

The ISO 9001:2015 Standard was published September 15, 2015. The Standard is written such that it may be used by any organization type for the purpose of implementing and maintaining a Quality Management System. It is important to remember that the standard was not written solely for the purpose of certification, though it is a standard by which an organization can be assessed against for the purpose of 3<sup>rd</sup> party certification. Because of the nature and ambiguity of the standard for maximum flexibility, it has become evident that clients and auditors alike require clarification and guidance and that is the purpose of this document. Please note that we expect that this document will change as we learn and experience system approaches and as additional guidance and direction is provided by the accreditation bodies.

When our auditors evaluate your management system, our focus will be on process-based systems, **not** on people based systems. Process based systems continue to operate in the absence of key personnel. This should be the goal of any management system to assure repeatability, reliability and effectiveness of the system.

Controls to assure repeatability come in many forms in management systems. Tools like software, travelers, checklists, and other forms are the best ways to ensure that processes happen the same way every time and also provide records to demonstrate the activity is performed as planned. These are typically strong controls because employees have to use them to do their job.

It is critical that clients and auditors alike understand the risk of informal systems:

<b>SYSTEM CONFIDENCE</b>	<b>Low</b>	<b>Verbal processes</b> <b>Verbal confirmation evidence</b>
	<b>Medium - High</b>	<b>Documented processes</b> <b>(e.g., procedures and work instructions)</b> <b>Verbal confirmations evidence</b> <b>Documented information retained (records) evidence</b>
	<b>High</b>	<b>System-based tools</b> <b>Documented information retained (records) evidence</b>

Documented procedures and instructions are other methods to communicate expectations to employees. They are unfortunately less reliable than work tools because they can be complicated and difficult to maintain. Instructions can be written or can exist in flow chart formats. Flowcharts work well for visual learners, but do not work for other learners and they often lack detailed information that is needed to execute the process. Employees also do not take time to read and re-read the documents and can find themselves drifting from the expected process. To be effective, written documents must be clear, as concise as possible and maintained up to date. They must explain how to assure requirements are met (i.e., describe the process), not parrot back the wording from the standard.

Emails to staff is another written method that we see people use to communicate expectations, but these must be controlled to ensure that new personnel get the same message as long-term

personnel. These types of instructions are usually better communicated using procedures and/or work instructions.

Verbal instructions work well for some people, but not all people. Verbal instructions put companies at risk because the processes that they control can so easily end-up being people based, not process-based. When verbal instructions are used, our auditors have to validate that the process implemented is communicated and effective through interviews and records if they exists. Consistent answers from interviewees then becomes critical. This is often difficult in an audit situation and though we work very hard to make the auditees comfortable and not threatened during our audits (we get the best results that way), people are always nervous in when being audited and this nervousness causes them to say all sorts of strange things – like, we never evaluate our suppliers! You are allowed to use verbal controls, but you must be aware of the risks associated with this method and do a very good job of verifying its effectiveness.

Where we will not have a high expectation of a documented process – it is usually due to the fact that there is a low risk that the process will “going wrong” that the requirements are addressed through “normal” business operations (such as knowing customers’ expectations). Often these processes produce records and other outputs that can provide tangible evidence of the process being performed (such as contracts and maintenance records).

Where the requirements are not usual or are complex and detailed, we need to rely more on controlled operations to ensure that everything is happening as required, and this is why we will have the expectation for more formal controls.

BUT, it’s important to note, that just because Platinum may not have a strong expectation for formal controls documented in this policy, does not mean that the organization should not have them if you need them. For example, in some industries, the risk associated with knowledge may be significant and management may decide that having a formal procedure to describe how to ensure that knowledge is obtained, maintained and updated reduces that risk...and in such a case, it is completely appropriate to have a formal control.

## 4 Context of the Organization

### 4.1 Understanding of the organization and its context

Platinum will have a strong expectation for documented information maintained controlling this process.

Platinum auditors will review the method of how the organization determines relevant external and internal issues (considering strategic direction and purpose and the affect that they may have on achieving intended results). Verbal evidence alone **will not suffice** to ensure that the process is understood.

Platinum auditors will require evidence of monitoring and review of these issues.

#### 4.2 Understanding the needs and expectations of interested parties

Platinum will **have** a strong expectation for documented information maintained controlling this process.

