 9001:2008, *Quality management systems — Requirements*

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

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, or both, 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 (see 4.2.4);

b) be adjusted or re-adjusted as necessary;

c) have identification in order to determine its calibration status;

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 Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

Guidance: Monitoring and measuring devices that are used to confirm or verify such things as moisture, flow rate, and seed counts should provide accurate information. Generally, the manufacturer of every measuring device has a 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 and hydrometers;

— standard materials and checklists used for sensory analysis.

Handling, clean-out and maintenance of processing equipment should meet the requirements specified by equipment manufacturers, the farm operation, and/or contract requirements.

In general, the accuracy and consistency of any data that are 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.

Where the farm operation performs monitoring and measuring activities utilizing non-physical means, such as checklists or questionnaires, these may need to be validated and controlled.

HELP This section is not meant to create more effort than is necessary to meet farm operation requirements unless customer or statutory and 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. At some stage goods may be sold based on regulated or standard tests, so a comparison improves internal decision-making.

8 Measurement, analysis and improvement

8.1 General

ISO 9001:2008, *Quality management systems — Requirements*

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

a) to demonstrate conformity to product requirements,

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: Note that the control of monitoring devices and measuring equipment is specifically addressed in 7.6, whereas 8.1 addresses the wider monitoring, measurement, analysis and improvement of the performance of the QMS.

The farm operation needs to plan how to carry out the monitoring and measuring activities to meet their own and their customer needs. The activities are:

— customer satisfaction (see 8.2.1)

— QMS performance (see 8.2.2)

— process conformity (see 8.2.3), and

— product and service conformity (see 8.2.4)

All subclauses cited above provide information to be analysed in accordance with 8.4. In 8.1 are outlined the activities for the measurement, analysis, and improvement of the QMS. This shows how the QMS is doing (system performance) and how it affects the farm operation.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

ISO 9001:2008, *Quality management systems — Requirements*

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.

NOTE Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.

Guidance: The primary customer is the person or group that receives the crop. There may be a chain of handlers leading to the end consumer and all of these may be considered customers based on the needs of the farm operation. 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:

a) customer surveys;

b) face-to-face conversations;

c) results of delivery of contracts;

d) customer complaints/feedback;

e) repeat customers.

In agricultural marketing, face-to-face contact with the customer or representative of the customer is common. If there are problems, a customer representative can be encouraged to immediately contact farm management to determine what to do. The most serious customer reaction is the rejection of product at delivery because of quality problems. ISO 9004:2009[2] has a more extensive explanation of customer satisfaction.

HELP 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 farm operations or individual producers.

8.2.2 Internal audit

ISO 9001:2008, *Quality management systems — Requirements*

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, and

b) is effectively implemented and maintained.

An audit programme 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. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results shall be maintained (see 4.2.4).

The management responsible for the area being audited shall ensure that any necessary corrections and corrective 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 [5] 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. Requirements 8.2.2 a) and 8.2.2 b) are that internal audits evaluate the effectiveness of the farm's QMS as well as conformity to regulatory and customer requirements and the farm's internal requirements. This is a very important part of gaining value from a QMS and in uncovering opportunities for improvements. Part of 8.2.2 requires that internal audits be objective and impartial. All internal audits should be undertaken with total objectivity. Internal audits should be done on a regular basis. In 8.2.2 are outlined the steps to consider in the auditing process and what other clauses need to be considered.

Internal audits can be conducted on the entire QMS at one time or on selected portions of it 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 is to understand the requirements for the part or parts to be audited, and to evaluate 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 (for corrective actions, see 8.5.2) from previous audits as a method of identifying recurring problems.

HELP Farm operations 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 representative that may be able to provide this help.

8.2.3 Monitoring and measurement of processes

ISO 9001:2008, *Quality management systems — Requirements*

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.

NOTE When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

Guidance: Understanding the most important elements of each activity is necessary to achieve good results. It may be difficult to measure some processes and the farm operation should take a practical approach with careful consideration given to customer, statutory, and regulatory requirements. An assessment of product quality (see 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.

Monitoring and measurement of food safety processes (cleaning, personal hygiene) should be considered as part of this process when appropriate.

HELP Less complex farm operations may find that direct observation and experience are sufficient to monitor processes.

8.2.4 Monitoring and measurement of product

ISO 9001:2008, *Quality management systems — Requirements*

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 for delivery to the customer (see 4.2.4).

The release of product and delivery of service to the customer 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 (growth) 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, statutory, and regulatory requirements as well as expectations have been met (or not met). Appropriate crop measurements and monitoring methods should be selected as appropriate to demonstrate conformity. These may include sensory analysis.