Platinum auditors will strongly expect evidence of the how the organization determines interested parties that are relevant to the management system and the requirements of those interested parties. Verbal evidence **will not suffice** to ensure that the process is understood.

Platinum auditors will require evidence of monitoring and review of information about the parties and their requirements.

#### 4.3 Determining the scope of the quality management system

##### Scope

Though the scope **must** be documented, Platinum will **not** have a strong expectation for documented information maintained controlling this process (i.e., how the scope is determined). This is because the risk is low that the organization will “get it wrong” and the scope will be validated during 3<sup>rd</sup> party and internal audits.

The scope of your system **must be documented, available and maintained** and must state the types of products and services controlled by the management system. The scope must be based upon customer expectations, ensuring conformity of products and services and the enhancement of customer satisfaction. All requirements that can be applied must be applied. Outsourced processes that affect the satisfaction of your clients must be controlled. Also, be careful with off-site delivery of services when considering your scope.

##### Requirements Not Applicable (AKA “Exclusions” in previous versions of the Standard)

Platinum will **not** have a strong expectation for documented information maintained controlling this process. This is because the risk of getting it wrong is low. It will also be validated through internal and 3<sup>rd</sup> party audits.

When considering applicability of requirements – we must have enough of the standard included to meet certification body reporting requirements. Therefore it will be very unlikely that sections 4, 5, 6, 7, 9 and 10 (except 7.1.5.2) could ever be considered Not Applicable. We do not have guidance or rules yet from the accreditation authorities, but if we need to address this for our customers, we will ask for clarification and guidance.

If you are considering claiming requirements as not applicable and it resides in one of the sections above, we strongly recommend that you contact our office to discuss the requirement and your justification.

Sections where we foresee companies may have valid requirements not applicable include:

- 7.1.5.2 Measurement Traceability
- 8.3 Design and development of products and services
- 8.4 Control of externally provided processes, products and services (though this would be rare)
- 8.5.3 Property belonging to customers or external providers
- 8.5.5 Post-delivery activities

Other requirements in section 8 could possibly be excluded, but proceed with caution.

#### 4.4 Quality management system and its processes

##### 4.4.1

Platinum will **not** have a strong expectation for documented information maintained controlling this process. This is because the activity occurs once and is validated through 3<sup>rd</sup> party and internal audits.

Platinum auditors will want to know how you establish, develop, implement and maintain your management system and assign responsibilities within it.

We will ask you to tell us what your business processes are using a process analysis tool or we will ask you to provide a review of your management system against the requirements of the standard. It's important you can demonstrate that you know the requirements and that you communicate them relative to your management system. We will use this information to prepare for your audit.

We will also need to understand how you address risks and opportunities associated with your business processes.

##### 4.4.2

Platinum will **not** have a strong expectation for documented information maintained controlling this process. This is because the activity occurs once and is validated through 3<sup>rd</sup> party and internal audits.

We will need to know what documented information (procedures, work instructions, forms) you use to support and control your processes and what information you will retain as evidence of effective implementation (records).

## 5 Leadership

### 5.1 Leadership and commitment

#### 5.1.1 General

Platinum will **not** have a strong expectation for documented information maintained controlling this process. We will look for tangible evidence to substantiate the methods, rather than verbal confirmation alone.

Management is clearly responsible for the quality management system and will be expected to be active participants in Platinum audits. It is important that you understand this shift in focus in the 2015 version of the Standard. Platinum auditors will be interviewing management and documented information retained to confirm leadership in how management:

- Takes accountability for the effectiveness of the management system.
- Establishes the quality policy and objectives and demonstrates their compatibility to the context and strategic direction of the organization.
- Integrates the requirements of the standard into their business processes and promotes the process approach and risk-based thinking. (No more standard based systems or internal audits.)
- Ensures that appropriate resources are made available for the operation and maintenance of the quality management system
- Communicates the importance of an effective quality management system and conformance to quality management system requirements
- Ensures that the quality management system achieves its intended results
- Engages, directs and supports people working in the organization
- Promotes improvement
- Supports management to demonstrate leadership

#### 5.1.2 Customer focus

Platinum will **not** have a strong expectation for documented information maintained controlling this process.

Through interviews and tangible evidence, Platinum auditors will confirm management's leadership and commitment by observing the methods used to ensure that

- Customer and applicable statutory and regulatory requirements are determined, understood and consistently met
- That risks and opportunities that can affect conformity of products and services and the organization's ability to enhance customer satisfaction are determined and addressed
- The focus on customer satisfaction is maintained

## **6 Planning**

### **6.1 Actions to address risks and opportunities.**

#### **6.1.1 and 6.1.2**

Platinum will have a strong expectation for documented information maintained controlling this process.

We will be looking for a system on how risks and opportunities are identified, considered and addressed (with appropriate actions and integration into the system and evaluation for effectiveness). We will not try to second guess your identified risks and opportunities as there will be a learning curve as these are identified. If we identify a potential risk or opportunity, we will identify it as a finding (opportunity for improvement or a minor nonconformance if it is clear that you haven't identified the risk and it is obvious that you should have). As with any finding, it will be up to management to consider and appropriately act upon the risk identified.

We will strongly expect evidence of the method you use to identify, consider, dismiss or act upon opportunities and risks. We will also look for evidence of what you identified, considered, dismissed and what you acted upon.

### **6.2 Quality objectives and planning to achieve them**

#### **6.2.1 and 6.2.2**

Platinum will have a strong expectation for documented information maintained controlling this process.

You cannot improve what you cannot measure.

We will ask you how you planned for your quality objectives (6.2.2) and will need to see documented quality objectives at relevant levels, functions and processes within your organization. They must meet all of the requirements of 6.2.1. In particular, they must be communicated, be measurable and relevant to conformity of products and services and to the enhancement of customer satisfaction.

Objectives can be a reflection on risks and opportunities. Objectives should be tactical and strategic (see 5.1.1b). Passing your ISO audit is not considered a strong objective. Sales objectives alone will not typically suffice as quality management objectives (though repeat sales can be a great indicator of customer satisfaction). Try not to change your objectives from year to year so that monitoring and measuring means something.

### **6.3 Planning of changes**

Platinum will have a strong expectation for documented information maintained controlling this process.

Change can occur for numerous reasons, but most can be classified into strategic changes directed by management, organizational changes and unexpected changes.

Platinum auditors will review the method by which the organization plans for any type of change, ensuring that the process includes the consideration of the requirements (purpose of changes and consequences, integrity of the management system, availability of resources, allocation or reallocation of responsibilities and authorities)

## 7 Support

### 7.1 Resources

#### 7.1.1 General

##### 7.1.2 People

Platinum will **not** have a strong expectation for documented information maintained controlling this process. Adequate resources will be evident.

Platinum auditors will evaluate the method that organization determines and provides resources in accordance with requirements. This can be verbal, but must be demonstrated with evidence of adequate resources.

##### 7.1.3 Infrastructure

Platinum will **not** have a strong expectation for documented information maintained controlling this process. Adequate resources will be evident.

Platinum auditors will evaluate the method that the organization uses to determine, provide and maintain the infrastructure (e.g., buildings, equipment, transportation, information and communications technologies, etc.) necessary for the operation of processes and to achieve conformity of products and services. This may be verbal, but will be substantiated with evidence, keeping in mind the ability for the processes to be repeatable and reliable.

##### 7.1.4 Environment for the operation of processes

Platinum will **not** have a strong expectation for documented information maintained controlling this process. Adequate resources will be evident.

Platinum auditors will evaluate the method that organization determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services. The organization determines the required environment. This may be verbal, but will be substantiated with evidence.

##### 7.1.5 Monitoring and measuring resources

###### 7.1.5.1 General and 7.1.5.2 Measurement traceability

Platinum will have a strong expectation for documented information maintained controlling this process.

Platinum auditors will evaluate the method that the organization uses to determine, provide and maintain suitable resources to ensure valid and reliable results when monitoring and measuring.

This process for identification, recall and protection may be verbal as this process is typically controlled using software or other methods and training. Calibration instructions will be expected for repeatability when calibration is performed in house.

Evidence of calibration (the basis of calibration when standards do not exist, records of identification, calibration and traceability to national/international standards and the determination of the validity of previous measurement results when equipment has been found to be unfit for its purpose and the actions taken) will be expected.

Don't forget test software, when it exists.