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

Monitoring and measurement of product related to food safety should be considered as part of this process when appropriate or in fulfilment of statutory or regulatory requirements.

8.3 Control of nonconforming product

ISO 9001:2008, *Quality management systems — Requirements*

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

Where applicable, 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;

d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

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

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

Guidance: Nonconforming products are crops that either fail to meet customer requirements or those that fail to meet production practice or statutory and 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, other marketing arrangements should be made.

Nonconforming product can be identified appropriately by visual inspection or crop testing. Nonconforming product should be immediately segregated and controlled by methods listed in 8.3 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 farm operation needs to notify the customer.

Steps need to be taken to identify the nonconforming product, and all workers need to be informed that the product cannot be included with the customer's order.

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

Food safety issues may be a critical consideration in the determination and identification of nonconforming product (see ISO 22000[6] as appropriate when issues of food safety are part of the QMS).

8.4 Analysis of data

ISO 9001:2008, *Quality management systems — Requirements*

The organization shall determine, collect and analyse 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 8.2.4),

c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and

d) suppliers (see 7.4).

Guidance: Effective decisions are based on the review of information that is continuously gathered during the process of crop production. This information should include the results of any evaluation of the crop produced. The review of this information should be used to identify any trends that would be helpful in planning, including planning of future production. Customer satisfaction, as measured in 8.2.1 needs to be part of the process used to prevent future problems.

ISO 9001:2008[1] requires that, at least, the data from the result of monitoring and measuring activities (see 8.2) are collected and analysed. Areas for improvement can be identified from this information and each nonconformity is an opportunity for improvement. This activity is often where the largest benefits of a QMS can be gained. The ongoing identification of trends that are not immediately apparent during the crop production cycle can help to reduce problems in the future. Results of monitoring, measurement and analysis should be a component of management review (see 5.6).

HELP For simple farm operations, using available information, including direct observation, may be sufficient to determine whether changes in production processes are required to better meet customer or market requirements.

Information may be recorded by means such as hand-written notes, annotation to calendars, diaries or other methods determined suitable by farm management.

8.5 Improvement

8.5.1 Continual improvement

ISO 9001:2008, *Quality management systems — Requirements*

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 an ongoing activity to make things better for the farm operation and/or its customers. When opportunities for improvement are identified and when improvements are justified, action should be taken to resolve the problem or make the improvement. Improvements may be initiated by personnel or farm management. These improvements may simply be an opportunity to make things better, or they may be triggered by a formally identified problem. Decisions on the actions to be taken to make improvements should be based on the availability of resources, the severity of the problem and whether or not the solution is practical. When more than one opportunity is identified, farm management should evaluate the circumstances and implement the most beneficial actions first.

Continual improvement is a permanent objective of the organization. Corrective action is an important component providing feedback into the continual improvement process. The entire quality system improves by taking corrective actions and implementing continual improvement. These benefits support the farm operation's quality policies and objectives.

8.5.2 Corrective action

ISO 9001:2008, *Quality management systems — Requirements*

The organization shall take action to eliminate the causes 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 the effectiveness of the corrective action taken.

Guidance: Both corrective (8.5.2) and preventive (8.5.3) actions are important steps in quality improvement. The goal of corrective actions is to eliminate 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. The actions reduce negative impacts on:

— business results;

— the farm operations' products, processes, QMS;

— the satisfaction of customers.

Corrective action should be taken on:

— product nonconformities;

— activities that do not meet requirements originally specified.

Actions need to be taken to determine that the problem has been resolved. When it is not resolved, the corrective action process can be repeated until the solution is found.

8.5.3 Preventive action

ISO 9001:2008, *Quality management systems — Requirements*

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 the effectiveness of the preventive action taken.

Guidance: The intention of 8.5.3 is to prevent problems before they occur. The steps for determining preventive action are very similar to those used for corrective action; however, the results can be beneficial to all areas of the QMS. Problems are prevented rather than corrected, leading to better product and/or reduced costs.

Possible nonconformities may be identified during farm operation or during internal audits. 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.

Risk analysis activities (including formulation of HACCPs) may be considered an important component of preventive action when appropriate.

Examples of preventive action include:

— planned preventive equipment maintenance,

— alarms, indicators, and mistake-proofing techniques,

— HACCPs (see ISO 22000:2005[6]).