#### **7.1.6 Organizational knowledge (from internal and external sources, as appropriate)**

Platinum will **not** have a strong expectation for documented information maintained controlling this process.

Platinum auditors will evaluate the method that the organization uses to determine the knowledge necessary for the operation of processes and to achieve conformity of products and services.

Where this knowledge is needed, Platinum auditors will evaluate how it is maintained and made available within the organization.

Platinum auditors will also review how the knowledge is updated and how additional knowledge is acquired and updated.

#### **7.2 Competence**

Platinum will have a strong expectation for documented information maintained controlling this process.

Platinum auditors will evaluate the methods that the organization uses to:

- Determine the necessary competence of persons doing work under its control that affects the performance and effectiveness of the QMS. We will expect something that will show how the organization can repeat this process using a process-based approach, not people-based.
- Ensure competence based upon appropriate education, training and/or experience
- Take actions to acquire competence and evaluate the effectiveness of actions taken.

Platinum auditors will expect appropriate documented information retained to demonstrate competence.

#### **7.3 Awareness**

Platinum will have a strong expectation for documented information maintained controlling this process.



Platinum auditors will evaluate the methods that the organization uses to ensure that persons doing work under its control are aware of the quality policy, their relevant quality objectives, their contributions to the effectiveness of the QMS, including the benefits of improved performance and the implications of not conforming with QMS requirements. This awareness will be confirmed through interviews.

#### **7.4 Communication**

Platinum will have a strong expectation for documented information maintained controlling this process.

Platinum auditors will evaluate the methods used by the organization to determine the internal and external communications relevant to the QMS. Platinum auditors will strongly expect documented methods for communicating including what to communicate, when to communicate it, with whom to communicate, how to communicate and the responsibility for communication.

#### **7.5 Documented information**

##### **7.5.1 General**

Platinum auditors will evaluate the system used to ensure that documented information required by the Standard or the organization (for the effectiveness of the QMS) is implemented and maintained. If your organization has tons of instructions and procedures, this implies that they are required and must be implemented, controlled and maintained.

##### **7.5.2 Creating and Updating and 7.5.3 Control of documented information**

Platinum will have a strong expectation for documented information maintained controlling this process.

Platinum auditors will review the method used by the organization to identify, format, review and approve documented information. Platinum auditors will also evaluate the methods used to control internal and external documents to ensure that they are available and suitable for use and that they are adequately protected. The organization must demonstrate that documented information is distributed with adequate access and that it is used and retrievable.

We will review evidence that demonstrate that retained documents are kept and protected according to policy.

#### **8 Operation**

##### **8.1 Operational planning and control**

Platinum will have a strong expectation for documented information maintained controlling this process.

Most organizations have methods in place that are controlling their operations. Procedures may not be needed if there are other mechanisms in place. We will look for maintained documented information that supports the defined process.

Platinum auditors will evaluate the methods used to plan, implement and control operational processes. Specifically, we will be looking at:

- The requirements for the products and services
- The criteria for the processes and acceptance of products and services
- The method used to determine resource requirements
- The implementation of controls in accordance with the criteria
- The documented information needed to be maintained and retained to control processes and demonstrate the effective implementation of the processes.

## 8.2 Requirements for products and services

### 8.2.1 Customer communication

Platinum will **not** have a strong expectation for documented information maintained controlling this process.

Platinum auditors will evaluate the method for communicating with customers and for handling and controlling customer property. We will also review the requirements for contingency actions (e.g., actions for damage to property or complaints), when relevant.

### 8.2.2 Determining the requirements for products and services

Platinum will **not** have a strong expectation for documented information maintained controlling this process. This is commonly controlled using forms and other documented information retained.

Platinum auditors will evaluate the process for determining the requirements for products and services offered by the organization and the method used to ensure that the requirements are defined (including statutory and regulatory requirements and those considered by the organization) and that the organization can meet the claims they make. This process may be verbal, but it will be expected to be supported by the documented information maintained and information in the organization's complaint and corrective action system as a cross-check.

### 8.2.3 Review of the requirements for products and services

Platinum will **not** have a strong expectation for documented information maintained controlling this process.

Platinum will review the process used by the organization to ensure that it has the ability to meet requirements (see 8.2.2 above) and that the organization conducts a review before committing to supply products and services and that contract or order requirements differing from those previously defined are resolved.