Annex A
(informative)

Typical crop processes and sub-processes

Tables A.1 to A.11 list 11 typical crop processes and associated sub-processes. These crop processes and sub-processes do not apply to all farm operations, rather they are intended to provide help, as appropriate. The size and complexity of the farm operation and associated crop requirements determine the actual applicability of the processes and sub-processes listed. Users of this International Standard may find it helpful to refer to this list and select the crop production processes or sub-processes, including pre-planting and post-harvest, storage and delivery and appropriate suggestions, that may apply to their unique needs.

Suggested crop processes are listed in Tables A.1 to A.11:

1) planning;
2) land allocation (field selection);
3) allocating/purchasing crop inputs;
4) land and water management;
5) 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.

Table A.1 — Planning

Sub-process	Tips
Determine customer requirements for the crop, such as hectareage and yield goal, and the farm operation's ability to meet contracts or 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 customer requirements are identified and translated into a plan (usually a farming plan). The plan is then designed to ensure customer, statutory, and regulatory requirements are met. If this sub-process applies, look for linkages to 7.1 and 5.4.2. Quality objectives may also be established at this point. Remember, quality objectives may be articulated within the farming plan. Quality objectives may consist of customer requirements, input requirements, crop quality standards and test results or certifications associated with the crop. If this sub-process applies, look for linkages to 5.4.1.
Determine the criteria for any known or anticipated inputs that are needed (seed, fertilizer, tools, field operations, delivery, outsource inputs, farm labour).	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 operation has suitable production capabilities; and/or — alignment of existing farm operation process with crop requirements. If this sub-process applies, look for linkages to 4.1, 7.2.2.c) and 7.4.1.

Table A.2 — Land allocation (field selection)

Sub-process	Tips
Determine the suitability of the land to meet the farming plan.	The land and associated environmental conditions should support the achievement of customer, statutory, regulatory and appropriate farm operation requirements. This alignment activity should help identify potential problems and can help in the creation of a farming plan that ensures results are met. If this sub-process applies, look for linkages to 5.4.2 and 7.1.

Table A.3 — Allocating and purchasing crop inputs

Sub-process	Tips
Allocating and purchasing seed and root stock	Selection of seed and root stock that meets customer 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 7.2.1 and 7.4.2.
Allocating and purchasing production inputs	Production inputs are the inputs (soil amendment, pest control, 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 fulfilment of customer, farm operation or statutory and regulatory requirements. If this sub-process applies, look for linkages to 7.2.1 and 7.4.2.
Allocating and outsourced inputs and labour	Labour includes the work done within the processes of crop production. These can be allocated from existing farm operation resources or they can be obtained from individual workers or from an individual or company that provides these services. This labour is used for farm operation processes and may include field activity, planting, etc. If this sub-process applies, look for linkages to 7.2.1 and 7.4.2.
Allocating and purchasing custom application services	These include purchased services for applying crop inputs and may include the application of crop protection chemicals, soil amendments, etc. If this sub-process applies, look for linkages to 7.2.1 and 7.4.2.
Allocating and purchasing other input purchases	This may include tools, equipment, and delivery. Bartered services may be considered. If this sub-process applies, look for linkages to 7.2.1 and 7.4.2.

Table A.4 — Land and water 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 done in regards to issues that impact requirements, such as prior land use, field isolation, field productivity, field border identification, and weather damage. If this sub-process applies, look for linkages to 7.1, 7.2 and 7.4.
Soil testing	Soil testing may be conducted to confirm that the field is capable of producing a crop that meets requirements. This testing may include soil characteristics, physical properties, soil acidity, nutritional status, tests for the presence of chemical residue, presence of unwanted genetic material, etc. If this sub-process applies, look for linkages to 7.1, 7.2, 7.4.1, 7.5.1 and 7.6.
Soil amendment	Amendment application or other steps may be taken during this process to make changes to the soil prior to planting. These changes and amendments are normally based on the results of the soil-testing process. If this sub-process applies, look for linkages to 7.1, 7.2, 7.4.1, 7.5.1, 7.5.3, 7.5.4, 7.5.5, and 7.6.
Crop protection measures	Methods of application may include field cultivation use 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 on direct observation of the field the previous year. If this sub-process applies, look for linkages to 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, such as functionality, set-up, maintenance, clean-out, inspection, and calibration including any corrective or preventive action. 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 7.1, 7.2, 7.4.1, 7.5.1, 7.5.3, 7.5.4, 7.6.

Table A.5 — Planting

Sub-process	Tips
Equipment management	This sub-process ensures that equipment is set-up, cleaned, inspected, and calibrated in a manner that ensures that customer, statutory, 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 7.5.1, 7.5.2, 7.5.3, 7.5.4, 7.6.
Reconfirm: — field plan; — field selection; — customer, farm operation, statutory, and regulatory requirements	This sub-process is a key process that reconfirms that everything is ready prior to planting. This process may be a simple step or can be complex regardless of farm operation size. The result of this sub-process is a final determination that customer requirements can be met. Steps in this process may involve a final review of planting conditions and a final review of requirements. If this sub-process applies, look for linkages to 7.1, 7.2, 7.4.
Identification, transportation, segregation, handling and storage of seed and root stock	This step is intended to ensure that seed and root stock that meets all requirements is available for planting. This may include verification of the identity of the material, transportation of the material, segregation of the material (particularly when errors can occur), handling practices and storage requirements. This may include, for example, a check of seed tags with appropriate verification against farm operation or field plan (only checking delivery receipts at this point could cause an irreversible error). Place genetic materials in proper delivery equipment that ensures identity, segregation, and qualities are maintained. If this sub-process applies, look for linkages to 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 reconfirmation of customer requirements. If this sub-process applies, look for linkages to 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 preventive measures that affect requirements are put into place. Depending on conditions and requirements, this could also include verification of soil conditions and genetics. If this sub-process applies, look for linkages to 7.5, 7.5.3, 7.6, 8.5.3.
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 7.1, 7.2, 7.4.3, 7.5.3, 7.5.4, 8.3, 8.5.2.
Replant	This step is only used when replanting is determined to be necessary to meet requirements. Plans for replanting may be included in the farming plan when this is determined to be appropriate by farm management. If this sub-process applies, look for linkages to 7.5, 7.5.3, 7.6, 8.3, 8.5.2.

Table A.6 — Field activities

Sub-process	Tips
Field observation	The field observation sub-process should identify problems or issues that prevent the farm operation from meeting requirements. When field observation is necessary, this activity should be included in the farming plan with timing and appropriate resources allocated. Field observation may identify problems where corrective action can be taken or the customer notified or both. If this sub-process applies, look for linkages to 7.2, 7.4, 7.5, 7.6.
Input application	This sub-process may include irrigation, fertilizer, soil amendments, or crop protection chemicals as indicated by the crop plan or the crop field observation report. Equipment associated with inputs should be suitable and calibrated as appropriate to ensure proper application. If this sub-process applies, look for linkages to 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 farming plan, customer or statutory and regulatory requirements. Use appropriate tools or equipment with proper adjustments or calibration as required to meet requirements. If this sub-process applies, look for linkages to 7.1, 7.2, 7.5, 8.2.
Field inspection and testing	This sub-process is designed to provide feedback on progress toward meeting requirements. This step may be part of the farming plan or other requirements or may be indicated by field observation 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 7.1, 7.2, 7.4, 7.5, 7.6.

Table A.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 are 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 7.1, 7.2, 7.2.3, 7.4.1, 7.5.1, 7.6, 8.3.
Crop attribute testing	This sub-process is designed to 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 specific customer requirements, this sub-process may be simple. When customer or statutory and 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 farming plan. This step may provide the final indication that harvest conditions can be met. If this sub-process applies, look for linkages to 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 7.1, 7.2, 7.4.1, 7.5.1, 7.6.
Final equipment preparation	This sub-process is designed to 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 7.5.1, 8.2.
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 operation 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 operation. If this sub-process applies, look for linkages to 7.1, 7.4.3, 7.5.3, 7.5.4.
Final verification of contract labour 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 labour, 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 farming plan. If this sub-process applies, look for linkages to 6.3, 7.5.1.
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 unintended mixing of crops as appropriate. Careful consideration should be given to all requirements when this step is undertaken. If this sub-process applies, look for linkages to 7.1, 7.2, 7.2.2 b), 7.2.2 c), 7.4, 8.3, 8.5.3.

Table A.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 7.1, 7.2, 7.5, 7.5.1, 7.6.
Harvest equipment clean-out	This sub-process may apply to farm operations that use farm operation equipment and where unintended mixing of crops can occur. When determined necessary, equipment clean-out should be undertaken as required before and during harvest. These activities should take into consideration unintended mixing of crops during harvest. If this sub-process applies, look for linkages to 6.3, 8.5.3.
Monitoring and adjustment of equipment	This sub-process may only apply to farm operations that use farm equipment. This sub-process may be ongoing as needed during harvest and should take into consideration unintended mixing of crops. 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 7.5.1, 7.6, 8.2.
Harvest crop	Steps involved with this sub-process ensure proper performance of tasks. In mechanized farm operations, this also includes 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 7.5, 7.5.3, 7.6.
Crop testing (quality, condition, etc.)	As appropriate, ongoing crop testing may be required to ensure requirements are met, and optimum yield and quality achieved. When required, this sub-process should outline requirements for these activities. If this sub-process applies, look for linkages to 7.1, 7.2, 7.4.1, 7.5.1, 7.6.