The auditors will also validate that customer's requirements are confirmed by the organization before acceptance, when the customer does not provide documented statement of their requirements (except where impractical for each order – but the relevant product information

must be reviewed, such as catalogues). Where this not a part of a standard process, it may be necessary for the organization to document this process to ensure that it is performed when it is relevant.

Platinum auditors will validate that documented information is retained on the results of the review and on any new requirements for the products and services.

#### **8.2.4 Changes to requirements for products and services.**

Platinum will **not** have a strong expectation for documented information maintained controlling this process.

Platinum will review the process used by the organization to ensure that relevant documented information is amended and that relevant persons are made aware of the changed requirements.

### **8.3 Design and development of products and services**

#### **8.3.1 General**

Platinum will have a strong expectation for documented information maintained controlling this process.

Platinum auditors will evaluate the establishment, implementation and maintenance of the design and development process.

#### **8.3.2 Design and development planning**

Platinum auditors will evaluate the planning process to validate that the organization considers the requirements of this section. We will look for evidence of planning (DI retained).

#### **8.3.3 Design and development inputs**

Platinum auditors will evaluate the design inputs and the process used in determining them to make sure that the requirements of this section are considered and that the inputs are adequate, complete and unambiguous. We will look for evidence of the design and development inputs (DI retained) and the resolution of conflicting inputs, where applicable.

#### **8.3.4 Design and development controls**

Platinum auditors will evaluate the design controls (reviews, verification and validation activities and actions taken in response to them). We will look for evidence of control (DI retained).

#### **8.3.5 Design and development outputs**

Platinum auditors will evaluate the outputs of design and the method used by the organization to ensure that the requirements of this section are met. We look for evidence of design outputs (DI retained).

### **8.3.6 Design and development changes**

Platinum auditors will evaluate the change process used by the organization to ensure that it identifies, reviews, and controls changes made during, or subsequent to, the design or products and services, to ensure that there is no adverse impact on conformity of products and services.

Platinum will validate that the organization retains documented information on changes, the results of reviews, the authorization of the changes, and actions taken to prevent adverse impacts.

## **8.4 Control of externally provided processes, products and services**

### **8.4.1 General**

#### **8.4.2 Type and extent of control**

Platinum will have a strong expectation for documented information maintained controlling this process.

Platinum auditors will review the method used by the organization for ensuring that externally provided processes, products and services conform to requirements by determining and applying controls when:

- Products and services are outsourced for incorporation into the organizations products and services
- Products and services are drop-shipped from outsourced suppliers to the customer site
- A process or part of a process is outsourced.

Platinum auditors will evaluate the process to validate that the organization applies criteria for the evaluation, selection, monitoring and performance and re-evaluation of external providers and retains documented information of these activities and any necessary actions arising from the evaluations and controls the external providers as planned.

#### **8.4.3 Information for external providers**

Platinum will have a moderate expectation for documented information maintained controlling this process.

Platinum auditors will interview and review records to ensure that adequate information is provided to external providers following the organization's internal plans.

## **8.5 Production and service provision**

### **8.5.1 Control of production and service provision**

Platinum will have a strong expectation for documented information maintained controlling this process.

Platinum auditors will interview and review documented information provided internally to control production and service provision. Procedures, instructions, forms drawings, etc., may or may not be needed in each organization. We will also be reviewing operations to ensure that adequate monitoring and measuring resources are made available and are used as planned to verify that the criteria for the control of processes or outputs have been met.

In addition we will verify that the organization has processes to prevent human error and to implement release, delivery and post-delivery activities.

#### 8.5.2 Identification and traceability

Platinum will **not** have a strong expectation for documented information maintained controlling this process.

Platinum auditors will evaluate each business process to ensure that the organization has a method for identification of process outputs as necessary and for identifying the status of monitoring and measuring requirements.

#### 8.5.3 Property belonging to customers or external providers

Platinum will have a moderate expectation for documented information maintained controlling this process. Some organizations will require extensive documented information for this process. Others will need minimal information. Each organization will need to determine the likelihood of personnel knowing what to do in the event the property is damaged as they determine the best method to communicate this requirement.