Table A.9 — Crop management — delivery and handling

Sub-process	Tips
Delivery and handling	When handling and delivery of the crop requires 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 operation. When appropriate, this may include maintenance of associated delivery and handling records, for example: — crop characteristic records; — yield monitor records; — crop conditioning; — scale tickets.
Identification and segregation	When crop identification and/or segregation are issues that need to be managed, this sub-process should be used. When specified by the farm operation or other requirements, records may be associated with these activities, for example: before, during and after transport, and may include: — spill clean-up; — truck clean-out; — border rows; — conveyance equipment. If this sub-process applies, look for linkages to 7.5.1, 7.5.3, 7.5.5.
Equipment clean-out	This sub-process may apply to farm operations that use farm equipment and where unintended mixing of future crops or other crops may need to be prevented. These requirements may be determined by the farm operation or by customer requirements. These activities should include, as appropriate: transport and handling equipment, etc. If this sub-process applies, look for linkages to 7.5.1, 7.6, 6.3, 8.5.3.
Crop verification	This sub-process is intended to confirm the final characteristics of the completed crop prior to transport to storage or to the customer. This sub-process may be undertaken whenever customer requirements, farm operation procedures or farm management determine that this is necessary. This step could also be taken as an initial check of quality and condition prior to storage. When this step is taken, records of these activities should be considered as appropriate to the needs of the farm operation. If this sub-process applies, look for linkages to 7.5.3.
Delivery	This sub-process normally takes place unless the customer or end-user of the crop assumes responsibility for these delivery 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 7.1, 7.4.3, 7.5.1, 7.5.3.

Table A.10 — Storage

Sub-process	Tips
Maintenance of identity and segregation	This sub-process should be considered whenever storage activities are the responsibility of the farm operation 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 operation 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 7.5.1, 7.5.3, 7.5.5.
Handling/processing equipment	Prior to storage, it may be necessary to confirm that any handling and processing equipment is 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 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 be put into place. When applicable to the farm operation, these processes may include any activity necessary to ensure methods for crop handling or processing are carried out under controlled conditions. Handling 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 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 reconfirm the cleanliness, functionality, and adequacy of any storage facility and conveyance equipment immediately preceding its use. Depending on the needs of the farm operation and as specified by requirements the farm should consider, for example: — bins/silos; — augers/legs/distributors/conveyers. If this sub-process applies, look for linkages to 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 operation 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 7.1, 7.4.3, 7.5.3, 7.5.4.
Control and monitor crop quality, conditions, specifications and characteristics	As necessary to meet farm operation or customer requirements it may be appropriate to control or monitor the crop in order to identify any deterioration and to enable appropriate actions to be taken to resolve identified issues. Considerations may include, as appropriate: — crop monitoring during storage; — crop identification; — periodic sampling and/or observation. If this sub-process applies, look for linkages to 7.1, 7.4.3, 7.5.3, 7.5.4, 8.3, 8.5.3.
Crop security	This sub-process should be considered whenever farm operation procedures, customer or statutory and 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 7.1, 7.2, 7.4, 7.5, 7.6.

Table A.11 — Distribution and delivery

Sub-process	Tips
Delivery planning	This sub-process contains the steps necessary to confirm the contract and delivery plan with customers. This sub-process, and its 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 the farming plan. If this sub-process applies, look for linkages to 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 7.1, 7.6, 8.2.1.
Handling equipment	As part of any distribution and delivery activities it may be necessary to reconfirm 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 operation, borrowed equipment, equipment provided by customers or equipment that is rented from a third party. If this sub-process applies, look for linkages to 7.4.1, 7.6.
Delivery equipment	As part of any distribution and delivery activities, it may be necessary to reconfirm appropriate transportation equipment as being capable of meeting requirements. When this is determined to be necessary, these steps may include delivery equipment owned by the farm operation, borrowed equipment, equipment provided by customers or equipment that is rented from a third party. If this sub-process applies, look for linkages to 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 operation 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 7.5.1, 7.4.3, 7.5.1, 7.5.3, 7.5.5.
Crop transfer and settlement	This sub-process is often conducted as the final step in the crop production cycle. This may include the final 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 7.5.1, 7.5.2, 8.2.1, 8.5.1.

Annex B
(informative)

Cross references between ISO 22000:2005[6] and ISO 22006:2009

Table B.1 — Cross references between clauses of ISO 22000:2005[6] and clauses of ISO 22006:2009

ISO 22000:2005[6]	ISO 22006:2009	
	0	Introduction
	0.1	General
	0.2	Process approach
	0.3	Relationship with ISO 9004 [2]
	0.4	Compatibility with other management systems
1	1	Scope
	1.1	General
	1.2	Application
2	2	Normative references
3	3	Terms and definitions
4	4	Quality management system
4.1	4.1	General requirements
4.2	4.2	Documentation requirements
4.2.1	4.2.1	General
4.2.2	4.2.3	Control of documents
4.2.3	4.2.4	Control of records
5	5	Management responsibility
5.1	5.1	Management commitment
5.2	5.3	Quality policy
5.3	5.4.2	Quality management system planning
5.4	5.5.1	Responsibility and authority
5.5	5.5.2	Management representative
5.6	5.5	Responsibility, authority and communication
5.6.1	7.2.1	Determination of requirements related to the product
	7.2.3	Customer communication
5.6.2	5.5.3	Internal communication
	7.3.7	Control of design and development changes
5.7	5.2	Customer focus
	8.5.3	Preventive action
5.8	5.6	Management review
5.8.1	5.6.1	General
5.8.2	5.6.2	Review input
5.8.3	5.6.3	Review output

Table B.1 (*continued*)

ISO 22000:2005[6]	ISO 22006:2009	
6	6	Resource management
6.1	6.1	Provision of resources
6.2	6.2	Human resources
6.2.1	6.2.1	General
6.2.2	6.2.2	Competence, awareness and training
6.3	6.3	Infrastructure
6.4	6.4	Work environment
7	7	Product realization
7.1	7.1	Planning of product realization
7.2	6.3	Infrastructure
7.2.1	6.4	Work environment
7.2.2	7.5.1	Control of production and service provision
7.2.3	8.5.3	Preventive action
	7.5.5	Preservation of product
7.3	7.3	Design and development
7.3.1		
7.3.2		
7.3.3	7.4.2	Purchasing information
7.3.4	7.2.1	Determination of requirements related to the product
7.3.5	7.2.1	Determination of requirements related to the product
7.4	7.3.1	Design and development planning
7.4.1		
7.4.2		
7.4.3		
7.4.4		
7.5	7.3.2	Design and development inputs
7.6	7.3.3	Design and development outputs
7.6.1	7.5.1	Control of production and service provision
7.6.2		
7.6.3		
7.6.4	8.2.3	Monitoring and measurement of processes
7.6.5	8.3	Control of nonconforming product
7.7	4.2.3	Control of documents
7.8	7.3.5	Design and development verification
7.9	7.5.3	Identification and traceability

Table B.1 (*continued*)

ISO 22000:2005[6]	ISO 22006:2009	
7.10	8.3	Control of nonconforming product
7.10.1	8.3	Control of nonconforming product
7.10.2	8.5.2	Corrective action
7.10.3	8.3	Control of nonconforming product
7.10.4	8.3	Control of nonconforming product
8	8	Measurement, analysis and improvement
8.1	8.1	General
8.2	8.4	Analysis of data
	7.3.6	Design and development validation
	7.5.2	Validation of processes for production and service provision
8.3	7.6	Control of monitoring and measuring equipment
8.4	8.2	Monitoring and measurement
8.4.1	8.2.2	Internal audit
8.4.2	7.3.4	Design and development review
	8.2.3	Monitoring and measurement of processes
8.4.3	8.4	Analysis of data
8.5	8.5	Improvement
8.5.1	8.5.1	Continual improvement
8.5.2	7.3.4	Design and development review

Table B.2 — Cross references between clauses of ISO 22006:2009 and clauses of ISO 22000:2005[6]

ISO 22006:2009		ISO 22000:2005[6]
Introduction		
General	0.1	
Process approach	0.2	
Relationship with ISO 9004[2]	0.3	
Compatibility with other management systems	0.4	
Scope	1	1
General	1.1	
Application	1.2	
Normative references	2	2
Terms and definitions	3	3
Quality management system	4	4
General requirements	4.1	4.1
Documentation requirements	4.2	4.2
General	4.2.1	4.2.1

Table B.2 (*continued*)