Platinum auditors will evaluate the process for identifying, verifying, protecting customer or external provider's property. Where this property is lost, damaged or otherwise found to be unsuitable, Platinum will validate that the organization reports the situation to the customer and retains documented information on what had occurred.

#### 8.5.4 Preservation

Platinum will **not** have a strong expectation for documented information maintained controlling this process.

Platinum auditors will evaluate the process for preservation of outputs and the method that that organization assures that personnel know what to do.

#### 8.5.6 Control of changes

Platinum will have a strong expectation for documented information maintained controlling this process.

Platinum auditors will evaluate the method that the organization uses to control change to ensure continued conformity of requirements.

Platinum will validate that the organization retains documented information describing the results of the review of the changes, the persons authorizing the change and the necessary actions resulting from the review.

### 8.6 Release of products and services

Platinum will have a strong expectation for documented information maintained controlling this process.

Platinum auditors will evaluate the planned arrangements that the organization establishes to verify products and services and to control the release until the planned arrangements have been satisfactorily completed, unless otherwise approved.

Platinum auditors will review documented information retained on the review of products and services to evidence of conformity and traceability to the person(s) authorizing the release.

### 8.7 Control of Nonconforming outputs

Platinum will have a strong expectation for documented information maintained controlling this process.

Platinum auditors will evaluate the method that the organization uses to ensure that nonconforming outputs are identified and controlled to prevent their unintended use or delivery.

Platinum will evaluate the process to ensure that appropriate actions are taken and the documented information retained describing the nonconformity and the actions taken, including concessions obtained, where applicable and the authority deciding the actions related to the nonconformity.

## 9 Performance evaluation

### 9.1 Monitoring, measurement, analysis and evaluation

#### 9.1.1 General

Platinum will **not** have a strong expectation for documented information maintained controlling this process.

Platinum auditors will evaluate the method used by the organization to determine what will be monitored and measured and the process, methods for performing those activities.

Platinum auditors will evaluate the method used to evaluate the performance and effectiveness of the management system.

Platinum auditors will review records to validate the monitoring and measuring process including the activities and their results.

#### 9.1.2 Customer satisfaction

Platinum will **not** have a strong expectation for documented information maintained controlling this process.

Platinum auditors will review the process used by the organization to determine the methods for obtaining, monitoring and reviewing customer's perceptions on satisfaction.

### **9.1.3 Analysis and evaluation**

Platinum will **not** have a strong expectation for documented information maintained controlling this process.

Platinum will review the methods used by the organization to analyze and evaluate data from monitoring and measuring activities.

## **9.2 Internal audit**

### **9.2.1 and 9.2.2**

Platinum will have a strong expectation for documented information maintained controlling this process.

Platinum will review the internal audit program to ensure that it satisfies requirements, audits are carried out at planned intervals, results are reported to relevant management, and that correction and corrective action is taken without undue delay. We will review documented information retained as evidence of implementation and of auditing activities.

## **9.3 Management review**

### **9.3.1 General**

### **9.3.2 Management review inputs**

### **9.3.3 Management review outputs**

Platinum will have a strong expectation for documented information maintained controlling this process.

Platinum auditors will review the management review process to ensure that reviews are carried out at defined intervals to ensure that the system is suitable, adequate, effective and in alignment with the strategic direction of the organization in accordance with requirements.

We will review documented information retained of evidence of management review activities.

## **10 Improvement**

### **10.1 General**

Platinum will **not** have a strong expectation for documented information maintained controlling this process.

Platinum auditors will review the methods that the organization uses to determine and select opportunities for improvement and implement actions to meet customer requirements and enhance customer satisfaction. Platinum will review documented information retained demonstrating that improvements are being made.

## **10.2 Nonconformity and corrective action**

### **10.2.1 and 10.2.2**

Platinum will have a strong expectation for documented information maintained controlling this process.

Platinum will review the method used by the organization to address nonconformities (including complaints) to ensure that the process meets requirements and is implemented as planned.

Platinum will review documented information retained that provides evidence that the process was implemented and effective.

## **10.3 Continual improvement**

Platinum will **not** have a strong expectation for documented information maintained controlling this process.

Platinum will review the methods used by the organization to continually improve the suitability, adequacy and effectiveness of the management system considering the results of analysis and evaluation and the outputs of management review.

Platinum will review documented information retained as evidence of continual improvement.