ISO 22006:2009		ISO 22000:2005[6]
Quality manual	4.2.2	
Control of documents	4.2.3	4.2.2
		7.7
Control of records	4.2.4	4.2.3
Management responsibility	5	5
Management commitment	5.1	5.1
Customer focus	5.2	5.7
Quality policy	5.3	5.2
Planning	5.4	
Quality objectives	5.4.1	
Quality management system planning	5.4.2	5.3
		8.5.2
Responsibility, authority and communication	5.5	5.6
Responsibility and authority	5.5.1	5.4
Management representative	5.5.2	5.5
Internal communication	5.5.3	5.6.2
Management review	5.6	5.8
General	5.6.1	5.8.1
Review input	5.6.2	5.8.2
Review output	5.6.3	5.8.3
Resource management	6	6
Provision of resources	6.1	6.1
Human resources	6.2	6.2
General	6.2.1	6.2.1
Competence, awareness and training	6.2.2	6.2.2
Infrastructure	6.3	6.3
		7.2
Work environment	6.4	6.4
		7.2
Product realization	7	7
Planning of product realization	7.1	7.1
Customer-related processes	7.2	
Determination of requirements related to the product	7.2.1	7.3.4
		7.3.5
		5.6.1
Review of requirements related to the product	7.2.2	
Customer communication	7.2.3	5.6.1
Design and development	7.3	7.3

Table B.2 (*continued*)

ISO 22006:2009		ISO 22000:2005[6]
Design and development planning	7.3.1	7.4
Design and development inputs	7.3.2	7.5
Design and development outputs	7.3.3	7.6
Design and development review	7.3.4	8.4.2
		8.5.2
Design and development verification	7.3.5	7.8
Design and development validation	7.3.6	8.2
Control of design and development changes	7.3.7	5.6.2
Purchasing	7.4	
Purchasing process	7.4.1	
Purchasing information	7.4.2	7.3.3
Verification of purchased product	7.4.3	
Production and service provision	7.5	
Control of production and service provision	7.5.1	7.2
		7.6.1
Validation of processes for production and service provision	7.5.2	8.2
Identification and traceability	7.5.3	7.9
Customer property	7.5.4	
Preservation of product	7.5.5	7.2
Control of monitoring and measuring equipment	7.6	8.3
Measurement, analysis and improvement	8	8
General	8.1	8.1
Monitoring and measurement	8.2	8.4
Customer satisfaction	8.2.1	
Internal audit	8.2.2	8.4.1
Monitoring and measurement of processes	8.2.3	7.6.4
		8.4.2
Monitoring and measurement of product	8.2.4	
Control of nonconforming product	8.3	7.6.5
		7.10
Analysis of data	8.4	8.2
		8.4.3
Improvement	8.5	8.5
Continual improvement	8.5.1	8.5.1
Corrective action	8.5.2	7.10.2
Preventive action	8.5.3	5.7
		7.2

Annex C
(informative)

Correspondence between ISO 14001:2004[3] and ISO 22006:2009

Table C.1 — Correspondence between ISO 14001:2004[3] and ISO 22006:2009

ISO 14001:2004[3]	ISO 22006:2009	
4 (title only)	4 (title only)	Quality management system
4.1	4.1	General requirements
4.2	5.1	Management commitment
	5.3	Quality policy
	8.5.1	Continual improvement
4.3 (title only)	5.4 (title only)	Planning
4.3.1	5.2	Customer focus
	7.2.1	Determination of requirements related to the product
	7.2.2	Review of requirements related to the product
4.3.2	5.2	Customer focus
	7.2.1	Determination of requirements related to the product
4.3.3	5.4.1	Quality objectives
	5.4.2	Quality management system planning
	8.5.1	Continual improvement
4.4 (title only)	7 (title only)	Product realization
4.4.1	5.1	Management commitment
	5.5.1	Responsibility and authority
	5.5.2	Management representative
	6.1	Provision of resources
	6.3	Infrastructure
4.4.2	6.2.1	(Human resources) General
	6.2.2	Competence, awareness and training
4.4.3	5.5.3	Internal communication
	7.2.3	Customer communication
4.4.4	4.2.1	(Documentation requirements) General
4.4.5	4.2.3	Control of documents
4.4.6	7.1	Planning of product realization
	7.2.1	Determination of requirements related to the product
	7.2.2	Review of requirements related to the product
	7.3.1	Design and development planning
	7.3.2	Design and development inputs
	7.3.3	Design and development outputs

Table C.1 (*continued*)

ISO 14001:2004[3]	ISO 22006:2009	
	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
	7.4.1	Purchasing process
	7.4.2	Purchasing information
	7.4.3	Verification of purchased product
	7.5.1	Control of production and service provision
	7.5.2	Validation of processes for production and service provision
	7.5.5	Preservation of product
4.4.7	8.3	Control of nonconforming product
4.5 (title only)	8 (title only)	Measurement, analysis and improvement
4.5.1	7.6	Control of monitoring and measuring equipment
	8.1	(measurement, analysis and improvement) General
	8.2.3	Monitoring and measurement of processes
	8.2.4	Monitoring and measurement of product
	8.4	Analysis of data
4.5.2	8.2.3	Monitoring and measurement of processes
	8.2.4	Monitoring and measurement of product
4.5.3	8.3	Control of nonconforming product
	8.4	Analysis of data
	8.5.2	Corrective action
	8.5.3	Preventive action
4.5.4	4.2.4	Control of records
4.5.5	8.2.2	Internal audit
4.6	5.1	Management commitment
	5.6	Management review (title only)
	5.6.1	General
	5.6.2	Review input
	5.6.3	Review output
	8.5.1	Continual improvement

Table C.2 — Correspondence between ISO 22006:2009 and ISO 14001:2004[3]

ISO 22006:2009		ISO 14001:2004[3]
Quality management system (title only)	4	4
General requirements	4.1	4.1
Documentation requirements (title only)	4.2	
General	4.2.1	4.4.4
Quality manual	4.2.2	
Control of documents	4.2.3	4.4.5
Control of records	4.2.4	4.5.4
Management responsibility (title only)	5	
Management commitment	5.1	4.2 4.4.1
Customer focus	5.2	4.3.1 4.3.2 4.6
Quality policy	5.3	4.2
Planning (title only)	5.4	4.3
Quality objectives	5.4.1	4.3.3
Quality management system planning	5.4.2	4.3.3
Responsibility, authority and communication (title only)	5.5	
Responsibility and authority	5.5.1	4.4.1
Management representative	5.5.2	4.4.1
Internal communication	5.5.3	4.4.3
Management review (title only)	5.6	
General	5.6.1	4.6
Review input	5.6.2	4.6
Review output	5.6.3	4.6
Resource management (title only)	6	
Provision of resources	6.1	4.4.1
Human resources (title only)	6.2	
General	6.2.1	4.4.2
Competence, awareness and training	6.2.2	4.4.2
Infrastructure	6.3	4.4.1
Work environment	6.4	
Product realization (title only)	7	4.4
Planning of product realization	7.1	4.4.6
Customer-related processes (title only)	7.2	
Determination of requirements related to the product	7.2.1	4.3.1 4.3.2 4.4.6

Table C.2 (*continued*)

ISO 22006:2009		ISO 14001:2004[3]
Review of requirements related to the product	7.2.2	4.3.1 4.4.6
Customer communication	7.2.3	4.4.3
Design and development (title only)	7.3	
Design and development planning	7.3.1	4.4.6
Design and development inputs	7.3.2	4.4.6
Design and development outputs	7.3.3	4.4.6
Design and development review	7.3.4	4.4.6
Design and development verification	7.3.5	4.4.6
Design and development validation	7.3.6	4.4.6
Control of design and development changes	7.3.7	4.4.6
Purchasing (title only)	7.4	
Purchasing process	7.4.1	4.4.6
Purchasing information	7.4.2	4.4.6
Verification of purchased product	7.4.3	4.4.6
Production and service provision (title only)	7.5	
Control of production and service provision	7.5.1	4.4.6
Validation of processes for production and service provision	7.5.2	4.4.6
Identification and traceability	7.5.3	
Customer property	7.5.4	
Preservation of product	7.5.5	4.4.6
Control of monitoring and measuring devices	7.6	4.5.1
Measurement, analysis and improvement (title only)	8	4.5
General	8.1	4.5.1
Monitoring and measurement (title only)	8.2	
Customer satisfaction	8.2.1	
Internal audit	8.2.2	4.5.5
Monitoring and measurement of processes	8.2.3	4.5.1 4.5.2
Monitoring and measurement of product	8.2.4	4.5.1 4.5.2
Control of nonconforming product	8.3	4.4.7 4.5.3
Analysis of data	8.4	4.5.1
Improvement (title only)	8.5	
Continual improvement	8.5.1	4.2 4.3.3 4.6
Corrective action	8.5.2	4.5.3
Preventive action	8.5.3	4.5.3

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ICS 03.120.10; 67.020

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